Final Report

SURVEY OF ASSISTED REPRODUCTIVE TECHNOLOGY: EMBRYO LABORATORY PROCEDURES AND PRACTICES

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1. INTRODUCTION

On October 24, 1992, Congress passed Public Law 102-493 entitled the Fertility Clinic Success Rate and Certification Act of 1992. In accordance with this statute, the Centers for Disease Control and Prevention is developing a model certification program for assisted reproductive technology (ART) embryo laboratories. This program is to include a set of quality standards specifically designed to assure the quality performance of embryo laboratory procedures. It will also include laboratory personnel qualifications, laboratory records maintenance procedures, and criteria for the certification and inspection of embryo laboratories. Once developed, this model program can be voluntarily adapted and/or implemented by States, or by independent accrediting organizations which are certified by States.

The purpose of this survey is to provide the Government with an enumeration of those ART embryo laboratory procedures and practices that are currently in use. These data will be used to finalize the development of a model certification program and also provide a baseline study for evaluating the impact and effectiveness of a certification program once implemented.

The only other similar survey of ART embryo laboratories was conducted by the U. S. General Accounting Office (GAO) in May of 1989. The GAO *Human Embryo Laboratory Survey* was distributed to 254 ART program directors "to obtain information on the personnel employed and the equipment, procedures and quality controls used in human embryo laboratories." One hundred ninety-eight laboratories responded to the original GAO survey (78% response).

2. MATERIALS AND METHODS

The following subsections describe the materials and methods used for conducting this survey of ART embryology laboratory procedures and practices.

2.1 Identification of ART Programs to Receive Survey

The primary source used for identifying candidate programs to receive the ART Survey was provided by CDC's Public Health Practice Program Office, Division of Laboratory Systems, from success rate information obtained by the National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health. This success rate information was originally provided to CDC by the American Society for Reproductive Medicine, Society for Assisted Reproductive Technology (SART). Since ART programs are constantly changing, up-to-date contact information was obtained directly from the Executive Director of ASRM and SART. Contact information and mailing addresses for these facilities were further updated during various communications with these programs as the survey progressed.

ASI took several approaches to identify additional ART programs which may not have been voluntarily submitting pregnancy success rate information to SART. First, we contacted manufacturers and vendors of equipment and materiels which are unique to ART embryology

programs (e.g., IVF retrieval needles, embryo transfer catheters, embryo culture media, etc.). Our goal was to obtain list of customers using these items. Unfortunately, the suppliers contacted could not or would not provide us with the requested information.

We next contacted the Commission of Office Laboratory Accreditation (COLA) to identify those laboratories participating in their accreditation program which may be offering ART embryology laboratory services. The COLA enrollment database of 7,500+ laboratories was searched for laboratories with the words "IVF," "ART," "Infertility," and/or Reproducti[on][ve]" in their names and which were performing semen analysis and estradiol testing. The resulting list of 54 laboratories was compared with the list of SART laboratories obtained from ASRM to remove duplicates. A program was considered duplicate if the address and/or contact person matched exactly. The remaining 31 laboratories were contacted by telephone to determine if they were in fact performing ART embryology procedures. The 15 programs that indicated ART procedures were being performed were added to our list of candidate survey recipients.

We did not contact the College of American Pathologists Laboratory Accreditation Program to obtain a list of accredited ART programs because of the College's long-standing policy of not releasing information about their program participants.

Contact information was obtained in both paper and electronic formats. These data were entered into a single Microsoft® Access97 tracking database and then sorted and compared to eliminate duplicate contact information. Information included in this database included:

- program SART identification number
- program medical director's name and telephone number
- laboratory director's name and telephone number
- facility name and address and facsimile machine number

During the course of the survey administration period, ASI identified several ART programs that had not received a survey. These were usually programs that had moved to another location, or were newly opened programs that were associated with personnel who had been at other ART programs on our list. Each of these newly identified ART programs were sent a survey booklet to complete and return.

2.2 Survey Development Process

The following sources of information were used for the developing the ART survey.

- GAO Human Embryo Laboratory Survey (May 1989)
- American Fertility Society Revised Minimum Standards for In Vitro Fertilization, Gamete Intrafallopian Transfer, and Related Procedures (November 1989)
- GAO Report to the Chairman, subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business, House of Representatives: Human Embryo Laboratories, Standards Favored to Ensure Quality (December 1989)

- American Fertility Society Guidelines for In Vitro Fertilization, Gamete Intrafallopian Transfer and Related Procedures (August 1991)
- American Fertility Society Guidelines for Human Embryology and Andrology Laboratories, Fertility and Sterility Vol. 58, Supplement 1 (October 1992)
- Public Law 102-493, the Fertility Clinic Success Rate and Certification Act of 1992 (October 1992)
- CAP Reproductive Laboratory Inspection Checklist (March 1996)
- ASRM Guidelines for the Provision of Infertility Services (June 1996)
- CDC/ASRM/Resolve 1995 Assisted Reproductive Technology Success Rates, National Summary and Fertility Clinic Reports (December 1997)

When possible, survey questions similar to the ones asked in the 1989 GAO survey were included in the present survey to facilitate comparison of aggregate responses over time. Comparison of individual laboratory responses between surveys are not possible since the original GAO survey data are not available.

2.3 Survey Pilot Testing Process

The following researchers currently serve as ART embryo laboratory directors or laboratory supervisors and were selected as representatives of the targeted respondent population. A draft of the ART Survey was distributed to these individuals for their evaluation and comments:

William Byrd, Ph.D.
University of Texas Southwestern Medical Center
Dallas, Texas

Gail Compton, M.S.
Greater Baltimore Medical Center Fertility Center
Baltimore, Maryland

Melanie Freeman, M.S.
Nashville Fertility Center
Nashville, Tennessee

Kristen Ivani, Ph.D.
Reproductive Science Center, Bay Area
San Ramon, California

Brooks A. Keel, Ph.D.
University of Kansas School of Medicine-Wichita
Wichita, Kansas

Jacob F. Mayer, Jr., Ph.D.
Eastern Virginia Medical School
Norfolk, Virginia

Thomas B. Pool, Ph.D.
Fertility Center of San Antonio
San Antonia, Texas

Terry Schlenker, M.A.
Colorado Center for Reproductive Medicine
Englewood, Colorado

Michael J. Tucker, Ph.D.
Reproductive Biology Associates
Atlanta, GA

Lucinda Veeck, MLT
Cornell University Medical College
New York, New York

Dr. Jacob Mayer was a paid consultant who provided ASI with technical expertise throughout the development of the survey questionnaire. All other consultants participated in the field test on a voluntary basis.

2.4 OMB Submission Process

A 60-day announcement for *Proposed Data Collections Submitted for Public Comment and Recommendations* was published in the *Federal Register* on November 7, 1997 (FR 62: 60248). No public comments on this survey were received during the 60-day comment period.

On February 18, 1998, An *Application for Clearance from the Office of Management and Budget* (OMB) was forwarded to the Project Officer and Technical Monitor. This application was then reviewed by the OMB Clearance Evaluation Officer in the CDC Office for Program Planning and Evaluation. The final application for OMB Clearance was forwarded to OMB by CDC on April 23, 1998. The following week (April 30, 1998), CDC published in the *Federal Register* (Agency Forms Undergoing Paperwork Reduction Act Review, FR 63: 23789-23790) a list of information collection requests under review by OMB in compliance with the Paperwork Reduction Act of 1992 (44 USC, Chapter 35). This allowed a final 30-day public comment period on the proposed survey prior to final OMB disposition of the application. No public comments were received on this survey.

On June 30, 1998, OMB approved the ART Survey as it was submitted, with no comments or requested revisions. The survey was assigned OMB Form Number 0920-0432, with an expiration date of April 30, 1999.

2.5 Survey Administration Process

During the final stages of the OMB review of the application, ASI began preparations for production and distribution of the ART Survey. During May and June, ASI finalized the mailing list of candidate ART facilities to receive the survey and made arrangements with a local printer for production of the survey booklets. These preparations are discussed in the following subsections.

2.5.1 Production

Once OMB approval was received, we made some final minor editorial and formatting changes to the survey document and added the OMB Form Number (0920-0432) and Expiration date to the approved version of the text. On July 8, 1998, the final survey document was submitted to a local printer for printing and binding. The printer had been previously alerted to the pending production need so that the print job could be scheduled as soon as possible after OMB approval. Cover and paperstock had been previously ordered by the printer and was available for immediate use. The completed print job was received from the printer on July 16, 1998.

2.5.2 Distribution

In preparation for distribution of the ART Survey, ASI published notices of the survey in the March 1998 issue of the ASRM journal *Fertility and Sterility* (Vol. 69, p. 610) and in the ASRM Quarterly Newsletter (see Appendix A for announcement text). These notices were to alert the ART community of the pending survey, and to provide a point-of-contact at CDC to respond to any questions. As a result of these announcements, several ART programs contacted CDC to

ensure that their programs were included on the survey mailing list. ASI updated the mailing database as notice of these contacts was forwarded to the Project Director by CDC.

On July 6, 1998, ASI produced and mailed solicitation letters (see Appendix B) to each ART program director on our list of candidate recipients. This letter was designed to alert candidate recipients of the pending survey, to solicit their cooperation in completing and returning the survey, and to provide them with the opportunity to contact ASI with any address or point-of-contact changes. Included with this letter was a self-addressed and stamped response postcard (see Appendix C) which the recipients were instructed to return to ASI by July 15, 1998, if their program did not conduct ART procedures or if they did not have an embryo laboratory on premises.

Address and point-of-contact changes were made to the database as telephone calls were received or post cards were returned. On July 16, 1998, a final update was made to the mailing database and a mail merge function was performed to generate individually-addressed survey cover letters (see Appendix D) to accompany the survey packets. These letters were generated in SART ID order. A companion set of survey booklet labels was printed in the same identification number sequence. A matching set of mailing labels were also generated to be placed on the outer survey packet mailing envelope.

Each survey packet contained the following materials:

- a survey cover letter
- the ART Survey booklet with the applied survey booklet label identification number matched to the cover letter addressee
- a pink Instruction Sheet
- a pre-addressed, franked business reply mail envelope

These four items were enclosed in an executive grey envelope with distinctive green “First Class Mail” printed repeatedly around the border. The mailing label corresponding to the enclosed cover letter and survey booklet was applied along with an eye-catching pink label indicating that the CDC ART Survey was enclosed. Stamps were used to frank the sealed envelopes as opposed to metered postage tapes. The assembled survey packets were delivered to the U. S. Postal Service for distribution on July 17, 1998.

Subsequent to mailing the survey, we discovered that the responses to Question # 80 had been formatted incorrectly. ASI immediately produced and distributed a postcard to each survey recipient with the correct response format.

2.5.3 Data Confidentiality

The database information received from CDC and ASRM identified candidate ART programs by their SART number. ASI chose to use this number for identifying ART programs for this survey since this was a number with which the facilities were familiar. Use of this number also greatly

facilitated communications with the candidates or survey respondents during phone conversations. Since the survey booklets were identified and tracked by the respondent's SART number, the following procedures were devised to maximize survey response and to protect the confidentiality of the respondent.

As completed survey booklets were returned to ASI, they were reviewed for completeness and legibility. If any problems were noted with the booklet, the survey coordinator contacted the individual who completed the booklet (as noted on the inside back cover) in an attempt resolve the issue(s) in question. For example, there were several cases where it appeared that the respondents had inadvertently skipped several survey pages in completing the survey. In these instances, we contacted the respondent to either obtain answers to the missing questions over the phone, or to obtain their fax number so that the blank pages could be faxed for their completion and return (by fax or mail). There were also numerous cases where the respondent's handwriting was indecipherable or their intended response was uncertain. These respondents were contacted as well for clarification.

Prior to receiving the returned surveys in the mail, the project programmer/analyst developed a short survey receipt program that automatically assigned the next available sequence number to the survey questionnaire, linked the response to the survey booklet number (i.e., SART number), and added an electronic time-stamp to the data record. This receipt program also allowed the entry of the name and telephone number of the individual who completed the survey as noted on the back cover, and whether or not the respondent wished to receive a summary of the survey results. Since this program linked the sequence and SART numbers, the database was password protected to restrict access to these data.

Once we were certain that the survey information was complete, the pink outer survey booklet cover was removed from the questionnaire pages and a sequence number label was applied to the upper right-hand corner of the first page of the questionnaire. This number was assigned by the survey receipt program. Only three ASI employees were allowed access to the contents of the tracking database once linkage information was recorded: the Project Director, the Survey Coordinator and the administrative assistant who was responsible for assigning the survey sequence number.

Once the final surveys had been returned, the Project Director extracted only those fields from the database that were needed for analyses purposes. The extracted fields never contained information that would allow linkage of survey responses with any information that could potentially be used to identify the respondent.

2.5.4 Response Tracking

Additional fields were added to the mailing database to facilitate response tracking. These fields included:

- **Sequence Number**: As each survey was received in the return mail, a sequence number label was assigned to each survey booklet as described above. This sequence number was used for identifying the survey responses during data entry and subsequent analysis or results.

- **Date/time Stamp**: This information was applied automatically by the survey receipt program as the sequence number was assigned.

- **Name and Telephone Number of the Respondent**: If the respondent name was recorded on the back page of the survey cover, this information was recorded when the sequence number was assigned.

- **Feedback**: An "X" was placed in this field if the respondent indicated that he/she was interested in receiving a summary of the survey results.

- **Comments**: Entries were made in this field to explain various aspects of an ART program response (or non-response).

- **Not Expected**: An "X" was placed in this field if a survey response was not expected from a given ART program. This annotation was added by the Project Director when, after discussions with the contact person within the program, it was believed that a survey would not be returned. Reasons for entries in this field were given in the comment field.

- **Link To**: This field was used to identify the ART embryo laboratory providing service to the indicated ART program if they indicated that they did not have their own functional embryo laboratory (or laboratory staff).

- **Primary**: This field was used to denote those ART programs whose embryo laboratories served other ART programs without embryo laboratory services.

- **Follow-up**: This field indicates which non-respondent facilities were contacted after September 1, 1998 and the outcome of these follow-up activities.

2.6 Non-Respondent Follow-Up Process

Whenever there was an indication from an ART program that a survey would not be returned (for example, if a late response postcard was received, if the program was no longer active, or they were using the services of an embryo laboratory at another ART program) the "Not Expected" field in the database was marked.

In the cover letter accompanying the original survey packet, we requested that the survey booklets be returned by July 31, 1998 (two weeks after the initial mailing). Many programs contacted us indicating that the key personnel necessary for completing the survey questions were on summer vacations or out of the office for other reasons. As a result, we waited until the second week of August to generate reminder post cards. These postcards (see Appendix E) were sent to the facilities which had not returned as survey by August 14, 1998, and which did not have an "X" in the "Not Expected" field in the tracking database. These reminder postcards extended the response date until August 31, 1998.

On September 2, 1998, we again determined which ART Programs had not yet responded and did not have the "Not Expected" field checked in the tracking database. A mail merge function was

used to generate follow-up materials (see Appendix F) to be used for telephone follow-up purposes. The Project Director then met with the Survey Coordinator and the project administrative assistants to discuss proper techniques for contacting each non-respondent. When contacted, each program was given the option to complete and return the previously mailed survey or was sent another copy of the survey if the original had not been received or had been either misplaced or misdirected.

If the contacted individual indicated that they were unable or unwilling to complete and return the survey, they were given the opportunity to answer five questions to enable ASI to gather basic information about the characteristics of their facility. These five questions were taken directly from questions 1, 2, 4, 6, and 7 in the survey booklet.

After all follow-up efforts were completed, the Project Director reviewed the information from each non-respondent and then made one more personal appeal to either the ART Program Director or Embryo Laboratory Director to complete and return the survey. The response to the follow-up efforts was recorded in the Follow-up field in the tracking database.

Nine codes (see section 3.2 below) were used in the FOLLOW_UP field in the tracking database for noting responses to these follow-up activities. These codes were assigned by the Project Director based on a review of the comments recorded on follow-up forms or in the database COMMENTS field, or based on linkage information recorded for those facilities which indicated they do not have an active ART embryo laboratory.

2.7 Eligibility Determination

All survey recipients were initially assumed to be eligible to respond. Ineligibility was determined by the Project Director based on several factors described below. During the course of the survey, many of the survey recipients contacted ASI with questions or comments about the survey or about their eligibility to respond. If, during these communications, the Project Director determined that a recipient was not eligible, the eligibility field in the tracking database was deselected and the *Not Expected* column was checked (so that follow-up actions would not be initiated).

A survey recipient was determined to be ineligible to respond if:

- the laboratory was not specifically performing embryology procedures according to the definitions provided with the survey instructions
- the programs received duplicate surveys (i.e., surveys were sent to different, or the same individuals at similar, but not identical addresses)
- programs were not performing ART embryology procedures in-house but were referring ART patients to other ART embryo laboratories identified in our database
- the program previously offered ART embryology procedures, but are no longer offering these services or have ceased operation altogether

- programs were temporarily not offering ART, or which had never offered ART embryology procedures to their patients
- the surveys were undeliverable by the postal service

2.8 Data Entry Process

ASI's computer programming staff developed a data entry application using proprietary data entry software. This application allowed for independent keying of survey results into the survey database by two different individuals. The program then compared the results of each individual keyed entry and produced a discrepancy report whenever the keyed values disagreed. These discrepancies were then adjudicated by the Data Manager in conjunction with the Project Director when necessary. The correct result was then re-entered into the database. The program provided an audit trail to document who performed all data entry and data correction operations and when they were performed.

Once the received surveys were reviewed for completeness and legibility and a sequence number was assigned, the outer pink survey booklet covers were removed and the inner survey booklet was provided to ASI's Data Manager. Survey booklets were grouped in batches of 10 for data entry. Data entry personnel were instructed to "key what you see" and to make no interpretations of the presented information. Whenever data entry personnel had difficulty deciphering a response or deciding what to enter, the item in question was flagged and the survey booklet was forwarded to the Project Director for interpretation. These interpretations were entered into the survey booklet in red ink, initialed and dated, and returned to data entry for completion.

Survey booklets were filed in sequence order to facilitate retrieval in the event of questions during analyses. The entire set of survey booklets are to be turned over to CDC upon completion of this task order.

2.9 Data Quality Assessment

After the first five survey booklets had been entered, the information captured in the survey database was reviewed to ensure there was 100% agreement with the survey booklets. Thereafter, 10% of the survey booklets were randomly pulled for comparison with information recorded in the survey database. Any discrepancies detected were resolved by the data manager and the appropriate corrections were made in the survey database.

3. RESULTS

The results of the ART embryology laboratory procedures and practices survey are presented below. A preliminary set of survey data were provided to the Project Officer on December 8, 1998. A final analyses data set is provided with this report.

3.1 Survey Response

A total of 356 programs were identified as having some association with ART embryology procedures during the course of the survey: 337 of these programs were identified by CDC or SART, 15 by COLA, and 4 were identified through contacts with survey recipients while the survey was in progress. The 352 programs identified through CDC/SART and COLA were sent a solicitation letter with a response postcard to return before the survey mailing date. Programs returning these post cards were instructed to mark a checkbox if they were not offering ART embryology procedures in their laboratories.

A total of 19 programs contacted ASI before the specified cut-off date–10 via postcard and 9 by phone call–and indicated that they did not want (or were not eligible) to receive a survey. Therefore on July 17, 1998, surveys were mailed out to the remaining 333 candidate programs.

As shown in Table 1, a total of 239 surveys were returned by October 27, 1998. Of these 239 surveys received, 7 were from ineligible respondents (as discussed below). Two survey booklets with valid survey responses were returned without covers, presumably because the respondents were concerned about confidentiality. Since the covers were removed, it was not possible to determined which of the 356 programs in the tracking database had responded. In order to track these responses however, 2 new entries were made to the tracking database identifying the programs as "Unknown 1" and "Unknown 2." Hence, the total number of programs in the tracking database appears to be 358 instead of 356. When tallying eligible ART programs not responding to the survey in the tracking database, there appears to be 70 eligible non-responding programs (rather than 68), because it is not possible to determine which two of the eligible programs actually did respond. Likewise, there appears to be 119 surveys not received in the tracking database instead of 117 because of these two unidentified respondents.

	SURVEYS RECEIVED	SURVEYS NOT RECEIVED	ROW TOTAL
Eligible to respond	232* (77.3%)	68 (22.7%)	300
Not eligible	7	49	56
Column Total	239	117	356

Table 1. Survey Response.
*includes 2 unidentified respondents

Of the 356 ART programs identified for this survey 300 (84%) were eligible to respond. The 232 eligible surveys received represented 77% of all eligible survey recipients. This is comparable to the response rate reported for the 1989 GAO survey.

Sixty-eight programs (22.7%) that were apparently eligible to return surveys did not do so for undetermined reasons. By eligible, we mean that no legitimate reasons could be determined during the follow-up period (see discussion in section 3.2) why a survey should not have been returned. Fifty-six programs were determined to be ineligible through various forms of communication

(primarily telephone calls) during the survey period or through our follow-up activities (see Section 3.2). Table 2 shows the distribution of these ineligible programs by the reason given for their ineligibility.

REASON FOR INELIGIBILITY	NUMBER (%)
Programs provided reason why they were ineligible (e.g., "Only doing IUIs") or returned postcard with reason	6 (10.7%)
Programs received duplicate surveys (i.e., surveys were sent to different, or the same individuals at similar, but not identical addresses)	8 (14.3%)
Programs were not performing ART embryology procedures in-house but were referring ART patients to other ART embryo laboratories identified in our database (including 18 identified during follow-up activities)	24 (42.9%)
Program previously offered ART embryology procedures, but are no longer offering these services or have ceased operation altogether	11 (19.6%)
Programs which are temporarily not offering ART, or which have never offered ART embryology procedures to their patients	3 (5.4%)
Surveys were undeliverable by the postal service	4 (7.1%)
Total	56

Table 2. Reasons for Program Ineligibility.

Sixteen facilities returned postcards after the mailing date, with 7 not providing a reason as to why they did not wish to participate. Since no reason for ineligibility could be assigned, these 7 programs were classified as eligible to respond.

During the course of the survey, we discovered that 21 ART embryo laboratories were providing services for more than one ART program. In addition to 7 programs which received duplicate surveys, there were 29 ART programs identified which did not have an active ART embryology program. Seventeen of these 29 facilities were identified during follow-up (see the following section). Twenty-five ART programs without embryo laboratory capability would stimulate patients for oocyte retrievals and would then send their patients to other programs with ART laboratories (usually local) to perform retrievals and embryology procedures as needed. Five of these 29 facilities had previously offered ART embryology services but were no longer doing so and were referring their patients to other programs. Two of these four programs still had the necessary laboratory equipment to perform embryology procedures and the necessary clinical personnel to induce and monitor ovulation, they contracted with two other ART programs which periodically provided embryology laboratory personnel to come in and perform the necessary embryo laboratory procedures on site for stimulated patients.

3.2 Follow-Up Activities

As indicated in Section 2.6, survey follow-up activities were initiated after September 1, 1998 to contact those survey recipients which had not responded by that date. Follow-up activities were primarily conducted to encourage the survey recipients to respond beyond the stipulated cut-off

date if they were eligible to do so, or to assign a reason for ineligibility if they were not. There were 121 outstanding surveys as of this date associated with laboratories that had not previously been deemed to be ineligible, and with eligible laboratories from which surveys were expected. These facilities were contacted via telephone to encourage them to complete and return the survey, or to determine why they would not be responding. Their responses were grouped into 9 categories as shown in the Table 3 below. The numbers in this section are a subset of those discussed above in Section 3.1. One hundred two facilities (codes 1-7) were determined to be eligible to respond. Contact individuals at 92 of these facilities (codes 1-4,7) *said* they would complete and return the survey, but only 41 (45%) of these facilities eventually did complete and return a survey (codes 2 and 4).

As discussed in section 2.6, a telephone survey had been prepared to ask five questions taken directly from the survey booklet (questions 1, 2, 4, 6, and 7) in order to characterize non-response. Of the 10 eligible facilities which indicated they would not be returning a survey (codes 5 and 6), only 3 opted to respond verbally to the questions extracted from the survey.

Of the 121 programs contacted during follow-up activities, we determined that 19 were not eligible to respond. These were ART programs without embryo laboratories which were referring patients to other ART programs with embryo laboratories (codes 8 and 9). These 19 programs were included with the 24 ineligible survey recipients previously listed in Table 2, Group 3.

CODE	FOLLOW-UP RESPONSE	NUMBER (%)
1	ASI contacted the laboratory and the contacted individual indicated that the survey would be completed and returned, but completed survey was ***not*** subsequently received at ASI.	10 (8%)
2	ASI contacted the laboratory and they completed and returned the survey as a result of our call.	27 (22%)
3	ASI contacted the laboratory and they requested that another copy of the survey be sent because the original had either been misplaced or not received. A replacement survey was sent, but it was ***not*** completed or returned by the recipient.	14 (12%)
4	The laboratory completed and returned a replacement survey that had been sent to them after the initial mailing date.	14 (12%)
5	We contacted the laboratory, but the contact individual could not (or would not) complete and return the survey, but opted to answer the five script questions instead.	3 (3%)
6	We contacted the laboratory, but the contact individual could not (or would not) complete and return the survey, nor answer the script questions.	7 (6%)
7	Our repeated efforts to contact knowledgeable personnel in the laboratory were unsuccessful, or the contact person did not/would not return our calls.	27 (22%)
8	The contacted laboratory was not doing ART embryology in-house but were referring ART patients to another ART facility in our database which ***did*** return the survey.	17 (14%)
9	The contacted laboratory was not doing ART embryology in-house but were referring ART patients to another ART facility in our database which ***did not*** return the survey.	2 (2%)

Table 3. Categorization of Follow-up Responses.

In an attempt to categorize the 68 eligible recipients not responding (also necessarily including the 2 unidentified responses), the facility names were reviewed and categorized in Table 4 according to the apparent type of program and were compared to the respondents. The distribution of non-respondents does not differ markedly from that of respondents.

TYPE OF FACILITY (BASED ON FACILITY NAME)	ELIGIBLE RESPONDENTS	ELIGIBLE NON-RESPONDENTS	TOTAL
Hospital-based ART programs	44 (19%)	7 (10%)	51 (17%)
University-based ART programs	55 (24%)	12 (17%)	67 (22%)
Independent ART programs	133 (57%)	49 (70%)	182 (60%)
ART programs at military installations	0 (0%)	2 (3%)	2 (1%)
Total	232	70*	302*

Table 4. Categorization of Eligible Respondents and Non-respondents by Facility Type.
*amount includes 2 unidentified respondents.

3.3 Summarization of Data

Before the final dataset was assembled, the following data cleaning and labeling efforts were implemented:

- SAS labels were attached to all variables
- SAS formats were attached to all applicable variables
- New SAS variables were created, grouping responses in "other" categories
- Data integrity checks were performed to identify invalid responses
- Data consistency checks were performed to identify variable discrepancies
- Skip-check violations were detected and identified
- Multiple response violations were detected

All of the errors detected in the datasets are documented in a Word Perfect document listed in the deliverables as "Validation Checks"(see section 5 below). More detailed data exhibiting the errors detected can be found in a separate Word Perfect document referred to as "Respondent Errors."

Before compiling the results of the survey, all of the data checks and edits discussed above were applied to the data. The resultant summarized survey responses can be found in Appendix G. The basic survey questionnaire format was revised by converting survey questions to statements and entering the number of respondents (and percent of the respondents *for that question)* in the appropriate response block. Where logical to do so, the responses were ranked with the most (or sometimes the least) frequent being placed at the top of the list. However, for some questions (e.g., question #4), it was more appropriate to present the responses in the order they were presented in the question.

In questions where an "Other" option was available, ASI has grouped and categorized these "other" responses whenever possible.

For two questions (#5 and #23) the survey respondents did not respond in the manner anticipated and thus the data for these questions are not easily interpreted.

In questions where a single numerical response was given (e.g., questions # 87 and 88) the mean response is presented along with the range and the number of respondents.

4. DISCUSSION

Our list of 300 eligible survey recipients is comprehensive and represents essentially all of the ART programs currently performing ART embryology laboratory procedures in the United States. When these 300 ART programs with embryo laboratories are added to the 32 ART programs without laboratories, the resulting 332 programs are comparable to the list of 337 ART programs (i.e., facilities with and without embryo laboratories) initially provided by CDC and SART. Our exercise of contacting the Commission on Office Laboratory Accreditation (COLA) to determine if there might be other ART programs that were not registered with SART initially appeared to be fruitful. However, many of the COLA laboratories identified as potentially performing ART embryology procedures either were duplicates of existing SART programs in our database, or were not eligible to participate because embryology procedures were not offered in these facilities.

Most of the facilities contacting ASI for various reasons during the survey period were very positive about participating in the survey and were very interested to see the eventual results of the survey. In fact 223 of the 232 eligible survey respondents (96%) checked the response box on the back page of the survey to indicate that they would like to receive a copy of the survey results. We strongly recommend that the results of this survey be disseminated among the ART community.

5. DELIVERABLES

Table 5 lists the datasets and materials that were used in preparing this report. These datasets and materials were provided to the Technical Monitor at the end of the Task Order to assist in the analyses of the survey results. Interim SAS data sets were provided to the Technical Monitor on December 8, 1998. Two slight modifications have been made to the labeling provided in this interim dataset: q45_a1 through q45_a3 were incorrectly labeled as "Media Area" instead of "Sperm Area" and q45_c1 through q45_c3 were not labeled (label should read “Media Area”). These corrections were made in the final dataset.

FILE TYPE	ITEM	DESCRIPTION
SAS Datasets	Main.sd2	The main body of the survey responses minus responses to staffing issues in questions 14–17 (n=232)
	Staff.sd2	The survey responses pertaining to staffing issues in survey questions 14–17 (n=835)
	Artlist.sd2	Demographic facility information for all ART programs (with and without embryo laboratories) considered for this survey. Four-digit ARTNUMs were assigned by ASI. (n=356)
	Tracking.sd2	Database used to track survey responses and eligibility. Provides reason codes for ineligible labs and provides follow-up codes for non-respondents. Includes 2 unknown respondents (n=358)
	LabLinks.sd2	Linking information associating ART programs without embryo laboratories with ART programs having embryo laboratories (n=36)
	Responses.sd2	Demographic information for eligible survey respondents requesting survey summary information (n=223 out of 232 eligible respondents)
SAS Programs	Formats.sas	SAS program containing all of the formats applied to variables in the 5 main survey datasets.
Documentation	Validation Checks.wpd	A Word Perfect table exhibiting all of the data cleaning checks and errors found for all survey variables. Recommendations are included.
	Respondent Errors.wpd	A Word Perfect document detailing data errors with more specificity.
	Final Report Documents.zip	A compressed file containing the 5 WordPerfect documents comprising this final report.
N/A	Survey Booklets	Survey booklets (without covers) ordered by sequence number (n=239)

Table 5. Deliverables.

APPENDIX A

ASRM Quarterly Newsletter Announcement Text

CDC to Sponsor an ART Embryo Laboratory Survey

The Centers for Disease Control and Prevention (CDC) is currently developing a model certification program for assisted reproductive technology (ART) embryo laboratories that are providing services to human fertility specialists in the U.S. In support of this effort CDC has selected Analytical Sciences, Inc.(ASI), an independent public health research contractor, to develop and administer a *Survey of Assisted Reproductive Technology Embryo Laboratory Procedures and Practices*. This survey will be distributed to all embryo laboratories in the US in late April or early May. ASI will independently collect and tabulate all survey results and provide an aggregate summary of embryo laboratory practices and procedures to CDC. ***All responses to this survey will remain confidential***: individual laboratory responses to the survey will not be provided to CDC or any other government agency, nor to any private or professional organizations. The summarized data will provide a baseline against which future changes may be measured so that CDC can evaluate the effectiveness of the certification program. In order to represent all aspects of the embryo laboratory in the model certification program, it is important that all embryo laboratories participate in the survey. If you have questions about this pending survey, please contact Steven J. Steindel, Ph.D., at (770) 488-4144 or at sns6@cdc.gov.

APPENDIX B

Sample Solicitation Letter Sent to ART Program Directors

July 1, 1998

John Doe, Ph.D.
XYZ Center for Reproductive Medicine
Embryology Laboratory
1234 Main Street
Suite 200
Our Town, USA 12345

RE: Centers for Disease Control and Prevention Survey of Assisted Reproductive Technology Embryology Laboratory Procedures and Practices

Dear Dr. Doe:

In October 1992, Congress passed the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). In accordance with this statute, the Centers for Disease Control and Prevention (CDC) is developing a model certification program for assisted reproductive technology (ART) embryo laboratories that are providing services to human fertility specialists in the U.S. This model certification program is to be voluntarily implemented by States or by independent accrediting or certifying agencies which are approved by the States. CDC defines embryo laboratories as those facilities which handle and process human oocytes, sperm, and/or embryos with the intent of establishing a pregnancy. Embryo laboratory procedures and processes include, but are not limited to, the examination of follicular aspirates, oocyte classification, sperm preparation, oocyte insemination, assessment of fertilization, assessment of embryo development, preparation of embryos for embryo transfer, cryopreservation of specimens, and/or micromanipulation.

The purpose of this letter is to solicit your help in evaluating this model certification program. In the near future, you will be receiving in the mail a copy of a *Survey of Assisted Reproductive Technology Embryo Laboratory Procedures and Practices*. This survey is designed to identify embryo laboratory practices and procedures currently in use in the United States so that informed decisions may be made in formulating the certification program. The data collected during this survey will also provide a baseline against which future changes may be measured so that CDC can evaluate the effectiveness of the resultant certification program. Thus, in order to represent all aspects of the embryo laboratory in the model certification program, ***your timely response to this survey is vitally important***.

CDC has selected Analytical Sciences, Inc.(ASI), an independent public health research contractor, to develop and administer this survey. ASI will collect and tabulate all survey results and provide an aggregate summary of embryo laboratory practices and procedures to CDC. ***You may be assured that all responses to this survey will remain confidential***: ASI will not provide individual laboratory responses to the survey to CDC or any other government agency, or to any private or professional organizations.

If you are not the most appropriate individual in your organization to receive and complete this pending survey, please contact Dr. Edward Gaunt at ASI's toll free number—**(800) 451-3930**—and provide the appropriate contact information no later than July 15, 1998. If your laboratory does not provide embryo services as defined above, please return the enclosed postcard so that a survey will not be sent to you. If you have questions about this survey, you may contact Dr. Gaunt at the number above or Dr. Steindel at (770) 488-4144.

Sincerely,

Steven J. Steindel, Ph.D.
Principal Investigator
Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Atlanta, Georgia

Jacob F. Mayer, Ph.D.
Eastern Virginia Medical School
Department of OB/GYN
IVF Laboratory
Norfolk, Virginia

APPENDIX C

Survey Response Postcard

Analytical Sciences, Inc.
2605 Meridian Parkway
Suite 200
Durham, NC 27713

Edward E. Gaunt, Ph.D.
ART Embryo Laboratory Survey
Analytical Sciences, Inc.
2605 Meridian Parkway
Suite 200
Durham, NC 27713

G Our laboratory does not provide embryo laboratory procedures.

Name _____ Phone Number _____

SART No. XXXX
John Doe, Ph.D.
XYZ Center for Reproductive Medicine
Embryology Laboratory
1234 Main Street
Suite 200
Our Town, USA 12345

APPENDIX D

Survey Cover Letters Accompanying the Survey Packets

July 17, 1998

John Doe, Ph.D.
XYZ Center for Reproductive Medicine
Embryology Laboratory
1234 Main Street
Suite 200
Our Town, USA 12345

RE: Centers for Disease Control and Prevention Survey of Assisted Reproductive Technology Embryology Laboratory Procedures and Practices

Dear Dr. Doe:

In October 1992, Congress passed the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). In accordance with this statute, the Centers for Disease Control and Prevention (CDC) has been tasked with developing a model certification program for embryo laboratories that are providing services to human fertility specialists in the U.S. This model certification program is to be voluntarily implemented by States or by independent certifying agencies such as the College of American Pathologists which are approved by the States. The enclosed *Survey of Assisted Reproductive Technology Embryo Laboratory Procedures and Practices* is being distributed to all embryo laboratory directors or supervisors in the country to provide an enumeration of current embryo laboratory procedures, equipment maintenance practices, and personnel qualifications. This information will help to finalize the development of the model certification program and also provide a baseline study for evaluating the impact and effectiveness of the resulting certification program.

Please review the instructions provided with the survey. We estimate that it will take approximately 90 minutes for you to complete this form. Once it has been completed, please ensure that the pink code sheet has been removed and place the survey booklet in the postage paid return mail envelope and mail it to the following address by no later than July 31, 1998:

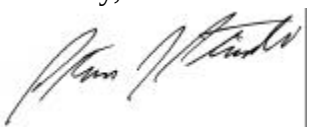
ART Survey Coordinator
Analytical Sciences, Inc.
2650 Meridian Parkway, Suite 200
Durham, NC 27713

Analytical Sciences, Inc. (ASI), is an independent health research organization selected by CDC to design and administer this survey and analyze the results. Your responses on this survey will be kept strictly confidential and will be used for statistical analysis only. *Please do not put your name or other identifying information anywhere on the survey booklet.* You will notice that the survey booklets are numbered for tracking purposes. Security measures are in place to ensure that your responses cannot be identified through this number. ASI will not provide identifying information from your embryology laboratory to CDC or any other party.

If you check the box at the end of the survey booklet, a summary of the survey results will be sent to you once it has been compiled.

If you have any questions about completing this survey, please contact ASI's Project Director, Dr. Ed Gaunt, toll-free at 800-451-3930. If you have questions about the purpose of this survey please contact the CDC Investigator, Dr. Steve Steindel, at (770) 488-8126.

Sincerely,



Steven J. Steindel, Ph.D.
Principal Investigator
Centers for Disease Control and Prevention
Public Health Practice Program Office
Division of Laboratory Systems
Atlanta, Georgia

Jacob F. Mayer, Ph.D.
Eastern Virginia Medical School
Department of OB/GYN
IVF Laboratory
Norfolk, Virginia

APPENDIX E

Reminder post cards

Analytical Sciences, Inc.
2605 Meridian Parkway, Suite 200
Durham, NC 27713

John Doe, Ph.D.
XYZ Center for Reproductive Medicine
Embryology Laboratory
1234 Main Street
Suite 200
Our Town, USA 12345

CDC ART Survey
Reminder!

On July 17, 1998, you were mailed a Centers for Disease Control and Prevention Survey of Assisted Reproductive Technology Embryo Laboratory Procedures and Practices. We had requested that these surveys be completed and returned by July 31, 1998. However, due to the summer holidays, a number of programs have indicated that vacations and other personnel commitments have prevented the timely return of these surveys. As a result, we have extended the response date to:

August 31, 1998

Our records show that, as of August 14, 1998, we have not yet received your valuable response to this survey. ***Your response is very important to us***. Please take a few moments now to locate this survey (look for the bright pink cover!) so that you can complete and return it to us as soon as possible. Even if your laboratory is not performing ART embryology procedures, please complete the first question in the survey booklet and return it.

If you cannot locate the survey booklet, we will be glad to send you another copy. Please contact the ART Survey Coordinator toll free at **(800) 451-3930** to request another copy.

APPENDIX F

Follow-up Scripts

TELEPHONE FOLLOW-UP WITH ART SURVEY NON-RESPONDENTS

Booklet Number: 123
Respondent Name: John Doe
Phone Number: (123) 456-7890
Address: XYZ Center for Reproductive Medicine
1234 Main Street
Anytown, USA 12345

Refer to the flow diagram and ask the following questions in the proper sequence.

1. **Does your laboratory perform activities where human gametes (oocytes, sperm) and/or embryos are subject to assisted reproductive technology embryo laboratory procedures and processes?**

   [ ] NO STOP. Thank the respondent for their time and hang up.
   [ ] Yes Continue with Question 2

2. **Did the individual receive the CDC Survey of ART Embryo Laboratory Procedures and Practices?**

   [ ] Yes Continue with Question 3
   [ ] NO Skip to Question 4

3. **Did the individual complete and return the survey?**

   [ ] Yes Ask when the survey was mailed and thank them for their time. Hang up
   [ ] NO Skip to Question 5

4. **Is the address printed above correct?**

   [ ] Yes Continue with Question 5
   [ ] NO Get correct address and resend the survey

5. **Does the recipient intend to complete and return the survey?**

   [ ] Yes Encourage them to do so ASAP. Thank then for their time and hang up
   [ ] NO Continue with Question 6

6. **Ask if the recipient would mind responding to several questions at the beginning of the survey for demographic purposes?**

   [ ] Yes Continue with Questions 7–11
   [ ] NO Thank them for their time and hang up

7. (2nd half of question 1 in survey booklet) What dates did your laboratory begin offering the following services? (Check all that apply)

Services offered	**laboratory began providing services during :**
Oocyte retrieval, assessment and gamete/embryo culturing	19__ __
Sperm preparations for IUIs	19__ __
Diagnostic Infertility testing	19__ __
Sperm cryopreservation (any type)	19__ __
Oocyte cryopreservation	19__ __
Embryo cryopreservation	19__ __
Micromanipulation (any type)	19__ __

8. (Question 2 in the survey booklet.) Which clinical or therapeutic procedures does your embryo laboratory support? Check all that apply

[ ] IVF
[ ] GIFT
[ ] ZIFT
[ ] IUIs
[ ] Cryopreservation
[ ] Other (please specify): _____

[ ] Oocyte donor program
[ ] Sperm donor program
[ ] Microbiopsy for genetic screening
[ ] Genetic analyses
[ ] Intravaginal culture

9. (Question 4 in the survey booklet.) So that we may assess the approximate size of your ART program, please estimate the number of ART cycles your embryo laboratory supported in 1997. Check only one response.

[ ] less than 50 ART cycles
[ ] 51-100 ART cycles
[ ] 101-250 ART cycles
[ ] 251-500 ART cycles
[ ] 501-750 ART cycles
[ ] 751-1000 ART cycles
[ ] over 1000 ART cycles

10. (Question 6 in the Survey booklet.) Which of the following agencies or organizations have accredited, licensed, or certified your embryo laboratory? Check all that apply

[ ] Our embryo laboratory is not currently accredited, licensed, or certified
[ ] Health Care Financing Administration (CLIA)
[ ] State please indicate state(s):_____
[ ] College of American Pathologists (CAP) Reproductive Laboratory Accreditation Program
[ ] American Association of Tissue Banks (AATB)
[ ] Food and Drug Administration (FDA)
[ ] Joint Commission on Accreditation of Health care Organizations (JCAHO)
[ ] Commission for Office Laboratory Accreditation (COLA)
[ ] Other accreditation/certification

11. (Question 7 in the survey booklet.) Which categories of CLIA-licensed testing are [being] performed in your embryo laboratory. Check all that apply

[ ] No CLIA-licensed testing is offered by our embryo laboratory
[ ] Diagnostic semen analysis/sperm morphology (doers not include analyses for inseminations)
[ ] Endocrine testing (e.g., E2, FSH, LH, hCG)
[ ] Microbiology testing (e.g., Ureaplasma, N. gonorrhoeae)
[ ] Hematology testing (e.g., CBCs, hematocrit)
[ ] Chemistry testing (e.g., glucose, hepatitis, electrolytes)
[ ] Immunology/Serology testing (e.g., CMV, syphilis serology)
[ ] Immunohematology testing (e.g., ABO/Rh typing)
[ ] Genetic analyses (e.g. FISH PCR)
[ ] Other CLIA-licensed testing (please specify)_____

APPENDIX G

Summarized Survey Responses

1. The mean year respondent embryo laboratories began performing activities where human gametes (oocytes, sperm) and/or embryos are subject to assisted reproductive technology embryo laboratory procedures and processes.

1987 (n = 188)	Diagnostic Infertility testing
1988 (n = 191)	Sperm preparations for IUIs
1989 (n = 228)	Oocyte retrieval, assessment and gamete/embryo culturing
1990 (n = 198)	Sperm cryopreservation (any type)
1991 (n = 224)	Embryo cryopreservation
1994 (n = 215)	Micromanipulation (any type)
1994 (n = 35)	Oocyte cryopreservation

2. *Clinical* or *therapeutic* procedures offered by embryo laboratory participating in the survey. Most frequently offered procedures are presented first.

231 (99.6%)	IVF
228 (98.3%)	Cryopreservation
194 (83.6%)	Oocyte donor program
188 (81.0%)	IUIs
140 (60.3%)	ZIFT
119 (51.3%)	Sperm donor program
22 (9.5%)	Microbiopsy for genetic screening
15 (6.5%)	Genetic analyses (e.g. FISH, PCR)
14 (6.0%)	Intravaginal culture
44 (19.0%)	Other (*53.5% Micromanipulation procedures (e.g., ICSI, Assisted Hatching) , 46.5% provided mixed responses)*

3. Procedures currently performed in respondent laboratories. Most frequently performed procedures are listed first.

A. Sperm Preparation Procedures	
Sperm motility	224 (96.6%)
Sperm concentration	223 (96.1%)
Sperm count	219 (94.4%)
Sperm wash/swim up	208 (89.7%)
Density gradient separations	204 (87.9%)
Sperm morphology	195 (84.1%)
Sperm viability	159 (68.5%)
Antisperm antibody testing	125 (53.9%)
Sperm viability testing (e.g., HOS)	85 (36.6%)
Semen biochemical testing (e.g., fructose)	78 (33.6%)
Computer-assisted semen analysis	58 (25.0%)
Sperm function assays (e.g., SPA, HZFO)	40 (17.2%)
Not done	4 (1.7%)

B. Oocyte/Embryo Procedures	
Oocyte insemination	229 (98.7%)
Oocyte identification/grading	228 (98.6%)
Embryo culturing/grading	230 (99.1%)
Preparation for embryo transfer	230 (99.1%)
ART media preparation	135 (58.2%)
Embryo co-culture with other cell lines	45 (19.4%)
Not done	0 (0.0%)

C. Cryopreservation Procedures	
2-cell to 8-cell embryo cryopreservation	202 (87.1%)
Sperm cryopreservation	194 (83.6%)
Zygote (2PN) cryopreservation	188 (81.0%)
>8-cell embryo cryopreservation	165 (71.1%)
Unfertilized oocyte cryopreservation	23 (9.9%)
Not done	1 (0.4%)

D. Microbiology Testing Procedures	
Not done	104 (44.8%)
Water cultures	46 (19.8%)
Culture media cultures	38 (16.4%)
Work surface/environmental cultures	32 (13.8%)
Chlamydia	27 (11.6%)
Semen cultures	27 (11.6%)
N. gonorrhoeae cultures	26 (11.2%)
Mycoplasma cultures	25 (10.8%)
Cervical cultures	22 (9.5%)
Urine cultures	17 (7.3%)
Viruses (e.g,. HSV, CMV)	16 (6.9%)

E. Micromanipulation Procedures	
Intracytoplasmic sperm injection (ICSI)	218 (94.0%)
Assisted embryo hatching	204 (87.9%)
Embryo defragmentation	71 (30.6%)
Diagnostic embryo (blastomere) biopsy	19 (8.2%)
Partial Zona Dissection (PZD)	15 (6.5%)
Subzonal Insertion (SUZI)	10 (4.3%)
Not done	9 (3.9%)
Cytoplasmic transfer	5 (2.2%)

F. Other Testing Procedures	
Animal testing activities (e.g., mouse embryos)	156 (67.2%)
Endocrine testing (e.g., E2, FSH, hCG)	103 (44.4%)
Post coital test	87 (37.5%)
Water production	67 (28.9%)
Cervical mucus tests	42 (18.1 %)
Infectious disease testing (e.g., HIV, HbSAg)	29 (12.5%)
Not done	17 (7.3%)

4. Estimated number of ART cycles respondent embryo laboratories supported in 1997.

17 (7.4%)	less than 50 ART cycles
60 (26.1%)	51–100 ART cycles
75 (32.6%)	101-250 ART cycles
54 (23.5%)	251-500 ART cycles
13 (5.7%)	501-750 ART cycles
5 (2.2%)	751-1000 ART cycles
6 (2.6%)	over 1000 ART cycles
2	No response

5. Respondents did not answer this question in the anticipated manner. Thus the data collected for this question are not easily interpreted.

6. Agencies or organizations accrediting, licensing, or certifying respondent embryo laboratories.

232 (100%)	Food and Drug Administration (FDA)
106 (45.7%)	Health Care Financing Administration (CLIA)
95 (40.9%)	College of American Pathologists Reproductive Laboratory Accreditation Program
61 (26.3%)	Embryo laboratory is not currently accredited, licensed, or certified
51 (22.0%)	State Agency
43 (18.5%)	Joint Commission on Accreditation of Health care Organizations (JCAHO)
21 (9.1%)	Commission for Office Laboratory Accreditation (COLA)
14 (6.0%)	American Association of Tissue Banks (AATB)
3 (1.3%)	Other accreditation/certification

7. Categories of CLIA-licensed testing performed in respondent embryo laboratories.

165 (71.1%)	Diagnostic semen analysis/sperm morphology
92 (39.7%)	Endocrine testing (e.g., E2, FSH, LH, hCG)
52 (22.4%)	No CLIA-licensed testing is offered by respondent embryo laboratory
17 (7.3%)	Microbiology testing (e.g., Ureaplasma, *N. gonorrhoeae*)
14 (6.0%)	Other CLIA-licensed testing
13 (5.6%)	Hematology testing (e.g., CBCs, hematocrit)
6 (2.6%)	Genetic analyses (e.g. FISH, PCR)
2 (0.9%)	Immunohematology testing (e.g., ABO/Rh typing)
2 (0.9%)	Chemistry testing (e.g., glucose, hepatitis, electrolytes)

8. Proximity of respondent embryo laboratories to the procedure room(s) where oocyte retrievals and/or gamete or embryo transfers take place.

a. The distance between the embryo laboratory and the procedure room where *retrievals* take place is:

Within 100 feet 215 (93.1%) Greater than 100 feet 16 (6.9%)

b. The distance between the embryo laboratory and the procedure room where *gametes/embryo transfers* take place is:

Within 100 feet 216 (96.4%) Greater than 100 feet 8 (3.6%)

9. How gametes/embryos are transported to and from the embryo laboratory.

118 (50.9%)	Gametes/embryos are transported at controlled temperature
112 (48.3%)	Gametes/embryos are transported at ambient environmental conditions
56 (24.1%)	Gametes/embryos are transported in a controlled atmosphere
20 (8.6%)	Other transport method

"Other" Responses included:

3 (15.0%)	Controlled atmosphere	2 (10.0%)	Controlled temperature
5 (25.0%)	Controlled atmosphere/temperature	10 (50.0%)	Not transported

10. Features, functions or capabilities available in respondent embryo laboratories.

217 (93.5%)	Sterile procedures are performed in the embryo laboratory
216 (93.1%)	Immediate communication is available to retrieval/transfer rooms
216 (93.1%)	Walls and floors are easily washed and disinfected
214 (92.2%)	Embryo laboratory is in a low-traffic location
203 (87.5%)	Ventilation system has active air filtration
169 (72.8%)	Embryo laboratory is secured at all times
125 (53.9%)	Disinfectants are sprayed on work surfaces
86 (37.1%)	Fluorescent lighting is used in the embryo laboratory
82 (35.3%)	Embryo laboratory is secured during non-business hours only
65 (28.0%)	Area is periodically cleaned by outside cleaning service
33 (14.2%)	Steam or gas sterilization is performed in the embryo laboratory
2 (0.9%)	Laboratory animals are housed in the embryo laboratory

11. Availability of a computer for use by embryo laboratory personnel.

Available	219 (94.4%)	Not available	13 (5.6%)

12. Availability of Internet access from computers within the respondent embryo laboratories.

Available	177 (76.3%)	Not available	55 (23.7%)

13. Facilities with more than 10 individuals working in the embryo laboratory

> 10 individuals	4 (1.7%)	10 or less individuals	228 (98.3%)

NOTE:
***There were 835 people noted in the responses to Questions 14-17 or 3.6 people per respondent embryo lab* oratory.**

14. The education and experience information provided for each of the individuals working the respondent embryo laboratories.

A. Education degrees related to ART

83 (10%)	Medical degree MD, DO, DVM
155 (18.7%)	Doctoral degree PhD, DrPH
17 (2%)	MD/PhD degree
114 (13.7%)	Master's degree
407 (49%)	Bachelor's degree
25 (3%)	Associate degree
17 (2%)	Certificate of technical training
13 (1.6%)	No college degree

B. The academic discipline associated with the highest degree noted for each respondent

28.6% Biology
18.1% Medical Technology
8.5% Reproductive Endocrinology

C. Years of relevant ART experience

mode = 10 yrs
median = 11 yrs

15. Duties performed by each individual working in the respondent embryo laboratories.

693 (83.3%)	Sperm preparation
636 (76.4%)	Oocyte identification
631 (75.8%)	Oocyte insemination
620 (74.6%)	Fertilization assessment
619 (74.5%)	QC testing
618 (64.4%)	Embryo quality assessment
603 (72.6%)	Cryopreservation
601 (72.3%)	Transfer catheter loading
541 (65.1%)	Andrology testing
492 (59.2%)	Micromanipulation
483 (58.0%)	QA/QC reviews
473 (56.9%)	Procedure manual content review
463 (55.7%)	Media preparation
444 (53.5%)	Maintenance manual content review
431 (52.0%)	Safety reviews
427 (51.4%)	Method development
425 (51.3%)	Method Verification
414 (49.9%)	Policy manual content review
319 (38.4%)	Employee competency review
206 (24.8%)	Endocrine testing
161 (19.4%)	Lab animal handling or care
149 (18.0%)	Phlebotomy

16. Distribution of individuals working in primary, secondary and tertiary positions within the respondent laboratories.

POSITION	Primary	Secondary	Tertiary
Total number of respondents	825	586	321
Andrologist	53 (6.4%)	108 (18.4%)	89 (27.7%)
Clinical Consultant	14 (1.7%)	16 (2.7%)	7 (2.2%)
Embryologist	222 (26.9%)	153 (26.1%)	60 (18.7%)
Laboratory Administrator	2 (0.2%)	10 (1.7%)	12 (3.7%)
Laboratory Assistant	9 (1.1%)	6 (1.0%)	1 (0.3%)
Laboratory Director	198 (24.0%)	8 (1.4%)	2 (0.6%)
Laboratory Supervisor (General)	67 (8.1%)	40 (6.8%)	19 (5.9%)
Laboratory Supervisor (Technical)	55 (6.7%)	72 (12.3%)	26 (8.1%)
Laboratory Manager	28 (3.4%)	13 (2.2%)	8 (2.5%)
Laboratory Technician	77 (9.3%)	41 (7.0%)	15 (4.7%)
Medical Assistant	5 (0.6%)	2 (0.3%)	6 (1.9%)
Medical Technologist	45 (5.5%)	32 (5.5%)	17 (5.3%)
Microbiologist	1 (0.1%)	1 (0.2%)	—
Nurse	5 (0.6%)	—	1 (0.3%)
Phlebotomist	—	16 (2.7%)	12 (3.7%)
Reproductive Biologist	21 (2.5%)	34 (5.8%)	29 (9.0%)
Reproductive Technologist	22 (2.7%)	25 (4.3%)	10 (3.1%)
Technical Consultant	1 (0.1%)	9 (1.5%)	8 (2.5%)
Average number of years in primary position?	5.7 years (range 0-60 years)	—	—

The average number of hours each person worked per week in the embryo lab

mean = 33.1 hours (range 1-70 hours)

Approximate number of ART cycles in which each individual participated in 1997

Number of respondents	<50	51-100	101-250	251-500	501-750	751-1000	>1000
804	205 (5.5%)	189 (23.0%)	216 (26.9%)	118(14.7%)	41 (5.1%)	17(2.1%)	18 (2.2%)

16 (continued) Approximate total number of ART cycles in which each individual *ever* participated (at any level of involvement)

Number of respondents	<100	100-500	501-1000	1001-2000	2001-5000	5001-10000	>10000
793	117 (14.8%)	191 (24.1%)	146 (18.4%)	141 (17.8%)	127 (16.0%)	52 (6.6%)	19 (2.4%)

17. Respondent embryo laboratories provided the following information about three major categories of training offered in each of their facilities.

A. Major areas in which training has been completed.

79.2%	General Embryology
77.4%	Cryopreservation
59.8%	Micromanipulation

B. Type of gametes or embryos used for training

	Human	Animal	Both
General Embryology	22.3%	7.3%	70.4%
Cryopreservation	23.8%	11.4%	64.8%
Micromanipulation	17.9%	8.6%	73.5%

C. The number of ART training procedures completed

	None	1-29	30-59	$60
General Embryology	14.4%	26.3%	36.7%	22.6%
Cryopreservation	16.0%	45.3%	24.7%	13.9%
Micromanipulation	28.4%	38.2%	20.4%	13.1%

D. Percent of facilities for which ART training that is documented in writing

	Training documented
General Embryology	52.3%
Cryopreservation	50.2%
Micromanipulation	46.5%

18. Information that retained in respondent embryo laboratory employee personnel files.

216 (93.1%)	Copy of resume or CV
205 (88.4%)	List of expected duties and responsibilities
202 (87.1%)	Copies of periodic performance reviews
182 (78.4%)	Record of attendance or personal participation in educational programs or technical meetings
171 (73.7%)	Copy of current license or registry certificates
170 (73.3%)	List of job qualifications
160 (69.0%)	List of professional organization memberships
153 (65.9%)	Documented training completed in the laboratory on each specific test the individual is authorized to perform
123 (53.0%)	Competency testing
103 (44.4%)	Level of supervision required
92 (39.7%)	College transcripts

19. Percent of facilities that *require* embryo laboratory technical personnel to participate in continuing education?

Participation is required by 131 (58.5%) laboratories.
Participation is not required by 93 (41.5%) laboratories

20. Distribution of the annual number of hours of ART-related continuing education (CE) that the respondent embryo laboratories require for each of the indicated employment levels

Employment Level	CE Not Required	Approximate number hours of CE required per year					
		#5	6-10	11-15	16-20	21-25	>25
Laboratory director	31 (21.2%)	19 (13.0%)	27 (18.5%)	21 (14.4%)	14 (9.6%)	12 (8.2%)	22 (15.1%)
Laboratory supervisor	32 (28.1%)	16 (14.0%)	29 (25.4%)	16 (14.0%)	8 (7.0%)	9 (7.9%)	4 (3.5%)
Technologists/technicians	50 (37.9%)	27 (20.5%)	29 (22.0%)	16 (12.1%)	3 (2.3%)	4 (3.0%)	3 (2.3%)
Non-technical personnel	61 (75.3%)	9 (11.1%)	5 (6.2%)	3 (3.7%)	1 (1.2%)	1 (1.2%)	1 (1.2%)

21. Types of ART-related continuing education (CE) opportunities in which personnel associated with the respondent embryo laboratories participate.

Type of continuing education	Lab Director	Lab Supervisor	Technical staff	Non-technical staff*
International professional/scientific workshops	124 (53.4%)	56 (24.1%)	38 (16.4%)	4 (1.7%)
National professional/scientific workshops	152 (65.5%)	102 (44.0%)	104 (44.8%)	5 (2.2%)
Regional professional/scientific workshops	115 (49.6%)	84 (36.2%)	85 (36.6%)	7 (3.0%)
State/local professional/scientific workshops	95 (40.9%)	78 (33.6%)	86 (37.1%)	9 (3.9%)
Video conference training seminars	24 (10.3%)	25 (10.8%)	23 (9.9%)	5 (2.2%)
Audio conference training seminars	9 (3.9%)	7 (3.0%)	4 (1.7%)	2 (0.9%)
In-house training	82 (35.3%)	90 (38.8%)	119 (51.3%)	27 (11.6%)
On-the-job training	76 (32.8%)	90 (38.8%)	120 (51.7%)	27 (11.6%)
Vendor- or manufacturer-sponsored training	69 (29.7%)	68 (29.3%)	78 (33.6%)	15 (6.5%)

*Non -technical staff = Management personnel, administrative personnel

22. The form in which ART patient information is retained by the respondent embryo laboratories

Information	Info. not kept	Information is retained in the following form:		
		Written records	microfilm/ microfiche	computerized records
Diagnostic test results	5 (2.2%)	219 (94.4%)	8 (3.4%)	108 (46.6%)
ART patient demographic information	7 (3.0%)	208 (89.7%)	8 (3.4%)	139 (59.9%)
ART stimulation cycle information	4 (1.7%)	221 (95.3%)	8 (3.4%)	113 (48.7%)
Gamete donor information	5 (2.2%)	204 (87.9%)	6 (2.6%)	89 (38.4%)
Oocyte/embryo assessment information	0	229 (98.7%)	9 (3.9%)	106 (45.7%)
Embryo cryopreservation information	0	225 (97.0%)	7 (3.0%)	134 (57.8%)
Gamete/embryo micromanipulation information	0	219 (94.4%)	8 (3.4%)	116 (50.0%)

23. Respondent embryo laboratories provided the following record retention information.

Records that are retained	Laboratories indicating that a defining event initiated record retention	Duration of record retention		
		Indefinitely	Specified # of years after defining event*	Records not retained
Oocyte/embryo assessment records	151 (65.1%)	204 (90.3%)	—	0 (0%)
Culture media QC records	150 (64.7%)	159 (71.9%)	—	0 (0%)
Water quality records	111 (47.8%)	123 (66.1%)	—	12 (6.5%)
Sperm preparation records	148 (63.8%)	182 (82.4%)	—	1 (0.5%)
Gamete/embryo cryopreservation records	147 (63.4%)	207 (92.8%)	—	0 (0%)
Donor sperm/oocyte records	138 (59.5%)	192 (91.0%)	—	1 (0.5%)
Infectious disease testing records	116 (50.0%)	155 (81.6%)	—	9 (4.7%)
Laboratory safety inspection records	138 (59.5%)	160 (74.8%)	—	3 (1.4%)
ART procedure records	149 (64.2%)	193 (86.9%)	—	0 (0%)
Personnel records	150 (64.7%)	177 (82.3%)	—	2 (0.9%)
Equipment/instrument calibration records	150 (64.7%)	155 (70.5%)	—	0 (0%)
Lab QA/QC records	147 (63.4%)	158 (71.8%)	—	0 (0%)

* Because of the diversity of responses to this question, results for this column cannot be categorized.

24. Measures employed by the respondent embryo laboratories to maintain data confidentiality.

218 (94.0%)	Limited access to laboratory test records/results
218 (94.0%)	Limited access to ART procedure results
213 (91.8%)	Limited/controlled access to patient medical records
206 (88.8%)	Physical access to embryo laboratory limited to lab personnel
125 (53.9%)	Password-protected computer files
4 (1.7%)	Other (see below)

"Other" Responses	
Alarm System in ART Building	1 (25.0%)
Confidentiality Agreement	1 (25.0%)
Magnetic door locks on incubator, cryotank storage room & lab	1 (25.0%)
Use of Patient ID# rather than Patient Name in statistical databases	1 (25.0%)

25. Percent of respondent embryo laboratories that log or record electronic access to confidential patient materials

42 (18.4%) of respondent laboratories log or record electronic access to patient materials
186 (81.6%) of respondent laboratories do not log or record electronic access to patient materials

26. How responding laboratories determine the use or disposition of gametes (i.e., sperm or oocytes) and/or embryos during ART procedures.

Laboratory Action	Use or disposition is governed by	
	Patient instructions	Laboratory/clinic policy
Disposition of excess viable embryos (i.e., embryos not transferred)	177 (76.3%)	66 (28.4%)
Placing gametes or embryos into cryostorage	202 (87.1%)	44 (19.0%)
Use of cryostored gametes/embryos	214 (92.2%)	29 (12.5%)
Disposition of "abandoned" cryostored gametes or embryos	104 (44.8%)	128 (55.2%)
Use of *donor* sperm for ART inseminations	206 (88.8%)	32 (13.8%)
Use of *donor* oocytes or embryos for transfers	182 (78.4%)	36 (15.5%)
Use of *donated* sperm	150 (64.7%)	67 (28.9%)
Use of *donated* oocytes or embryos	143 (61.6%)	72 (31.0%)

27. How the respondent embryo laboratories indicated that are notified of impending ART procedures

192 (82.8%) of laboratories receive verbal notification of pending ART procedures from clinic staff
115 (49.6%) of laboratories receive written notification of pending ART procedures from clinic staff
58 (25.0%) of laboratories are notified by "other"means of communication

Distribution of responses for "Other" means of notification:
31% use **verbal** forms of notification
60% use **written** forms of notification
9% use **both** verbal and written forms

28. The amount of advanced notification respondent embryo laboratory staff receive for pending ART procedures

143 (61.6%) of the laboratories were notified prior to ovulation induction for the intended ART cycle
58 (25.0%) were notified at the time of ovulation induction for intended ART cycle
38 (16.4%) were notified after ovulation induction has been initiated for the intended ART cycle
11 (4.7%) Other

28 (continued)

ASI grouping of "Other" Responses:

1. After ovulation induction, 4 (36.4%)
- At ovulation induction, 3 (27.3%)
- Other, 4 (36.4%)

29. How respondent embryo laboratories are notified of patient informed consent for ART procedures

36 (15.5%)	Laboratory is not informed.
80 (34.5%)	Verbal notification is provided by clinical staff
75 (32.3%)	A copy of the *entire informed consent* is provided to the laboratory
41 (17.7%)	Written notification that informed consent has been obtained is verified by the *embryo laboratory* on a support request form
30 (12.9%)	Written notification that informed consent has been obtained is verified by the *requesting physician* on embryo laboratory support request form
49 (21.1%)	*Other method of notification used* (80% Written, 10% Verbal, 10% Both)

30. How respondent embryo laboratory are notified that informed consent has been provided when *changes* to the intended ART procedures occur

81 (34.9%)	Verbal notification is provided by clinical staff with written follow-up
78 (33.6%)	Verbal notification is provided by clinical staff without written follow-up
55 (23.7%)	A copy of the entire *revised* informed consent form is provided
29 (12.5%)	Other means of notification (65% Written, 27% Verbal, 3% Both, 3% Unknown)
22 (9.5%)	Written notification that informed consent has been revised, is verified by the requesting physician on embryo laboratory support request form
22 (9.5%)	The laboratory is not informed.
10 (4.3%)	A copy of only the signature page from the *revised* consent form is provided

31. What elements of informed consent are provided to the embryo laboratory? ***Check all that apply*** .

174 (75.0%)	Consent for gamete/embryo cryopreservation
152 (65.5%)	Consent for disposal of gametes or embryos
145 (62.5%)	Consent for micromanipulation of gametes or embryos
141 (60.8%)	Consent for oocyte retrieval
127 (54.7%)	Consent for use of donor oocytes
126 (54.3%)	Consent for donor sperm insemination of oocytes
91 (39.2%)	Consent for embryo transfer (with a *maximum* number of embryos specified)
80 (34.5%)	Consent for in vitro research use of gametes or embryos
69 (29.7%)	Consent for embryo transfer (with a *no maximum* number of embryos specified)
43 (18.5%)	None

32. Laboratory response to whether they will proceed with ART procedures if informed consent for ART procedures is *not* provided.

126 (65.6%)	Laboratory will ***not*** proceed without verification that patient hasprovided informed consent
66 (34.4%)	Laboratory ***will*** proceed with ART procedures under physician direction without patient informed consent

33. Laboratory response to whether animal cell lines used in the embryo laboratory for QA testing or for co-culture purposes

117 (50.4%)	Animal cells are used for QA testing
94 (40.5%)	Animal cells are not used
19 (8.2%)	Animal cells are used for co-culture purposes

34. Source of cells or cell lines used for QA testing or co-culture

98 (73.1%)	Ready-for-use cell lines are obtained from a vendor
23 (17.2%)	Cell line stocks are maintained and prepared in facility forlaboratory use
13 (9.7%)	Both of the above

35. Animal species and cellular components used for QA testing purposes in the respondent embryo laboratories.

Species	Cells from these species are used in the laboratory for testing purposes			
	sperm	oocytes	embryos	other cells
Hamster	1 (0.4%)	41 (17.7%)	1 (0.4%)	0 (0%)
Mice	4 (1.7%)	15 (6.5%)	142 (61.2%)	1 (0.4%)
Rat	0 (0%)	0 (0%)	1 (0.4%)	2 (0.9%)
Bovine	0 (0%)	0 (0%)	1 (0.4%)	3 (1.3%)
Rabbit	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Human	78 (33.6%)	6 (2.6%)	6 (2.6%)	4 (1.7%)
Rhesus monkey	0 (0%)	0 (0%)	0 (0%)	1 (0.4%)

36. Where laboratory animals are housed in relation to the embryo laboratory.

146 (62.9%)	Laboratory animals are not used.
48 (20.7%)	In a separate building
15 (6.5%)	In the same building as the embryo laboratory, but not in the laboratory
3 (1.3%)	In the andrology laboratory
0 (0%)	In the embryo laboratory

37. Laboratory response to whether animal testing is performed by an independent facility

43 (19.5%) laboratories said Yes
177 (80.5%) laboratories said No
12 laboratories did not reply

38. Properties or features present in *technical procedure* manuals used in the respondent embryo laboratories

230 (99.1%)	There is a written procedure for each embryo laboratory activity
225 (97.0%)	Procedures are written in sufficient detail to assure reproducibility and competence
220 (94.8%)	Manuals specify equipment and/or materials to be used for a given procedure
216 (93.1%)	Manuals specify the source of materials or reagents to be used
215 (92.7%)	Procedure changes are signed/dated by the director or supervisor
211 (90.9%)	Manual specifies how biological materials are to be handled, processed and/or disposed of
211 (90.9%)	Procedure document shows director review and approval
192 (82.8%)	Manual(s) are readily available for use or referral at each work station
183 (78.9%)	Procedure manual format follows the most recent NCCLS recommendations
174 (75.0%)	Reference materials (slides, pictures, textbooks, etc.) are availablefor comparison with patient specimens
131 (56.5%)	A page is provided in the manual to record who has received training or updated training on new or revised procedures
7 (3.0%)	No procedure manuals are available for use in our embryo laboratory

39. Properties or features present in equipment *maintenance and/or equipment operation* manuals used in the respondent embryo laboratories

217 (93.5%)	Equipment/maintenance manual(s) are readily available for use or referral in the vicinity of the referenced equipment
205 (88.4%)	A log is provided to document all maintenance procedures and corrective actions taken
190 (81.9%)	Manuals provide trouble-shooting procedures to diagnosing equipment problems
187 (80.6%)	Manuals specify the frequency with which operational checks should be performed
186 (80.2%)	Operation/maintenance procedures are written in sufficient detail to assure proper/safe operation
185 (79.7%)	Manuals specify who to contact for service or parts
179 (77.2%)	Each piece of equipment used in the embryo laboratory has a written procedure on its proper use and maintenance
67 (28.9%)	Abbreviated operation/maintenance procedures are posted near each piece of equipment
54 (23.3%)	Manuals specify the level of personnel competence required to operate each piece of equipment
8 (3.4%)	No maintenance manuals are available for use in our embryo laboratory

40. Properties or features present in *policy* manuals used in the respondent embryo laboratories

212 (91.4%)	Specimen handling/Universal Precaution policies
209 (90.1%)	Quality Control/Quality Assurance manuals
204 (87.9%)	Chemical hygiene (safety) plan
198 (85.3%)	Accident/incident policies
192 (82.8%)	Personnel duties and responsibilities
180 (77.6%)	Policies specify how test and ART procedure results are to be reported
179 (77.2%)	Policy manuals contain written procedure for their regular review
179 (77.2%)	Policies discuss laboratory chain of command
179 (77.2%)	Disaster preparedness policies
174 (75.0%)	Training and/or competency testing
166 (71.6%)	Personnel policies for job performance review
146 (62.9%)	Manuals specify which records must be kept and for how long
129 (55.6%)	Personnel policies for continuing education
5 (6.5%)	Policy manuals are not available for use in our embryo laboratory

41. Frequency of embryo laboratory staff review procedure, policy and maintenance manuals.

Frequency of review	Procedure	Maintenance	Policy
Annually	153 (65.9%)	141 (60.8%)	150 (64.7%)
Semi-annually	14 (6.0%)	20 (8.6%)	10 (4.3%)
Quarterly	6 (2.6%)	7 (3.0%)	2 (0.9%)
Whenever the manual is revised	72 (31.0%)	58 (25.0%)	56 (24.1%)
Whenever the Laboratory Director changes	22 (9.5%)	18 (7.8%)	22 (9.5%)
There is no formal policy for review	14 (6.0%)	22 (9.5%)	21 (9.1%)

42. Devices or techniques used for controlling the environment for gamete/embryo manipulations.

201 (86.6%)	heating blocks
198 (85.3%)	microscope warming stage
161 (69.4%)	slide warmer/warming trays for culture containers
134 (57.8%)	water bath for warming fluid substances
120 (51.7%)	dry heat incubator for warming equipment/utensils
74 (31.9%)	Hoffman IVF or MBT Chamber
66 (28.4%)	dry bath for warming equipment/utensils
66 (28.4%)	Modified pediatric isolette
31 (13.4%)	Other *(Controlled atm 39%, Controlled atm/temp 42%, Controlled temp 19%)*
19 (8.2%)	K-Systems Mini-Incubator/workstation

43. Types of hoods that are used in indicated areas within the respondent embryo laboratories

Hood Type	Laboratory area(s) where these hoods are located		
	sperm prep area	oocyte/embryo culture area	media prep area
Hood not used	55 (23.7%)	22 (9.5%)	10 (4.3%)
Fume hood (non-filtered air vented outside lab)	4 (1.7%)	0 (0%)	3 (1.3%)
Clean bench (i.e., horizontal laminar flow hood)	84 (36.2%)	130 (56.0%)	124 (53.4%)
Class I biological safety cabinet (air flows in at front, out at rear and top through HEPA filter)	35 (15.1%)	34 (14.7%)	36 (15.5%)
Class II biological safety cabinet (HEPA filtered vertical laminar airflow and HEPA filtered exhaust air)	47 (15.1%)	44 (19.0%)	53 (22.8%)

44. Types of room air filtration systems used by the respondent embryo laboratories

174 (75.0%)	HEPA filter
142 (61.2%)	Positive air pressure
76 (32.8%)	Particulate filter
63 (27.2%)	Carbon filter
22 (9.5%)	Embryo laboratory does not filter room air
7 (3.0%)	Electrostatic filtration system

45. Types of incubators that are used in the areas indicated within the respondent embryo laboratories.

Incubator Type	Laboratory area(s) where these incubators are located		
	Sperm preparation area	Oocyte or embryo culture area	Media preparation area
Water-jacketed, gas & humidity controlled	154 (66.4%)	227 (97.8%)	155 (66.8%)
Dry heat incubator/oven	40 (17.2%)	41 (17.7%)	61 (26.3%)
Portable incubator (e.g., pediatric isolette)	12 (5.2%)	70 (30.2%)	9 (3.9%)

46. Responses to how environmental parameters are monitored in the incubator(s) used for gamete/embryo culture

A. Atmospheric gas content is monitored by:

Chemical (Fyrite)	211 (90.9%)
Media pH	139 (59.9%)
Check here if gas content is automatically recorded by any of the devices above	40 (17.2%)
Infrared gas monitor (external)	38 (16.4%)
Other method(s) of monitoring atmospheric gas content *(Active/Automatic 73%, Passive/Manual 24%, Other 3%)*	33 (14.2%)
Mass Spectrometer	2 (0.9%)
Incubator atmospheric gas content is not monitored	2 (0.9%)

46 (Continued)

B. Temperature is monitored by:

Internal thermometer (in addition to the inherent temperature monitor)	230 (99.1%)
External/remote temperature monitoring device (e.g., YSI digital thermometer)	63 (27.2%)
Check here if temperature is automatically recorded by any of the devices above	57 (24.6%)
Other method of monitoring temperature *(Active/Automatic 67%, Passive/Manual 33%)*	9 (3.9%)
Incubator temperature is not monitored	0 (0%)

C. Humidity is monitored by:

[Incubator humidity is not monitored]	122 (52.6%)
Hygrometer	71 (30.6%)
Other method of monitoring humidity *(Active/Auto 6%, Passive/Manual 85%, Other 9%)*	33 (14.2%)
Thermal conductivity	14 (6.0%)
Check here if humidity is automatically recorded by any of the devices above	13 (5.6%)
Wet-bulb thermometer	4 (1.7%)

47. Frequently at which incubator conditions monitored during the period when human gametes/embryos are in the incubator

Monitoring Frequency	Condition monitored		
	Temperature	Gas levels	Humidity
Not monitored	0 (0%)	2 (0.9%)	77 (38.5%)
Continuously (strip chart recorder)	27 (11.8%)	25 (10.9%)	5 (2.5%)
Hourly	4 (1.7%)	3 (1.3%)	1 (0.5%)
Twice daily	20 (8.7%)	20 (8.7%)	11 (5.5%)
Daily	166 (72.5%)	166 (72.5%)	90 (45.0%)
Before each use	6 (2.6%)	6 (2.6%)	9 (4.5%)
Other interval	6 (2.6%)	7 (3.1%)	7 (3.5%)

48. Response to whether there Is there a *written* on-call policy for the embryo laboratory so that a staff member can be contacted in the event of a problem?

Yes 175 (76.8%) No 53 (23.2%)

49. Parameters or conditions monitored by a laboratory alarm/alert system

214 (92.2%)	Incubator temperature
198 (85.3%)	Incubator gas content
166 (71.6%)	Liquid nitrogen levels
162 (69.8%)	Electrical power is on
118 (50.9%)	Smoke detectors
65 (28.0%)	Controlled rate freezers
62 (26.7%)	Refrigerator or mechanical freezer temperatures
57 (24.6%)	Noise level detectors
34 (14.7%)	Motion detectors
34 (14.7%)	Oxygen level sensors
24 (10.3%)	Infrared (heat) detectors
5 (2.2%)	No alarm or alert system is used

50. Laboratory response to how the emergency power system is activated in the event of a power failure.

Type of emergency power system	Is the system automatically activated?	Is the system manually activated by the embryo lab staff?
NO back up system is available	5 (2.2%)	1 (0.4%)
Battery powered back up system	89 (38.4%)	3 (1.3%)
Fuel powered generator	160 (69.0%)	14 (6.0%)
Other system	17 (7.3%)	2 (0.9%)

51. How emergency alarms and power back up systems are checked to ensure correct function.

Who checks the system?	Emergency alarm systems	Back-up system for electrical power
System is NOT periodically checked	7 (3.0%)	5 (2.2%)
Periodically checked embryo laboratory staff	148 (63.8%)	57 (24.6%)
Periodically checked by facility maintenance staff	66 (28.4%)	153 (65.9%)
Periodically checked by other personnel	12 (5.2%)	13 (5.6%)
Respondent did not know	4 (1.7%)	6 (2.6%)

52. Safety inspections conducted within the respondent embryo laboratories:

198 (85.3%)	Hood/biological safety cabinet operation
194 (83.6%)	Fire extinguisher operation
190 (81.9%)	Electrical hazards
185 (79.7%)	Fire hazards
161 (69.4%)	Hazardous materials storage
136 (58.6%)	Infection hazards
125 (53.9%)	Volatile materials storage
16 (6.9%)	Radioactive materials storage

53. Types of devices used in the respondent embryo laboratories for ART procedures

Device	Disposable	Re-usable	Not used
Syringes	230 (99.1%)	7 (3.0%)	0 (0%)
Serological pipettes	229 (98.7%)	1 (0.4%)	2 (0.9%)
Transfer pipettes	231 (99.6%)	0 (0%)	1 (0.4%)
Oocyte/embryo culture dishes	232 (100%)	0 (0%)	0 (0%)
Oocyte retrieval needles	223 (96.1%)	8 (3.4%)	1 (0.4%)
Embryo transfer catheters	226 (97.4%)	8 (3.4%)	0 (0%)

54. Methods used for sterilizing equipment and/or materials used by the respondent embryo laboratories.

216 (93.1%)	Materials are purchased pre-sterilized by the manufacturer
180 (77.6%)	Steam sterilization (e.g. autoclave)
131 (56.5%)	Dry heat sterilizers
76 (32.8%)	Gas (e.g., ethylene oxide)
17 (7.3%)	Liquid chemical (e.g. Cidex)
7 (3.0%)	Ionizing radiation
4 (1.7%)	Microwave radiation
4 (1.7%)	Other sterilizing method *Etoh 70%; Sterad (H_2O_2 Gas) 50%; U.V. Light, 25%*

55. Quality control methods used to verify device sterilization.

186 (80.2%)	Heat-sensitive tape affixed to outside of autoclaved or dry heat sterilized packets
159 (68.5%)	Date of sterilization noted on the outside of the packet
118 (50.9%)	Heat- or chemical-sensitive indicators placed inside of sterilized packets
107 (46.1%)	Date of sterilization expiration noted on the outside of the packet
98 (42.2%)	Mechanical monitoring (e.g., monitor and record autoclave temperature, pressure and duration of sterilization cycles)
63 (27.2%)	*B. subtilis* spore strips/vials to monitor the effectiveness of dry heat or gas sterilization
63 (27.2%)	Chemical-sensitive tape affixed to outside of gas-sterilized packets
61 (26.3%)	*B. stearothermophilus* spore strips/vials to monitor the effectiveness of steam or microwave sterilization

56. Laboratory response to whether embryo manipulation procedures carried out under oil.

Yes 206 (89.2) No 25 (10.8%)

57. Types of protected environments in which ART procedures are performed in the respondent embryo laboratories

Procedure	Procedure is performed in			
	environmentally controlled chamber	a hood with the		non-controlled environment
		fan turned on	fan turned off	
Preparation of culture media	16 (7.7%)	170 (82.1%)	14 (6.8%)	7 (3.4%)
Oocyte identification & assessment	92 (40.4%)	78 (34.2%)	39 (17.1%)	19 (8.3%)
Sperm preparation	10 (4.5%)	135 (60.3%)	16 (7.1%)	63 (28.1%)
Oocyte insemination	84 (36.7%)	86 (37.6%)	40 (17.5%)	19 (8.3%)
Fertilization assessment	92 (40.4%)	65 (28.5%)	39 (17.1%)	32 (14.0%)
Embryo assessment	93 (40.6%)	60 (26.2%)	37 (16.2%)	39 (17.0%)
Transfer catheter loading	88 (38.4%)	82 (35.8%)	43 (18.8%)	16 (7.0%)
Cryopreservation procedures	34 (15.3%)	100 (45.0%)	42 (18.9%)	46 (20.7%)
Micromanipulation (any type)	69 (31.9%)	10 (4.6%)	21 (9.7%)	116 (53.7%)

58. Laboratory response to whether embryo laboratory procedures are routinely photographed or video taped.

No 117 (51.1%) Yes 112 (48.9%)

59. Procedures which are routinely photographed or video taped by those laboratories responding "Yes" to question 58

107 (46.1%)	Embryo quality assessment
72 (31.0%)	Thawed gametes/embryo assessment
39 (16.8%)	Micromanipulation procedures
11 (4.7%)	Oocyte location/identification
8 (3.4%)	Oocyte insemination
7 (3.0%)	Semen motility
1 (0.4%)	Sperm preparation

60. How photographs or video tapes are used by laboratories responding "Yes" to question 58.

89 (38.4%)	to maintain a record of the procedure
73 (31.5%)	for teaching/training purposes
38 (16.4%)	for embryo identification
36 (15.5%)	for oocyte/embryo morphometrics
31 (13.4%)	to evaluate employee competency
28 (12.1%)	for oocyte quality assessment
23 (9.9%)	Other reason *(for Lab Purposes, 9%; for Patient records, 87%; Both ,4%)*
6 (2.6%)	for oocyte identification

61. Information documented as a part of embryo laboratory procedures

230 (99.1%)	Number of embryos transferred
230 (99.1%)	Date/time of embryo transfer
230 (99.1%)	Embryo quantity/quality assessments
230 (99.1%)	ART procedure date/time
230 (99.1%)	Fertilization assessments
229 (98.7%)	Information about oocyte insemination
229 (98.7%)	Number/quality of oocytes identified
227 (97.8%)	Information about sperm preparation procedures
225 (100%)	Patient identifiers
225 (97.0%)	Disposition of non-transferred embryos
223 (96.1%)	Identity of lab staff participating in the ART procedures
222 (95.7%)	Lot/batch numbers of media used
215 (92.7%)	Information about micromanipulation procedures
212 (91.4%)	Gamete/embryo identifiers
210 (90.5%)	Partner identifiers
208 (89.7%)	Donor identifiers
118 (50.9%)	Verification of informed consent
109 (47.0%)	Information about follicular fluids aspirated
105 (45.3%)	Lot/batch numbers of disposable supplies used
10 (4.3%)	Other information

62. Response to whether the embryo laboratory makes their own embryo culture media.

No 168 (72.7%) Yes 63 (27.3%)

63. Type of water is used for formulating embryo culture media by those laboratories responding "Yes" to question 62.

17 (7.3%)	HPLC-grade water
7 (3.0%)	distilled/deionized water
4 (1.7%)	Deionized water
1 (0.4%)	Distilled water
39 (16.8%)	Other water source *DI-(probably RO) 5%, Purchased 23%, RO 54%, Other 18%*

64. Type of nutrient media is used for gamete/embryo culture by those laboratories responding "Yes" to question 62

201 (86.6%)	Commercially prepared liquid media (i.e., ready-to-use media)
28 (12.1%)	Media prepared in the embryo lab using commercially prepared powdered media base, other added reagents (e.g., antibiotics), and*facility-prepared* water
24 (10.3%)	Media prepared in the embryo lab using commercially prepared Powdered media base, other added reagents (e.g., antibiotics), and*commercially prepared* water
22 (9.5%)	Media prepared entirely in the embryo lab using stock chemicals/reagents and *facility-prepared* water (i.e., prepared from "scratch")
11 (4.7%)	Media prepared entirely in the embryo lab using stock chemicals/reagents and *commercially-prepared* water (i.e., prepared from "scratch")
2 (0.9%)	Other *(Commercial serum w/ in-house serum)*

65. Substances are used to supplement media used for embryology procedures by laboratories responding "Yes" to question 62.

169 (72.8%)	Synthetic serum substitute
127 (54.7%)	Antibiotics (e.g., penicillin)
126 (54.3%)	Anticoagulants (e.g., heparin)
114 (49.1%)	Human serum albumin
48 (20.7%)	Maternal (patient) plasma/serum
40 (17.2%)	Bovine serum albumin
16 (6.9%)	Donor plasma/serum
15 (6.5%)	Plasmanate
12 (5.2%)	Fetal calf serum
6 (2.6%)	Other non-protein macro molecules
5 (2.2%)	Plasmatein
4 (1.7%)	Cord blood
2 (0.9%)	Other protein source *(MOM 50%, Plasmarc 50%)*

66. Information recorded in respondent embryo laboratory records to document use of chemicals, prepackaged media, and/or other media components or reagents used in ART procedures.

223 (96.1%)	Lot number
220 (94.8%)	Source (manufacturer/vendor)
206 (88.8%)	Expiration/use by/discard by date
197 (84.9%)	Receipt date
183 (78.9%)	Date opened
90 (38.8%)	Purchase order number
25 (10.8%)	Temperature upon receipt

67. Criteria routinely used by respondent embryo laboratory personnel to assess oocyte quality and maturity (excluding microfertilization or ICSI procedures)

204 (87.9%)	Corona-cumulus complex
136 (58.6%)	Appearance of oocyte cytoplasm
130 (56.0%)	Presence/absence of 1st polar body
124 (53.4%)	Presence/absence of germinal vesicle
123 (53.0%)	Appearance of granulosa cells
73 (31.5%)	Presence/absence of cytoplasmic vesicles
47 (20.3%)	Zona pellucida thickness
8 (3.4%)	Other criteria

68. Laboratory response to how oocytes that are judged to be immature are routinely handled.

142 (61.2%)	Inseminate at the same time as mature oocytes
104 (44.8%)	Incubate until mature, then inseminate
28 (12.1%)	Immature oocytes are discarded
10 (4.3%)	Other procedure
9 (3.9%)	Immature oocytes are used for research purposes

69. Laboratory response to how are oocytes incubated.

161 (69.4%)	Multiple oocytes (from the same source)are incubated in a volume of culture media
88 (37.9%)	Oocytes are cultured Individually in own volume of culture media

70. Laboratory response to whether they perform sperm preparation for embryology procedures.

Yes 227 (98.7%) No 3 (1.3%)

71. Laboratory response to how semen specimens are transported to the embryo laboratory from an external site.

136 (58.6%)	All specimens are collected at the facility and no transport is required
110 (47.4%)	Patient/partner delivers specimen to embryo lab
80 (34.5%)	Specimen is transported to embryo lab at ambient temperature
40 (17.2%)	Specimen is kept warm (e.g., 37EC) using active or passive warming devices
6 (2.6%)	Courier service delivers specimen

72. Purposes for which sperm isolation procedures are used in the respondent embryo laboratories.

7 (3.0%)	Sperm are not isolated by the respondent embryo laboratory
221 (95.3%)	Sperm are used for in vitro oocyte inseminations/ICSI
153 (65.9%)	Sperm are used for intrauterine inseminations
151 (65.1%)	Sperm are used for gamete intrafallopian transfer (GIFT)
60 (25.9%)	Sperm are used for diagnostic testing (e.g., SPA)

73. Laboratory categorization of the usefulness of the listed criteria for assessing normal (i.e., 2PN) fertilization.

Criteria	Very useful	Moderately useful	Not very useful
Presence or absence of pronuclei	228 (99.1%)	2 (0.9%)	0 (0%)
2nd polar body extrusion	76 (33.5%)	111 (48.9%)	40 (17.6%)
Cleavage	69 (30.8%)	65 (29.0%)	90 (40.2%)
Cytoplasmic traits	22 (10.0%)	69 (31.5%)	128 (58.4%)
Dissolution of corona-cumulus complex	13 (5.9%)	50 (22.8%)	156 (71.2%)
Presence of sperm in perivitelline space	7 (3.2%)	32 (14.6%)	180 (82.2%)
Thickness of the zonae pellucida	13 (5.9%)	37 (16.8%)	170 (77.3%)

74. Laboratory categorization of the usefulness of the listed criteria for assessing embryo quality for possible transfer.

Criteria	Very useful	Moderately useful	Not very useful
Number of blastomeres present	224 (97.0%)	7 (3.0%)	0 (0%)
Rate of cleavage	196 (84.8%)	32 (13.9%)	3 (1.3%)
Uniform/irregular blastomere size/shape	196 (84.5%)	36 (15.5%)	0 (0%)
Absence/presence of fragments/blebs	188 (81.4%)	42 (18.2%)	1 (0.4%)

Cytoplasmic granularity	68 (29.8%)	138 (60.5%)	22 (9.6%)
Thickness of the zonae pellucida	35 (15.5%)	114 (50.4%)	77 (34.1%)
Evidence of fertilization (esp. for reinseminated oocytes)	119 (54.8%)	56 (25.8%)	42 (19.4%)

75. Laboratory response to how polyploid zygotes are handled.

200 (86.2%)	They are discarded
124 (53.4%)	They are used for training lab personnel in various handling techniques
87 (37.5%)	They are frozen/thawed for training purposes
58 (25.0%)	They are allowed to continue to develop
0 (0%)	They are transferred with other embryos
12 (5.2%)	Other *(Discarded, 17%; QC, 33%; Research, 42%; Transferred, 8%)*

76. Laboratory response to whether they routinely culture embryos to the blastocyst stage for embryo transfer.

No 157 (68.3%) Yes 73 (31.7%)

77. Circumstances under which respondent embryo laboratories indicated they would allow embryos to progress to the blastocyst stage.

54 (23.3%)	Poor quality (morphology) embryos are cultured to blastocyst stage
29 (12.5%)	Embryos are cultured to blastocyst when previous embryo transfers have failed to implant
12 (5.2%)	Embryos from older patients are cultured to blastocyst stage
9 (3.9%)	All embryos are routinely cultured to blastocyst stage
46 (19.8%)	Other circumstance *(Excess embryos 30%, Cryopreservation 21%, Lab Purposes/Other 33%, Patient instructions 16%)*

78. Laboratory response to whether transfer devices are flushed and the flush solution examined for un-transferred embryos after embryo transfer procedures

Yes, devices are flushed and examined	231 (100%)	No, devices are not flushed and examined	0 (0%)

79. Disposition of excess zygotes or embryos that are not transferred or frozen and how this disposition is governed in the respondent laboratories.

Excess zygotes or embryos	Disposition is	
	with patient consent	without patient consent
are immediately discarded	115 (49.6%)	15 (6.5%)
are cultured to demise and discarded	107 (46.1%)	28 (12.1%)
are donated for research purposes	55 (23.7%)	0 (0%)
are donated for diagnostic purposes	27 (11.6%)	0 (0%)
are donated for training purposes	52 (22.4%)	9 (3.9%)
are donated to another patient/couple	43 (18.5%)	0 (0%)

80. Laboratory response to whether or not they perform cryopreservation procedures.

No 12 (5.3%) Yes 215 (94.7%)

81. Cyopreservation procedures used by embryo laboratories responding "Yes" to question 80.

Cell type	Cells are		Check cryoprotectant used (for clinical procedures):			
	frozen for patient use	frozen for research, training purposes	Glycerol	DMSO	Propylene glycol	Other
Oocytes	25 (10.8%)	17 (7.3%)	7 (3.0%)	1 (0.4%)	30 (12.9%)	1 (0.4%)
Pronuclear cells	188 (81.0%)	15 (6.5%)	5 (2.2%)	2 (0.9%)	180 (77.6%)	8 (3.4%)
2-8 cell embryos	199 (85.8%)	15 (6.5%)	5 (2.2%)	13 (5.6%)	184 (79.3%)	10 (4.3%)
>8 cell to blastocyst embryos	159 (68.5%)	15 (6.5%)	139 (59.9%)	10 (4.3%)	28 (12.1%)	9 (3.9%)
Ejaculated sperm	190 (81.9%)	19 (8.2%)	135 (58.2%)	0 (0%)	4 (1.7%)	57 (24.5%)
Epididymal sperm	158 (68.1%)	5 (2.2%)	110 (47.4%)	0 (0%)	4 (1.7%)	49 (21.1%)
Testicular sperm	151 (65.1%)	7 (3.0%)	102 (44.0%)	0 (0%)	5 (2.2%)	49 (21.1%)
Single sperm cells	15 (6.5%)	4 (1.7%)	11 (4.7%)	0 (0%)	0 (0%)	4 (1.7%)

82. Response to how frozen QA/QC cells or cell lines are stored by laboratories responding "Yes" to question 80.

91 (39.2%)	Cells or cell lines from different species are stored in different dewars/freezers from human embryos
67 (28.9%)	Frozen cells are not used for QA or co-culture in the embryo laboratory
64 (27.6%)	Cells from different species are stored in the same dewar/freezer as human embryos

83. Information recorded when cryopreservation is performed by laboratories responding "Yes to question 80.

229 (98.7%)	Date/time of freezing
227 (97.8%)	Gamete/embryo stage of development at freezing
227 (97.8%)	Date/time of thawing
226 (97.4%)	Cryostorage location (e.g. freezer number, position)
224 (96.6%)	Name/identifier of patient/female donor
217 (93.5%)	Identification of individual(s) performing freezing/thawing procedure
209 (90.1%)	Date/time of gamete collection/retrieval
206 (88.8%)	Cryopreservation protocol followed
199 (85.8%)	Cryoprotectant/media formulation(s) used
195 (84.1%)	Gamete/embryo identification number
183 (78.9%)	Freezing program (e.g., rate and of cooling, program duration etc.)
166 (71.6%)	Name/identifier of partner/male donor
139 (59.9%)	Procedure number
61 (26.3%)	Pre-freeze photos/video of gametes/embryos

84. Response to whether duplicate records of cryopreserved specimens are maintained by laboratories responding "Yes" to question 80.

164 (70.7%)	Duplicate records are maintained elsewhere in the facility, not in the embryo laboratory
61 (26.3%)	Duplicate records are maintained off-site
23 (9.9%)	Duplicate records are NOT maintained

85. Information recorded on embryo cryocontainers prior to freezing by laboratories responding "Yes" to question 80.

217 (93.5%)	Female patient name
211 (90.9%)	Date of freezing
156 (67.2%)	Number of gametes/embryos in container
125 (53.9%)	Female patient identifiers
120 (51.7%)	Container (i.e., straw, vial, ampule) number
114 (49.1%)	Embryo number
53 (22.8%)	ART procedure number
26 (11.2%)	Name of Laboratory/facility
25 (10.8%)	Partner name or identifiers
16 (6.9%)	Date of retrieval
12 (5.2%)	Name of staff member performing cryopreservation
29 (12.5%)	Other information *(Embryo, 50%; Lab, 21%; Patient 11%; Procedure, 18%)*

86. Categorization of the usefulness of the listed criteria for assessing *thawed* embryo quality for possible transfer by laboratories responding "Yes" to question 80.

Criteria	Usefulness for assessing thawed embryo quality:		
	Very useful	Moderately useful	Not very useful
Number of blastomeres present	196 (86.3%)	27 (11.9%)	4 (1.8%)
Continued cell cleavage	210 (93.8%)	10 (4.5%)	4 (1.8%)
Uniform/irregular blastomere size/shape	152 (67.0%)	70 (30.8%)	5 (2.2%)
Absence/presence of fragments/blebs	147 (65.0%)	68 (30.1%)	11 (4.9%)
Cytoplasmic traits	59 (27.1%)	126 (57.8%)	33 (15.1%)
Thickness of the zonae pellucida	27 (12.3%)	79 (36.1%)	113 (51.6%)

87. Number of continuous years respondent embryo laboratory personnel have performed any type of micromanipulation procedures.

3.9 years (range 0-16 years), n = 232

88. The approximate percentage of procedures responding embryo laboratories performed during 1997 in which micromanipulation (any type) was used.

44.8% (range 0-100%), n = 226

89. Information recorded on reagent or laboratory chemical containers.

Information Recorded	Information recorded on containers of:	
	reagents purchased from commercial vendors	reagents prepared by embryo lab staff
Receipt or preparation date	215 (92.7%)	178 (76.7%)
Date opened or placed into use	214 (92.2%)	117 (50.4%)
Expiration/use by/discard by date	216 (93.1%)	152 (65.5%)
Storage temperature	158 (68.1%)	32 (13.8%)
Temperature on receipt	19 (8.2%)	4 (1.7%)
Lot/batch number	219 (94.4%)	130 (56.0%)
Initials of preparer	70 (30.2%)	139 (59.9%)
Initials of individual opening reagent	103 (44.4%)	45 (19.4%)
Special handling requirements	93 (40.1%)	36 (15.5%)
Other	4 (1.7%)	12 (5.2%)

90. Evaluation procedures responding embryo laboratories use to control the quality of media used for gamete/embryo culture

Evaluation procedure		Substance being evaluated: Culture Media	Water	Glassware	Disposables
This item **not** evaluated.		10 (4.3%)	48 (20.7%)	58 (25.0%)	33 (14.2%)
Cultures for sterility		90 (38.8%)	78 (33.6%)	16 (6.9%)	26 (11.2%)
Presence of endotoxins		87 (37.5%)	77 (33.2%)	8 (3.4%)	14 (6.0%)
Residual organics (e.g., plasticizers, detergents)		6 (2.6%)	9 (3.9%)	28 (12.1%)	13 (5.6%)
Development of mouse 1-cell or 2-cell embryos to blastocyst		182 (78.4%)	53 (22.8%)	52 (22.4%)	133 (57.3%)
Human sperm survival		106 (45.7%)	21 (9.1%)	29 (12.5%)	88 (37.9%)
Hamster sperm motility or viability		3 (1.3%)	1 (0.4%)	2 (0.9%)	4 (1.7%)
Other bioassay		8 (3.4%)	2 (0.9%)	0 (0%)	4 (1.7%)
Results of media quality testing ARE recorded	**YES**	204 (87.9%)	104 (44.8%)	74 (31.9%)	146 (62.9%)
	NO	28 (12.1%)	128 (55.2%)	158 (68.1%)	86 (37.1%)

91. Additional procedures responding embryo laboratories use to assure that water produced or obtained for embryo laboratory procedures is of suitable quality for use.

114 (49.1%)	None, water quality verified by commercial source
73 (31.5%)	Culture for microorganism growth
65 (28.0%)	Endotoxin
43 (18.5%)	Check pH of product
37 (15.9%)	Check for residual chloride levels
13 (5.6%)	Check for hardness
4 (1.7%)	Check for residual formaldehyde levels
36 (15.5%)	Other method *(Bioassay/Cell Culture 14%, Not Used 8%, Resistivity/Conductivity 36%, Silicates 28%, Verified by Commercial Source 14%)*

92. Laboratory response to which of the listed human-derived materials are screened for the presence of infectious agents.

94 (40.5%)	Human derived materials are not screened.
72 (31.0%)	Partner sperm/semen for ART or IUI inseminations
28 (12.1%)	Donor serum for supplementing media
24 (10.3%)	Maternal (autologous) serum for supplementing media
20 (8.6%)	Other substances
19 (8.2%)	Freshly obtained donor sperm for ART or IUI inseminations
3 (1.3%)	Donor follicular fluid for media supplementation
1 (0.4%)	Maternal (autologous) follicular fluid for media supplementation

93. Laboratory response to which infectious disease tests are performed on human-derived materials used for ART procedures.

112 (48.3%)	Hepatitis B Virus (HBV)
103 (44.4%)	Human immunodeficiency virus Type I (HIV-I)
97 (41.8%)	Hepatitis C Virus (HCV)
68 (29.3%)	Human immunodeficiency virus Type II (HIV-II)
63 (27.2%)	Chlamydia trachomatis
60 (25.9%)	*N. gonorrhea*
59 (25.4%)	Human T-lymphotropic virus types I & II (HTLV-I/ II)
40 (17.2%)	Mycoplasma
40 (17.2%)	Cytomegalovirus (CMV)
35 (15.1%)	Ureaplasma
27 (11.6%)	Herpes simplex virus (HSV)
27 (11.6%)	Other agents *(Rubella 11%,Syphilis 59%, Syphilis/Rubella 4%, Other 26%)*

94. Laboratory response to which glassware washing procedures specified in the embryo laboratory procedure manuals.

125 (53.9%)	The water type is specified
123 (53.0%)	The number of rinses are specified
116 (50.0%)	Sterilization procedures are specified
115 (49.6%)	Drying procedures are specified
110 (47.4%)	Our laboratory only uses single-use or disposable plasticware
76 (32.8%)	The detergent type is specified
75 (32.3%)	Storage procedures are specified
59 (25.4%)	The detergent source is specified
8 (3.4%)	No specified procedure
5 (2.2%)	Glassware washing procedures are not specified
14 (6.0%)	Other

95. Frequently at which equipment function checks made by responding embryo laboratories.

Equipment functions checked:	Frequency of equipment function check						
	Not done	Daily	Weekly	Monthly	Quarterly	Annually	Other interval
Emergency power generator operation	18 (8.3%)	9 (4.1%)	46 (21.2%)	69 (31.8%)	34 (15.7%)	19 (8.8%)	22 (10.1%)
Emergency power transfer switch	25 (13.0%)	6 (3.1%)	37 (19.2%)	61 (31.6%)	34 (17.6%)	9 (4.7%)	21 (10.9%)
After-hours alarm/alert system operation	27 (12.8%)	36 (17.1%)	30 (14.2%)	42 (19.9%)	31 (14.7%)	21 (10.0%)	24 (11.4%)
Water system conductivity checks	57 (30.2%)	80 (42.3%)	17 (9.0%)	14 (7.4%)	8 (4.2%)	4 (2.1%)	9 (4.8%)
Incubator microbial contamination	84 (38.7%)	27 (12.4%)	15 (6.9%)	38 (17.5%)	24 (11.1%)	7 (3.2%)	22 (10.1%)
Incubator gas %	5 (2.2%)	210 (91.7%)	5 (2.2%)	1 (0.4%)	3 (1.3%)	1 (0.4%)	4 (1.7%)
Incubator humidity	96 (42.9%)	103 (46.0%)	12 (5.4%)	6 (2.7%)	1 (0.4%)	0 (0%)	6 (2.7%)
Liquid nitrogen level alarm	30 (13.8%)	84 (38.5%)	59 (27.1%)	16 (7.3%)	6 (2.8%)	12 (5.5%)	11 (5.0%)
Centrifuge tachometer check	15 (6.7%)	3 (1.3%)	3 (1.3%)	11 (4.9%)	46 (20.4%)	114 (50.7%)	33 (14.7%)
Biological safety cabinet/hood air-flow velocity	11 (5.0%)	2 (0.9%)	2 (0.9%)	1 (0.5%)	13 (6.0%)	147 (67.4%)	42 (19.2%)
Hood certification	9 (4.0%)	1 (0.4%)	0 (0%)	0 (0%)	9 (4.0%)	161 (72.2%)	43 (19.3%)
Pipettor calibrations	22 (9.7%)	2 (0.9%)	0 (0%)	6 (2.7%)	37 (16.4%)	111 (49.1%)	48 (21.2%)
Thermometer calibrations	19 (8.3%)	3 (1.3%)	0 (0%)	5 (2.2%)	24 (10.5%)	137 (60.1%)	40 (17.5%)

96. Laboratory response to which agents are used to disinfect/decontaminate equipment and/or work surfaces in the embryo laboratory.

Cleaning Agent	Agent is used in the		
	General Lab for clean up	Embryo lab during ART cycles	Embryo lab during down time
Mild soap/detergent and water	94 (40.5%)	50 (21.6%)	119 (51.3%)
Peroxide-based compounds	5 (2.2%)	4 (1.7%)	15 (6.5%)
0.5% bleach solution	68 (29.3%)	25 (10.8%)	76 (32.8%)
Quaternary ammonium agents	6 (2.6%)	4 (1.7%)	13 (5.6%)
Phenolic agents	3 (1.3%)	1 (0.4%)	5 (2.2%)
Alcohols (i.e., ethanol, methanol)	191 (82.3%)	178 (76.7%)	170 (73.3%)
Iodophores	1 (0.4%)	1 (0.4%)	2 (0.9%)
Aldehydes	1 (0.4%)	0 (0%)	2 (0.9%)
Class I/II water	112 (48.3%)	128 (55.2%)	105 (45.3%)
Other cleaning agents	13 (5.6%)	6 (2.6%)	27 (11.6%)

97. Methods used in respondent embryo laboratories to document and improve quality of laboratory procedures.

222 (95.7%)	Laboratory procedure records are reviewed by laboratory director or supervisor
218 (94.0%)	Quality control records are reviewed by supervisor or director
205 (88.4%)	Corrective actions taken to resolve technical problems are documented
200 (86.2%)	Corrective action records are reviewed by supervisor or director
186 (80.2%)	Laboratory participates in an interlaboratory proficiency testing program
172 (74.1%)	There is a written plan stating quality assurance expectations
156 (67.2%)	Trends in technical problems are documented and improvement plan initiated
151 (65.1%)	Internal laboratory proficiency testing is performed
131 (56.5%)	Staff performing ART procedures undergo periodic competency assessment
5 (2.2%)	Other method

98. Laboratory response to how the results of laboratory quality assurance efforts are communicated.

181 (78.0%)	Results are presented at embryo laboratory staff meetings
110 (47.4%)	Results are presented at Clinical staff meetings
59 (25.4%)	Results are presented during individual staff performance review
50 (21.6%)	The embryo laboratory is represented on institutional quality assurance committee(s)
33 (14.2%)	Results are posted in the embryo laboratory for review
31 (13.4%)	Results are presented at peer group presentations
13 (5.6%)	QA review results are **not** communicated
9 (3.9%)	Other methods

99. Methods used to validate assays or procedures that are newly implemented in the respondent embryo laboratories.

187 (80.6%)	New assay performance compared with existing assay or known performance standards
145 (62.5%)	Compare success rates obtained using new procedures with success rates obtained by other programs
136 (58.6%)	New procedures are tested using animal models prior to being used on human cells (gametes, embryos, etc.)
68 (29.3%)	Assess new assay/test performance on interlaboratory proficiency testing or performance evaluation programs.
5 (2.2%)	Other methods *Direct split /w patient material 20%* *Intralab personnel testing comparison 20%* *Success in use at Medical Director's own lab 20%* *Statistics 20%* *Use of human cells for discard 20%*

100. Response to procedures used in the embryo laboratory to ensure and improve the quality of services provided

215 (92.7%)	Live birth rates are monitored
190 (81.9%)	A written procedure is in place for documenting problems that arise in the laboratory
183 (78.9%)	Laboratory performance success rates compared to embryology laboratories
169 (72.8%)	The laboratory has a written program in place for monitoring and evaluating the quality and appropriateness of patient care services
167 (72.0%)	A written procedure is in place for resolving identified problems
158 (68.1%)	A written procedure is in place for reviewing corrective actions the appropriate individuals
152 (65.5%)	A minimum fertilization rate or other measure of success is maintained in order to continue offering embryology services
150 (64.7%)	A written procedure is in place for detecting clerical, transcription, or analytical errors
124 (53.4%)	The laboratory director and/or supervisor participate as member(s) of quality improvement committee(s) or efforts of the facility/institution
95 (40.9%)	Laboratory performance thresholds adjusted annually to encourage improvement in success rates

SURVEY

Sequence Number

1. Does your laboratory perform activities where human gametes (oocytes, sperm) and/or embryos are subject to assisted reproductive technology embryo laboratory procedures and processes as defined on page 2 of this survey?

NO ° **STOP.** ***Please do not complete the remainder of this survey. Return the survey to ASI in the envelope provided.***

Yes ° Please complete the following table and continue with survey.

Services offered	Our laboratory began providing services during :
Oocyte retrieval, assessment and gamete/embryo culturing	19 ☐☐
Sperm preparations for IUIs	19 ☐☐
Diagnostic Infertility testing	19 ☐☐
Sperm cryopreservation (any type)	19 ☐☐
Oocyte cryopreservation	19 ☐☐
Embryo cryopreservation	19 ☐☐
Micromanipulation (any type)	19 ☐☐

2. Which *clinical* or *therapeutic* procedures does your embryo laboratory support? *Check all that apply.*

IVF	☐ 1
ZIFT	☐ 2
IUIs	☐ 3
Cryopreservation	☐ 4
Oocyte donor program	☐ 5
Sperm donor program	☐ 6
Microbiopsy for genetic screening	☐ 7
Genetic analyses (e.g. FISH, PCR)	☐ 8
Intravaginal culture	☐ 9
Other *(please specify)*:_____	☐ 10

3. Please indicate which of the following procedures are currently performed in your embryo laboratory. *Check all that apply*.

A. Sperm Preparation Procedures		B. Oocyte/Embryo Procedures		C. Cryopreservation Procedures	
Sperm count	☐ 1	Oocyte identification/grading	☐ 1	Sperm cryopreservation	☐ 1
Sperm concentration	☐ 2	Oocyte insemination	☐ 2	Unfertilizated oocyte cryopreservation	☐ 2
Sperm motility	☐ 3	Embryo cultureing/grading	☐ 3	Zygote (2PN) cryopreservation	☐ 3
Sperm viability	☐ 4	Preparation for embryo transfer	☐ 4	2-cell to 8-cell embryo cryopreservation	☐ 4
Sperm morphology	☐ 5	Embryo co-culture with other cell lines	☐ 5	>8-cell embryo cryopreservation	☐ 5
Sperm wash/swim up	☐ 6	ART media preparation	☐ 6	Not done	☐ 6
Density gradient separations	☐ 7	Not done	☐ 7		
Antisperm antibody testing	☐ 8				
Semen biochemical testing (e.g., fructose)	☐ 9				
Computer-assisted semen analysis (CASA)	☐ 10				
Sperm viability testing (e.g., HOS)	☐ 11				
Sperm function assays (e.g., SPA, HZFO)	☐ 12				
Not done	☐ 13				

D. Microbiology Testing Procedures		E. Micromanipulation Procedures		F. Other Testing Procedures	
N. gonorrhoeae cultures	☐ 1	Intracytoplasmic sperm injection (ICSI)	☐ 1	Post coital test	☐ 1
Mycoplasma cultures (e.g., *U. urealyticum*)	☐ 2	Partial Zona Dissection (PZD)	☐ 2	Cervical mucus tests	☐ 2
Cervical cultures	☐ 3	Subzonal Insertion (SUZI)	☐ 3	Endocrine testing (e.g., E2, FSH, hCG)	☐ 3
Chlamydia	☐ 4	Assisted embryo hatching	☐ 4	Water production	☐ 4
Urine cultures	☐ 5	Diagnostic embryo (blastomere) biopsy	☐ 5	Animal testing activities (e.g., mouse embryos)	☐ 5
Semen cultures	☐ 6	Embryo defragmentation	☐ 6	Infectious disease testing (e.g., HIV, HbSAg)	☐ 6
Water cultures	☐ 7	Cytoplasmic transfer	☐ 7	Not done	☐ 7
Culture media cultures	☐ 8	Not done	☐ 8		
Work surface/environmental cultures	☐ 9				
Viruses (e.g,. HSV, CMV)	☐ 10				
Not done	☐ 11				

4. So that we may assess the approximate size of your ART program, please estimate the number of ART cycles your embryo laboratory supported in 1997. (NOTE: By definition, this includes canceled cycles, thaw cycles, donor oocyte cycles, IVF/GIFT, etc.) ***Check only one response.***

less than 50 ART cycles	☐ 1
51–100 ART cycles	☐ 2
101-250 ART cycles	☐ 3
251-500 ART cycles	☐ 4
501-750 ART cycles	☐ 5
751-1000 ART cycles	☐ 6
over 1000 ART cycles	☐ 7

5. Please indicate the percentage of ART cycles that are contributed by physicians in each of the following clinical settings. Estimates are acceptable. ***Please enter a whole number value for each row, even if it is zero.***

Clinical setting	Percentage of our patients come from this setting
Physicians who are only affiliated with your ART program	9 9 9 %
Another private physician's ART practice	9 9 9 %
Private hospital-affiliated ART program	9 9 9 %
Public/community hospital-affiliated ART program	9 9 9 %
Academic medical training/teaching center ART program	9 9 9 %
Managed care organization	9 9 9 %
Ambulatory-care surgical center	9 9 9 %

6. Which of the following agencies or organizations have accredited, licensed, or certified your embryo laboratory? ***Check all that apply.***

Our embryo laboratory is not currently accredited, licensed, or certified	☐ 1
Health Care Financing Administration (CLIA)	☐ 2
State Agency. *Please indicate state(s)*:_____	☐ 3
College of American Pathologists (CAP) Reproductive Laboratory Accreditation Program	☐ 4
American Association of Tissue Banks (AATB)	☐ 5
Food and Drug Administration (FDA)	☐ 6
Joint Commission on Accreditation of Health care Organizations (JCAHO)	☐ 7
Commission for Office Laboratory Accreditation (COLA)	☐ 8
Other accreditation/certification	☐ 9

7. Please indicate which categories of CLIA-licensed testing are also performed in your embryo laboratory. *Check all that apply.*

No CLIA-licensed testing is offered by our embryo laboratory	☐ 1
Diagnostic semen analysis/sperm morphology (does not include analyses for inseminations)	☐ 2
Endocrine testing (e.g., E2, FSH, LH, hCG)	☐ 3
Microbiology testing (e.g., Ureaplasma, *N. gonorrhoeae*)	☐ 4
Hematology testing (e.g., CBCs, hematocrit)	☐ 5
Chemistry testing (e.g., glucose, hepatitis, electrolytes)	☐ 6
Immunohematology testing (e.g., ABO/Rh typing)	☐ 7
Genetic analyses (e.g. FISH, PCR)	☐ 8
Other CLIA-licensed testing (*please specify*)_____	☐ 9

8. Please indicate the proximity of your embryo laboratory to the procedure room(s) where oocyte retrievals and/or gamete or embryo transfers take place. (*A convenient means of measuring distances between rooms it to count ceiling tiles: typical ceiling tiles measure 2' x 2' or 2' X 4'*).

a. The distance between the embryo laboratory and the procedure room where *retrievals* take place is (check only one).

Within 100 feet ☐ 1	Greater than 100 feet ☐ 2

b. The distance between the embryo laboratory and the procedure room where *gametes/embryo transfers* take place is (check only one).

Within 100 feet ☐ 1	Greater than 100 feet ☐ 2

9. Please indicate how gametes/embryos are transported to and from the lab. *Check all that apply.*

Gametes/embryos are transported at ambient environmental conditions (e.g., room temperature, room air)	☐ 1
Gametes/embryos are transported at controlled temperature (e.g., 37EC)	☐ 2
Gametes/embryos are transported in a controlled atmosphere (e.g., 5% CO_2)	☐ 3
Other transport method (*please specify):*_____	☐ 4

10. Please indicate which of the following features, functions or capabilities are available in your embryo laboratory. *Check all that apply*.

Ventilation system has active air filtration	☐ 1
Walls and floors are easily washed and disinfected	☐ 2
Embryo laboratory is secured during non-business hours only	☐ 3
Embryo laboratory is secured at all times	☐ 4
Embryo laboratory is in a low-traffic location	☐ 5
Immediate communication is available to retrieval/transfer rooms	☐ 6
Sterile procedures are performed in the embryo laboratory	☐ 7
Area is periodically cleaned by outside cleaning service	☐ 8
Disinfectants are sprayed on work surfaces	☐ 9
Steam or gas sterilization is performed in the embryo laboratory	☐ 10
Fluorescent lighting is used in the embryo laboratory	☐ 11
Laboratory animals are housed in the embryo laboratory	☐ 12

11. Is a computer available for use by embryo laboratory personnel?

Yes	☐ 1
No	☐ 2

12. Is there Internet access from computers in the facility?

Yes	☐ 1
No	☐ 2

13. Are there more than 10 individuals working in the embryo laboratory?

Yes	☐ 1
No	☐ 2

*Complete questions No. 14 -17, for the **10 most senior staff** in the embryo laboratory.*

For the next four questions involving personnel working in the embryo laboratory, please remove and refer to the* PINK SHEET *of instructions inserted in the front of the survey booklet.

14. For each of the individuals in the embryo laboratory, please complete the educational and experience information requested in the following table, as shown in the example column.

For each individual check the ***highest*** education degree related to ART (check only 1 degree)	INDIVIDUAL CODE number from pink sheet										
	Example	a.	b.	c.	d.	e.	f.	g.	h.	i.	j.
Medical degree MD, DO, DVM 1											
Doctoral degree PhD, DrPH 2	X										
MD/PhD degree 3											
Master's degree 4											
Bachelor's degree 5											
Associate degree 6											
Certificate of technical training 7											
No college degree 8											
List the DISCIPLINE CODE (from PINK SHEET) for the highest degree held for each individual	19										
# Years of relevant ART experience	10										

In the example column above, the individual listed (e.g., Dr. Smith) is a physician specializing in OB/GYN with 10 years of ART-related experience.

15. In the following table, please check the duties that are actually performed by each individual working in the embryo laboratory as shown in the example column. ***Check all duties and responsibilities assigned to each individual***.

Duties and responsibilities	INDIVIDUAL CODE number from pink sheet										
	Example	a.	b.	c.	d.	e.	f.	g.	h.	i.	j.
Media preparation											
Phlebotomy											
QC testing	X										
Oocyte identification	X										
Sperm preparation											
Oocyte insemination	X										
Fertilization assessment	X										
Embryo quality assessment	X										
Micromanipulation	X										
Transfer catheter loading											
Cryopreservation	X										
Endocrine testing											
Lab animal handling or care											
Andrology testing											
QA/QC reviews											
Safety reviews	X										
Method development	X										
Method Verification	X										
Employee competency review	X										
Procedure manual content review	X										
Maintenance manual content review	X										
Policy manual content review	X										

The example column lists the duties and responsibilities performed by “Dr. Smith” given in the example column for question 14.

16. Please refer to the pink sheet codes and provide the following position description information for each individual working in the embryo laboratory as shown in the example column.

Information requested	INDIVIDUAL CODE number from pink sheet										
	Example	a.	b.	c.	d.	e.	f.	g.	h.	i.	j.
List the current primary POSITION DESCRIPTION code (from PINK SHEET) for each individual	F										
Number of years in this primary position	4										
List another POSITION DESCRIPTION code for a secondary role that may be filled for each individual (or N/A)	I										
List a third POSITION DESCRIPTION code for another position that may be filled for each individual (or N/A)	N/A										
What is the average number of hours this person works per week in the embryo lab?	40										
Approximate number of ART cycles in which this individual participated in 1997 A = less than 50 B = 51-100 C = 101-250 D = 251-500 E = 501-750 F = 751-1,000 G = more than 1,000	C										
Approximate total number of ART cycles in which individual has *ever* participated (at any level of involvement) H = less than 100 I = 100-500 J = 501-1,000 K = 1,001-2,000 L = 2,001-5,000 M= 5,001-10,000 N = more than 10,000	K										

Continuing with the examples given in questions 14 and 15, this question indicates that “Dr. Smith” has served as the laboratory director for 4 years and also serves as the embryo laboratory technical supervisor. Dr. Smith works full-time in the embryo laboratory and participated in 128 ART procedures in 1997. Dr. Smith has participated in a total of approximately 1,100 ART procedures during his/her career.

17. For each of the individuals listed in the tables above, please provide information about the training. ***Enter N/A for items that are not applicable.***

Training completed		INDIVIDUAL CODE number from pink sheet										
		Example	a.	b.	c.	d.	e.	f.	g.	h.	i.	j.
Has training been completed in each of these areas? (indicate Yes or No):	general embryology	Yes										
	cryopreservation	Yes										
	micromanipulation	Yes										
Indicate type of gametes or embryos used for training A=animal H=human B=both human and animal	general embryology	H										
	cryopreservation	A										
	micromanipulation	B										
Indicate the total # of ART training procedures completed.	general embryology	30										
	cryopreservation	40										
	micromanipulation	20										
Is ART training documented in writing (Yes or No)	general embryology	Yes										
	cryopreservation	Yes										
	micromanipulation	Yes										

The example column lists the training completed by the “Dr. Smith” given in the examples for the previous three questions.

18. Please indicate which information is retained in each laboratory employee's personnel file. ***Check all that apply.***

College transcripts	☐ 1
Copy of current license or registry certificates	☐ 2
Copy of resume or CV	☐ 3
Copies of periodic performance reviews	☐ 4
Documented training completed in the laboratory on each specific test the individual is authorized to perform	☐ 5
Level of supervision required	☐ 6
List of expected duties and responsibilities	☐ 7
List of job qualifications	☐ 8
List of professional organization memberships	☐ 9
Record of attendance or personal participation in educational programs or technical meetings	☐ 10
Competency testing	☐ 11

19. Does your *facility require* that embryo laboratory technical personnel participate in continuing education?

Yes. Please continue ☐ 1	**No º** SKIP to question 22 ☐ 2

20. In the table below, please check the appropriate columns to indicate how many hours of ART-related continuing education (CE) is required annually by your facility. ***Check one box in each row***.

Employment Level	CE Not Required	Approximate number hours of CE required per year					
		#5	6-10	11-15	16-20	21-25	>25
Laboratory director	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Laboratory supervisor	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Technologists/technicians	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Non-technical personnel	9 1	9 2	9 3	9 4	9 5	9 6	9 7

21. In what types of ART-related continuing education (CE) opportunities do personnel in the embryo laboratory participate? ***Check all rows that apply for each job type*****.**

Type of continuing education	Lab Director	Lab Supervisor	Technical staff	Non-technical staff*
International professional/scientific workshops	9	9	9	9
National professional/scientific workshops	9	9	9	9
Regional professional/scientific workshops	9	9	9	9
State/local professional/scientific workshops	9	9	9	9
Video conference training seminars	9	9	9	9
Audio conference training seminars	9	9	9	9
In-house training	9	9	9	9
On-the-job training	9	9	9	9
Vendor- or manufacturer-sponsored training	9	9	9	9

*Non -technical staff = Management personnel, administrative personnel

22. Please indicate how the following ART patient information is retained in the facility. ***Check all that apply.***

Information	Info. not kept	Information is retained in the following form:		
		Written records	microfilm/ microfiche	computerized records
Diagnostic test results	9	9	9	9
ART patient demographic information	9	9	9	9
ART stimulation cycle information	9	9	9	9
Gamete donor information	9	9	9	9
Oocyte/embryo assessment information	9	9	9	9
Embryo cryopreservation information	9	9	9	9
Gamete/embryo micromanipulation information	9	9	9	9

23. Please complete the following table regarding the retention of information about embryo laboratory.

Records that are retained	Is there a defining event initiating record retention?		How Long are records retained?		
	Circle Y =Yes or N =No	If Yes, Specify event (e.g. live birth)	Indefinitly	# of years after defining event	These records are not retained
Oocyte/embryo assessment records	Y N		9 1	9 2	9 3
Culture media QC records	Y N		9 1	9 2	9 3
Water quality records	Y N		9 1	9 2	9 3
Sperm preparation records	Y N		9 1	9 2	9 3
Gamete/embryo cryopreservation records	Y N		9 1	9 2	9 3
Donor sperm/oocyte records	Y N		9 1	9 2	9 3
Infectious disease testing records	Y N		9 1	9 2	9 3
Laboratory safety inspection records	Y N		9 1	9 2	9 3
ART procedure records	Y N		9 1	9 2	9 3
Personnel records	Y N		9 1	9 2	9 3
Equipment/instrument calibration records	Y N		9 1	9 2	9 3
Lab QA/QC records	Y N		9 1	9 2	9 3

24. What measures are used in the embryo laboratory to maintain data confidentiality *Check all that apply*?

- ☐ 1 Limited/controlled access to patient medical records
- ☐ 2 Limited access to laboratory test records/results
- ☐ 3 Limited access to ART procedure results
- ☐ 4 Password-protected computer files
- ☐ 5 Physical access to embryo laboratory limited to lab personnel
- ☐ 6 Other (*please specify*):_____

25. Do you log or record electronic access to confidential patient materials?

Yes ☐ 1	No ☐ 2

26. For each of the actions listed in the table below, please indicate who determines the use or disposition of gametes (i.e., sperm or oocytes) and embryos in the laboratory. *Check one box in each row*.

Laboratory Action	Use or disposition is governed by	
	Patient instructions	Laboratory/clinic policy
Disposition of excess viable embryos (i.e., embryos not transferred)	9 1	9 2
Placing gametes or embryos into cryostorage	9 1	9 2
Use of cryostored gametes/embryos	9 1	9 2
Disposition of "abandoned" cryostored gametes or embryos	9 1	9 2
Use of *donor* sperm for ART inseminations	9 1	9 2
Use of *donor* oocytes or embryos for transfers	9 1	9 2
Use of *donated* sperm	9 1	9 2
Use of *donated* oocytes or embryos	9 1	9 2

27. How is the embryo laboratory notified of impending ART procedures? *Check all that apply.*

Verbal notification by clinic staff	☐ 1
Clinic staff submit a written procedure request form with anticipated embryo laboratory support indicated	☐ 2
Other means of notification used *(please specify)*: _____	☐ 3

28. How far in advance of ART procedures is the embryo laboratory notified of its pending involvement? *Check only one*.

Prior to ovulation induction for the intended ART cycle	☐ 1
At the time of ovulation induction for intended ART cycle	☐ 2
After ovulation induction has been initiated for the intended ART cycle	☐ 3
Other *(please specify)*: _____	☐ 4

29. How Is the embryo laboratory notified of patient informed consent for ART procedures? *Check all that apply*.

Laboratory is not informed.	☐ 1
Verbal notification is provided by clinical staff	☐ 2
A copy of the *entire informed consent* is provided to the laboratory	☐ 3
Written notification that informed consent has been obtained is verified by the *requesting physician* on embryo laboratory support request form	☐ 4
Written notification that informed consent has been obtained is verified by the *embryo laboratory* on a support request form	☐ 5
*Other method of notification used (please specify):*_____	☐ 6

30. How is the embryo laboratory notified that informed consent has been provided when *changes* to the intended ART procedures occur? *Check all that apply*.

The laboratory is not informed.	☐ 1
Verbal notification is provided by clinical staff with written follow-up	☐ 2
Verbal notification is provided by clinical staff without written follow-up	☐ 3
A copy of the <u>entire</u> *revised* informed consent form is provided	☐ 4
A copy of <u>only the signature page</u> from the *revised* consent form is provided	☐ 5
Written notification that informed consent has been revised, is verified by the requesting physician on embryo laboratory support request form	☐ 6
Other means of notification *(please specify)*: _____	☐ 7

31. What elements of informed consent are provided to the embryo laboratory? *Check all that apply*.

None	☐ 1
Consent for oocyte retrieval	☐ 2
Consent for donor sperm insemination of oocytes	☐ 3
Consent for use of donor oocytes	☐ 4
Consent for embryo transfer (with a *maximum* number of embryos specified)	☐ 5
Consent for embryo transfer (with a *no maximum* number of embryos specified)	☐ 6
Consent for micromanipulation of gametes or embryos	☐ 7
Consent for gamete/embryo cryopreservation	☐ 8
Consent for in vitro research use of gametes or embryos	☐ 9
Consent for disposal of gametes or embryos	☐ 10

32. If informed consent for ART procedures is *not* provided to the embryo laboratory please indicate which of the following two statements are true. *Check only one*.

Laboratory will ***not*** proceed without verification that patient has provided informed consent	☐ 1
Laboratory ***will*** proceed with ART procedures under physician direction without patient informed consent	☐ 2

33. Are any animal cell lines used in the embryo laboratory for QA testing or for co-culture purposes?

No **º Skip to question 36.**	☐ 1
Yes, animal cells are used for QA testing	☐ 2
Yes, animal cells are used for co-culture purposes	☐ 3

34. What is the source of cells or cell lines used for QA testing or co-culture?

Cell line stocks are maintained and prepared in facility for embryo laboratory use	☐ 1
Ready-for-use cell lines are obtained from a vendor	☐ 2
Both of the above	☐ 3

35. In the table below, please indicate which species and cellular components are used for QA testing purposes in the embryo laboratory. *Check all that apply*.

Species	Check which cells from these species are used in the laboratory for testing purposes			
	sperm	oocytes	embryos	other cells
Hamster	9	9	9	9
Mice	9	9	9	9
Rat	9	9	9	9
Bovine	9	9	9	9
Rabbit	9	9	9	9
Human	9	9	9	9
Other species *(please specify)*	9	9	9	9

36. If laboratory animals are used for testing in your facility, where are they housed in relation to the embryo laboratory? *Check all that apply*.

- Laboratory animals are not used. ☐ 1
- In a separate building ☐ 2
- In the same building as the embryo laboratory, but not in embryo laboratory ☐ 3
- In the embryo laboratory ☐ 4
- In the andrology laboratory ☐ 5

37. Is animal testing performed by an independent facility?

- Yes ☐ 1
- No ☐ 2

38. Please indicate whether *technical procedure* manuals used in the embryo laboratory have the following properties or features. *Check all that apply*.

No procedure manuals are available for use in our embryo laboratory	☐ 1
There is a written procedure for each embryo laboratory activity	☐ 2
Manual(s) are readily available for use or referral at each work station	☐ 3
Procedures are written in sufficient detail to assure reproducibility and competence	☐ 4
Procedure manual format follows the most recent NCCLS recommendations	☐ 5
Manuals specify equipment and/or materials to be used for a given procedure	☐ 6
Manuals specify the source of materials or reagents to be used	☐ 7
Manual specifies how biological materials are to be handled, processed and/or disposed of	☐ 8
A page is provided in the manual to record who has received training or updated training on new or revised procedures	☐ 9
Procedure changes are signed/dated by the director or supervisor	☐ 10
Procedure document shows director review and approval	☐ 11
Reference materials (slides, pictures, textbooks, etc.) are availablefor comparison with patient specimens	☐ 12

39. Please indicate whether equipment *maintenance and/or equipment operation* manuals used in the embryo laboratory have the following properties or features. *Check all that apply.*

No maintenance manuals are available for use in our embryo laboratory	☐ 1
Each piece of equipment used in the embryo laboratory has a written procedure on its proper use and maintenance	☐ 2
Equipment/maintenance manual(s) are readily available for use or referral in the vicinity of the referenced equipment	☐ 3
Abbreviated operation/maintenance procedures are posted near each piece of equipment	☐ 4
Operation/maintenance procedures are written in sufficient detail to assure proper/safe operation	☐ 5
Manuals specify the level of personnel competence required to operate each piece of equipment	☐ 6
Manuals specify the frequency with which operational checks should be performed	☐ 7
Manuals provide trouble-shooting procedures to diagnosing equipment problems	☐ 8
Manuals specify who to contact for service or parts	☐ 9
A log is provided to document all maintenance procedures and corrective actions taken	☐ 10

40. Please indicate whether *policy* manuals used in the embryo laboratory have the following properties or features. *Check all that apply*.

Policy manuals are not available for use in our embryo laboratory	☐ 1
Manuals specify which records must be kept and for how long	☐ 2
Policies specify how test and ART procedure results are to be reported	☐ 3
Policies discuss laboratory chain of command	☐ 4
Personnel duties and responsibilities	☐ 5
Training and/or competency testing	☐ 6
Personnel policies for job performance review	☐ 7
Personnel policies for continuing education	☐ 8
Accident/incident policies	☐ 9
Disaster preparedness policies	☐ 10
Quality Control/Quality Assurance manuals	☐ 11
Chemical hygiene (safety) plan	☐ 12
Specimen handling/Universal Precaution policies	☐ 13
Policy manuals contain written procedure for their regular review	☐ 14

41. Please indicate how often embryo laboratory staff review manuals. *Only check one box in each column.*

Frequency of review	Check how frequently each type of manual is reviewed		
	Procedure	Maintenance	Policy
Annually	9 1	9 1	9 1
Semi-annually	9 2	9 2	9 2
Quarterly	9 3	9 3	9 3
Whenever the manual is revised	9 4	9 4	9 4
Whenever the Laboratory Director changes	9 5	9 5	9 5
There is no formal policy for review	9 6	9 6	9 6

42. Which of the following devices or techniques are used for controlling the environment for gamete/embryo manipulations? *Check all that apply.*

Modified pediatric isolette	☐ 1
K-Systems Mini-Incubator/workstation	☐ 2
Hoffman IVF or MBT Chamber	☐ 3
microscope warming stage	☐ 4
slide warmer/warming trays for culture containers	☐ 5
heating blocks	☐ 6
dry heat incubator for warming equipment/utensils	☐ 7
dry bath for warming equipment/utensils	☐ 8
water bath for warming fluid substances	☐ 9
Other (*please specify):* _____	☐ 10

43. Please indicate the types of hoods that are used in various areas within the embryo laboratory. *Check all columns that apply for each row.*

Hood Type	Check the laboratory area(s) where these hoods are located		
	sperm prep area	oocyte/embryo culture area	media prep area
Hood not used	9	9	9
Fume hood (non-filtered air vented outside lab)	9	9	9
Clean bench (i.e., horizontal laminar flow hood)	9	9	9
Class I biological safety cabinet (air flows in at front, out at rear and top through HEPA filter)	9	9	9
Class II biological safety cabinet (HEPA filtered vertical laminar airflow and HEPA filtered exhaust air)	9	9	9

44. Does the embryo laboratory have a room air filtration system? ***Check all that apply.***

No. Embryo laboratory does not filter room air	☐ 1
HEPA filter	☐ 2
Particulate filter	☐ 3
Carbon filter	☐ 4
Positive air pressure	☐ 5
Electrostatic filtration system	☐ 6

45. Please indicate the types of incubators that are used in the areas indicated within the embryo laboratory. ***Check all columns that apply for each row.***

Incubator Type	Check the laboratory area(s) where these incubators are located		
	Sperm prep area	**Oocyte/embryo culture area**	**Media prep area**
Water-jacketed, gas & humidity controlled	**9**	**9**	**9**
Dry heat incubator/oven	**9**	**9**	**9**
Portable incubator (e.g., pediatric isolette)	**9**	**9**	**9**

46. How are the following environmental parameters monitored in the incubator(s) used for gamete/embryo culture? ***Check all that apply*****.**

A. Atmospheric gas content

Incubator atmospheric gas content is not monitored	☐ 1
Infrared gas monitor (external)	☐ 2
Mass Spectrometer	☐ 3
Chemical (Fyrite)	☐ 4
Media pH	☐ 5
Check here if gas content is automatically recorded by any of the devices above	☐ 6
Other method of monitoring atmospheric gas content *(please specify)*: _____	☐ 7

46. (cont.) How are the following environmental parameters monitored in the incubator(s) used for gamete/embryo culture? *Check all that apply*.

B. Temperature

Incubator temperature is not monitored	☐ 1
Internal thermometer (in addition to the inherent temperature monitor)	☐ 2
External/remote temperature monitoring device (e.g., YSI digital thermometer)	☐ 3
Check here if temperature is automatically recorded by any of the devices above	☐ 4
Other method of monitoring temperature *(please specify)*: _____	☐ 5

C. Humidity

Incubator humidity is not monitored	☐ 1
Thermal conductivity	☐ 2
Wet-bulb thermometer	☐ 3
Hygrometer	☐ 4
Check here if humidity is automatically recorded by any of the devices above	☐ 5
Other method of monitoring humidity *(please specify)*: _____	☐ 6

47. How frequently are incubator conditions monitored during the period when human gametes/embryos are in the incubator? *Check one box in each column.*

Monitoring Frequency	Check how frequently this condition is monitored		
	Temperature	Gas levels	Humidity
Not monitored	9 1	9 1	9 1
Continuously (strip chart recorder)	9 2	9 2	9 2
Hourly	9 3	9 3	9 3
Twice daily	9 4	9 4	9 4
Daily	9 5	9 5	9 5
Before each use	9 6	9 6	9 6
Other interval *(please specify)*: _____	9 7	9 7	9 7

48. Is there a *written* on-call policy for the embryo laboratory so that a staff member can be contacted in the event of a problem?

Yes	☐ 1
No	☐ 2

49. Which of the following parameters or conditions are monitored by a laboratory alarm/alert system? *Check all that apply.*

No alarm or alert system is used	☐ 1
Incubator temperature	☐ 2
Incubator gas content	☐ 3
Liquid nitrogen levels	☐ 4
Electrical power is on	☐ 5
Refrigerator or mechanical freezer temperatures	☐ 6
Motion detectors	☐ 7
Noise level detectors	☐ 8
Infrared (heat) detectors	☐ 9
Smoke detectors	☐ 10
Controlled rate freezers	☐ 11
Oxygen level sensors	☐ 12

50. In the event of a power failure, please indicate whether the following components are activated automatically or manually. *Check one column for each row.*

Type of emergency power system	Is the system automatically activated?	Is the system manually activated by the embryo lab staff?
NO back up system is available	**9** 1	**9** 2
Battery powered back up system	**9** 1	**9** 2
Fuel powered generator	**9** 1	**9** 2
Other system	**9** 1	**9** 2

51. How are emergency alarms and power back up systems checked to ensure correct function? ***Check one box in each column.***

Who checks the system?	Emergency alarm systems	Back-up system for electrical power
System is NOT periodically checked	9 1	9 1
Periodically checked embryo laboratory staff	9 2	9 2
Periodically checked by facility maintenance staff	9 3	9 3
Periodically checked by other personnel	9 4	9 4
Do not know	9 5	9 5

52. Please indicate which of the following safety inspections are conducted within the embryo laboratory? ***Check all that apply.***

Fire hazards	☐ 1
Electrical hazards	☐ 2
Infection hazards	☐ 3
Fire extinguisher operability	☐ 4
Hazardous materials storage	☐ 5
Volatile materials storage	☐ 6
Radioactive materials storage	☐ 7
Hood/biological safety cabinet operation	☐ 8

53. In the table below, please check the appropriate column to indicate if the listed devices used in the embryo laboratory are disposable or reusable. ***Check only one box in each row.***

Device	Disposable	Re-usable	Not used
Syringes	9 1	9 2	9 3
Serological pipets	9 1	9 2	9 3
Transfer pipets	9 1	9 2	9 3
Oocyte/embryo culture dishes	9 1	9 2	9 3
Oocyte retrieval needles	9 1	9 2	9 3
Embryo transfer catheters	9 1	9 2	9 3

54. Which of the following methods are used for sterilizing equipment and/or materials used by the laboratory? ***Check all that apply.***

Materials are purchased pre-sterilized by the manufacturer	☐ 1
Steam sterilization (e.g. autoclave)	☐ 2
Dry heat sterilizers	☐ 3
Gas (e.g., ethylene oxide)	☐ 4
Liquid chemical (e.g. Cidex)	☐ 5
Microwave radiation	☐ 6
Ionizing radiation	☐ 7
Other sterilizing method *(please specify)*: _____	☐ 8

55. Which quality control methods are used to verify sterilization? *Check all that apply*.

Mechanical monitoring (e.g., monitor and record autoclave temperature, pressure and duration of sterilization cycles)	☐ 1
Heat-sensitive tape affixed to outside of autoclaved or dry heat sterilized packets	☐ 2
Chemical-sensitive tape affixed to outside of gas-sterilized packets	☐ 3
Heat- or chemical-sensitive indicators placed inside of sterilized packets	☐ 4
B. subtilis spore strips/vials to monitor the effectiveness of dry heat or gas sterilization	☐ 5
B. stearothermophilus spore strips/vials to monitor the effectiveness of steam or microwave sterilization	☐ 6
Date of sterilization noted on the outside of the packet	☐ 7
Date of sterilization expiration noted on the outside of the packet	☐ 8

56. Are embryo manipulation procedures carried out under oil (i.e., in oil droplets)?

Yes	☐ 1	No	☐ 2

Please continue on page 26.

57. In the table below, please indicate how each of the following procedures are performed in the embryo laboratory. ***Check one box in each row.***

Procedure	Procedure is performed in			
	environmentally controlled chamber	a hood with the		non-controlled environment
		fan turned on	fan turned off	
Preparation of culture media	9 1	9 2	9 3	9 4
Oocyte identification & assessment	9 1	9 2	9 3	9 4
Sperm preparation	9 1	9 2	9 3	9 4
Oocyte insemination	9 1	9 2	9 3	9 4
Fertilization assessment	9 1	9 2	9 3	9 4
Embryo assessment	9 1	9 2	9 3	9 4
Transfer catheter loading	9 1	9 2	9 3	9 4
Cryopreservation procedures	9 1	9 2	9 3	9 4
Micromanipulation (any type)	9 1	9 2	9 3	9 4

58. Do you routinely photograph or video tape embryo laboratory procedures?

No. ° **Skip to question 61.** ☐ 1

Yes ☐ 2

59. Which procedures are routinely photographed or video taped? ***Check all that apply.***

Oocyte location/identification ☐ 1
Oocyte insemination ☐ 2
Semen motility ☐ 3
Sperm preparation ☐ 4
Embryo quality assessment ☐ 5
Thawed gametes/embryo assessment ☐ 6
Micromanipulation procedures ☐ 7

60. How are these photographs or video tapes used? *Check all that apply.*

for oocyte identification	☐ 1
for oocyte quality assessment	☐ 2
for oocyte/embryo morphometrics	☐ 3
for embryo identification	☐ 4
for teaching/training purposes	☐ 5
to maintain a record of the procedure	☐ 6
to evaluate employee competency	☐ 7
Other reason *(please specify)*: _____	☐ 8

61. Which information is documented as a part of embryo laboratory procedures? *Check all that apply*.

Patient identifiers	☐ 1
Partner identifiers	☐ 2
Donor identifiers	☐ 3
Gamete/embryo identifiers	☐ 4
ART procedure date/time	☐ 5
Identity of lab staff participating in the ART procedures	☐ 6
Lot/batch numbers of media used	☐ 7
Lot/batch numbers of disposable supplies used	☐ 8
Information about follicular fluids aspirated	☐ 9
Number/quality of oocytes identified	☐ 10
Information about sperm preparation procedures	☐ 11
Information about oocyte insemination	☐ 12
Fertilization assessments	☐ 13
Embryo quantity/quality assessments	☐ 14
Date/time of embryo transfer	☐ 15
Number of embryos transferred	☐ 16
Disposition of non-transferred embryos	☐ 17
Verification of informed consent	☐ 18
Information about micromanipulation procedures	☐ 19
Other information *(please specify)*: _____	☐ 20

62. Is embryo culture media made in your laboratory?

No. ° Skip to question 64. ☐ 1	Yes ☐ 2

63. What type of water is used for formulating embryo culture media? *Check all that apply.*

HPLC-grade water	☐ 1
Distilled water	☐ 2
Deionized water	☐ 3
distilled/deionized water	☐ 4
Other water source *(please specify)*: _____	☐ 5

64. Which type of nutrient media is used for gamete/embryo culture? *Check all that apply.*

Commercially prepared liquid media (i.e., ready-to-use media)	☐ 1
Media prepared in the embryo lab using commercially prepared powdered media base, other added reagents (e.g., antibiotics), and *facility-prepared* water	☐ 2
Media prepared in the embryo lab using commercially prepared Powdered media base, other added reagents (e.g., antibiotics), and *commercially prepared* water	☐ 3
Media prepared entirely in the embryo lab using stock chemicals/reagents and *facility-prepared* water (i.e., prepared from "scratch")	☐ 4
Media prepared entirely in the embryo lab using stock chemicals/reagents and *commercially-prepared* water (i.e., prepared from "scratch")	☐ 5
Other *(please specify)*: _____	☐ 6

65. Which of the following substances are used to supplement media used for embryology procedures? *Check all that apply.*

Antibiotics (e.g., penicillin)	☐ 1
Anticoagulants (e.g., heparin)	☐ 2
Maternal (patient) plasma/serum	☐ 3
Donor plasma/serum	☐ 4
Synthetic serum substitute	☐ 5
Fetal calf serum	☐ 6
Cord blood	☐ 7
Human serum albumin	☐ 8
Bovine serum albumin	☐ 9
Plasmatein	☐ 10
Plasmanate	☐ 11
Other non-protein macro molecules	☐ 12
Other protein source *(please specify)*: _____	☐ 13

66. Please indicate which of the following information is recorded in the embryo laboratory records to document use of chemicals, prepackaged media, and/or other media components or reagents used in ART procedures. *Check all that apply.*

Source (manufacturer/vendor)	☐ 1
Receipt date	☐ 2
Date opened	☐ 3
Expiration/use by/discard by date	☐ 4
Temperature upon receipt	☐ 5
Lot number	☐ 6
Purchase order number	☐ 7

67. *Excluding microfertilization or ICSI procedures*, which of the following criteria do the embryo laboratory personnel routinely use to assess oocyte quality and maturity? *Check all that apply*.

Corona-cumulus complex	☐ 1
Presence/absence of 1st polar body	☐ 2
Zona pellucida thickness	☐ 3
Presence/absence of cytoplasmic vesicles	☐ 4
Presence/absence of germinal vesicle	☐ 5
Appearance of oocyte cytoplasm	☐ 6
Appearance of granulosa cells	☐ 7
Other criteria *(please specify)*: _____	☐ 8

68. How are oocytes that are judged to be immature routinely handled in the embryo laboratory? *Check all that apply.*

Incubate until mature, then inseminate	☐ 1
Inseminate at the same time as mature oocytes	☐ 2
Immature oocytes are discarded	☐ 3
Immature oocytes are used for research purposes	☐ 4
Other procedure *(please specify)*:_____	☐ 5

69. How are oocytes incubated?

Oocytes are cultured Individually in own volume of culture media	☐ 1
Multiple oocytes (from the same source)are incubated in a volume of culture media	☐ 2

70. Does the laboratory perform sperm preparation for embryology procedures?

Yes	☐ 1	No	☐ 2

71. Are semen specimens transported to the embryo laboratory from an external site? ***If yes, check all that apply.***

NO. All specimens are collected at the facility, no transport required	☐ 1
Patient/partner delivers specimen to embryo lab	☐ 2
Courier service delivers specimen	☐ 3
Specimen is transported to embryo lab at ambient temperature	☐ 4
Specimen is kept warm (e.g., 37EC) using active or passive warming devices	☐ 5

72. For which purposes are sperm isolation procedures used in the embryo laboratory? ***Check all that apply.***

NONE. Sperm are not isolated by our embryo laboratory	☐ 1
Diagnostic testing (e.g., SPA)	☐ 2
Intrauterine inseminations	☐ 3
In vitro oocyte inseminations/ICSI	☐ 4
Gamete intrafallopian transfer (GIFT)	☐ 5

73. In the following table, please indicate the usefulness of the criteria presented for assessing normal (i.e., 2PN) fertilization. ***Check one box for each row.***

Criteria	Very useful	Moderately useful	Not very useful
Presence or absence of pronuclei	9 1	9 2	9 3
2nd polar body extrusion	9 1	9 2	9 3
Cleavage	9 1	9 2	9 3
Cytoplasmic traits	9 1	9 2	9 3
Dissolution of corona-cumulus complex	9 1	9 2	9 3
Presence of sperm in perivitelline space	9 1	9 2	9 3
Thickness of the zonae pellucida	9 1	9 2	9 3

74. In the following table, please rank the usefulness of the criteria for assessing embryo quality for possible transfer. ***Check one box for each row.***

Criteria	Very useful	Moderately useful	Not very useful
Number of blastomeres present	9 1	9 2	9 3
Rate of cleavage	9 1	9 2	9 3
Uniform/irregular blastomere size/shape	9 1	9 2	9 3
Absence/presence of fragments/blebs	9 1	9 2	9 3
Cytoplasmic granularity	9 1	9 2	9 3
Thickness of the zonae pellucida	9 1	9 2	9 3
Evidence of fertilization (esp. for reinseminated oocytes)	9 1	9 2	9 3

75. How do you handle polyploid zygotes? ***Check all that apply.***

- They are discarded ☐ 1
- They are allowed to continue to develop ☐ 2
- They are transferred with other embryos ☐ 3
- They are used for training lab personnel in various handling techniques ☐ 4
- They are frozen/thawed for training purposes ☐ 5
- Other *(please specify)*:_____ ☐ 6

76. Does the embryo laboratory routinely culture embryos to the blastocyst stage for transfer?

No º **Skip to question 78.** ☐ 1

Yes ☐ 2

77. Under what circumstances are embryos allowed to progress to the blastocyst stage? ***Check all that apply.***

All embryos are routinely cultured to blastocyst stage	☐ 1
Poor quality (morphology) embryos are cultured to blastocyst stage	☐ 2
Embryos from older patients are cultured to blastocyst stage	☐ 3
Embryos are cultured to blastocyst when previous embryo transfers have failed to implant	☐ 4
Other circumstance *(please specify)*:_____	☐ 5

78. After embryo transfer procedures, is the transfer device flushed and the flush solution examined for un-transferred embryos?

Yes	☐ 1
No	☐ 2

79. What is usually done with excess zygotes or embryos that are not transferred or frozen? ***Check all that apply.***

Disposition of excess zygotes or embryos	Disposition is	
	with patient consent	without patient consent
are immediately discarded	**9**	**9**
are cultured to demise and discarded	**9**	**9**
are donated for research purposes	**9**	**9**
are donated for diagnostic purposes	**9**	**9**
are donated for training purposes	**9**	**9**
are donated to another patient/couple	**9**	**9**

80. Does the embryo laboratory perform cryopreservation procedures?

No **º Skip to question 87.**	☐ 1
Yes	☐ 2

81. Which cryopreservation procedures does the embryo laboratory perform? *Check all that apply.*

Cell type	Check here if cells are;		Check cryoprotectant used (for clinical procedures):			
	Frozen for patient use	Frozen for research, training purposes	Glycerol	DMSO	Propylene glycol	Other
Oocytes	9	9	9	9	9	9
Pronuclear cells	9	9	9	9	9	9
2-8 cell embryos	9	9	9	9	9	9
>8 cell to blastocyst embryos	9	9	9	9	9	9
Ejaculated sperm	9	9	9	9	9	9
Epididymal sperm	9	9	9	9	9	9
Testicular sperm	9	9	9	9	9	9
Single sperm cells	9	9	9	9	9	9

82. How are frozen QA/QC cells or cell lines stored? *Check all that apply.*

- ☐ 1 Cells or cell lines from different species are stored in different dewars/freezers from human embryos
- ☐ 2 Cells from different species are stored in the same dewar/freezer as human embryos
- ☐ 3 Frozen cells are not used for QA or co-culture in the embryo laboratory

83. When cryopreservation is performed, what information is recorded about the procedure? *Check all that apply.*

Procedure number	☐ 1
Gamete/embryo identification number	☐ 2
Date/time of gamete collection/retrieval	☐ 3
Date/time of freezing	☐ 4
Date/time of thawing	☐ 5
Gamete/embryo stage of development at freezing	☐ 6
Cryopreservation protocol followed	☐ 7
Cryoprotectant/media formulation(s) used	☐ 8
Freezing program (e.g., rate and of cooling, program duration etc.)	☐ 9
Name/identifier of patient/female donor	☐ 10
Name/identifier of partner/male donor	☐ 11
Cryostorage location (e.g. freezer number, position)	☐ 12
Identification of individual(s) performing freezing/thawing procedure	☐ 13
Pre-freeze photos/video of gametes/embryos	☐ 14

84. Are duplicate records of cryopreserved specimens maintained? *Check all that apply.*

No, duplicate records are NOT maintained	☐ 1
Yes, duplicate records are maintained off-site	☐ 2
Yes, duplicate records are maintained elsewhere in the facility, not in the embryo laboratory	☐ 3

Please continue on page 36.

85. Which information is recorded on embryo cryocontainers prior to freezing? *Check all that apply.*

Name of Laboratory/facility	☐ 1
Name of staff member performing cryopreservation	☐ 2
Embryo number	☐ 3
Container (i.e., straw, vial, ampule) number	☐ 4
ART procedure number	☐ 5
Female patient name	☐ 6
Female patient identifiers	☐ 7
Partner name or identifiers	☐ 8
Number of gametes/embryos in container	☐ 9
Date of freezing	☐ 10
Date of retrieval	☐ 11
Other information *(please specify)*:_____	☐ 12

86. In the following table, please rank the usefullness of the criteria for assessing *thawed* embryo quality for possible transfer. *Check one box per row*.

Criteria	Usefulness for assessing thawed embryo quality:		
	Very useful	Moderately useful	Not very useful
Number of blastomeres present	9 1	9 2	9 3
Continued cell cleavage	9 1	9 2	9 3
Uniform/irregular blastomere size/shape	9 1	9 2	9 3
Absence/presence of fragments/blebs	9 1	9 2	9 3
Cytoplasmic traits	9 1	9 2	9 3
Thickness of the zonae pellucida	9 1	9 2	9 3

87. For how many continuous years (to the nearest half-year) has the embryo laboratory performed any type of micromanipulation procedures? *Enter zero (0) if none*.

_____years

88. During 1997, what is the approximate percentage (to the nearest 10%) of procedures performed in the embryo laboratory in which micromanipulation (any type) was used? Enter zero (0) if none.

_____%

89. What information is recorded on reagent or laboratory chemical containers? *Check all that apply.*

Information Recorded	Check if this information is recorded on containers of:	
	reagents purchased from commercial vendors	reagents prepared by embryo lab staff
Receipt or preparation date	9	9
Date opened or placed into use	9	9
Expiration/use by/discard by date	9	9
Storage temperature	9	9
Temperature on receipt	9	9
Lot/batch number	9	9
Initials of preparer	9	9
Initials of individual opening reagent	9	9
Special handling requirements	9	9
Other	9	9

90. Which evaluation procedures are used to control the quality of media used for gamete/embryo culture? *Check all that apply*.

Evaluation procedure	Substance being evaluated:			
	Culture Media	Water	Glassware	Disposables
This item **not** evaluated.	9	9	9	9
Cultures for sterility	9	9	9	9
Presence of endotoxins	9	9	9	9
Residual organics (e.g., plasticizers, detergents)	9	9	9	9
Development of mouse 1-cell or 2-cell embryos to blastocyst	9	9	9	9
Human sperm survival	9	9	9	9
Hamster sperm motility or viability	9	9	9	9
Other bioassay	9	9	9	9
Are the results of media quality testing recorded (Circle Y or N)?	Y N	Y N	Y N	Y N

91. Which additional procedures are used to assure that water produced or obtained for embryo laboratory procedures is of suitable quality for use? *Check all that apply.*

None, water quality verified by commercial source	☐ 1
Check pH of product	☐ 2
Check for residual chloride levels	☐ 3
Check for hardness	☐ 4
Check for residual formaldehyde levels	☐ 5
Culture for microorganism growth	☐ 6
Endotoxin	☐ 7
Other method method *(please specify)*:_____	☐ 8

92. Which of the following human-derived materials are screened for the presence of infectious agents? *Check all that apply*.

Human derived materials are not screened. **º Skip to question 94**.	☐ 1
Maternal (autologous) serum for supplementing media	☐ 2
Donor serum for supplementing media	☐ 3
Partner sperm/semen for ART or IUI inseminations	☐ 4
Freshly obtained donor sperm for ART or IUI inseminations	☐ 5
Maternal (autologous) follicular fluid for media supplementation	☐ 6
Donor follicular fluid for media supplementation	☐ 7
Other substances *(please specify)*:_____	☐ 8

93. For infectious disease testing of human-derived materials, please answer the following. *Check all that apply*.

Human immunodeficiency virus Type I (HIV-I)	☐ 1
Human immunodeficiency virus Type II (HIV-II)	☐ 2
Human T-lymphotropic virus types I & II (HTLV-I/ II)	☐ 3
Hepatitis B Virus (HBV)	☐ 4
Hepatitis C Virus (HCV)	☐ 5
Chlamydia trachomatis	☐ 6
Mycoplasma	☐ 7
Ureaplasma	☐ 8
N. gonorrhoeae	☐ 9
Cytomegalovirus (CMV)	☐ 10
Herpes simplex virus (HSV)	☐ 11
Other agents *(please specify)*:_____	☐ 12

94. Which of the following glassware washing procedures are specified in the embryo laboratory procedure manuals? *Check all that apply*.

No specified procedure	☐ 1
Our laboratory only uses single-use or disposable plasticware	☐ 2
Glassware washing procedures are not specified	☐ 3
The detergent type is specified	☐ 4
The detergent source is specified	☐ 5
The water type is specified	☐ 6
The number of rinses are specified	☐ 7
Drying procedures are specified	☐ 8
Sterilization procedures are specified	☐ 9
Storage procedures are specified	☐ 10
Other *(please specify)* _____	☐ 11

Please continue on page 41.

95. How frequently are the following equipment function checks made? ***Check one box per row***.

Equipment functions checked:	Frequency of equipment function check						
	Not done	Daily	Weekly	Monthly	Quarterly	Annually	Other interval
Emergency power generator operation	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Emergency power transfer switch	9 1	9 2	9 3	9 4	9 5	9 6	9 7
After-hours alarm/alert system operation	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Water system conductivity checks	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Incubator microbial contamination	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Incubator gas %	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Incubator humidity	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Liquid nitrogen level alarm	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Centrifuge tachometer check	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Biological safety cabinet/hood air-flow velocity	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Hood certification	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Pipettor calibrations	9 1	9 2	9 3	9 4	9 5	9 6	9 7
Thermometer calibrations	9 1	9 2	9 3	9 4	9 5	9 6	9 7

96. Please indicate which agents are used to disinfect/decontaminate equipment and/or work surfaces in the embryo laboratory, during ART cycle operations, after general use and after spills or contamination. *Check all that apply*.

Cleaning Agent	General Lab Clean up	Embryo lab during ART cycles	Embryo lab during down time
Mild soap/detergent and water	9	9	9
Peroxide-based compounds	9	9	9
0.5% bleach solution	9	9	9
Quaternary ammonium agents	9	9	9
Phenolic agents	9	9	9
Alcohols (i.e., ethanol, methanol)	9	9	9
Iodophores	9	9	9
Aldehydes	9	9	9
Class I/II water	9	9	9
Other cleaning agents	9	9	9

97. Please indicate which methods are used in your embryo laboratory to document and improve quality of laboratory procedures. *Check all that apply*.

There is a written plan stating quality assurance expectations	☐ 1
Laboratory procedure records are reviewed by laboratory director or supervisor	☐ 2
Quality control records are reviewed by supervisor or director	☐ 3
Corrective actions taken to resolve technical problems are documented	☐ 4
Corrective action records are reviewed by supervisor or director	☐ 5
Trends in technical problems are documented and improvement plan initiated	☐ 6
Laboratory participates in an interlaboratory proficiency testing program	☐ 7
Internal laboratory proficiency testing is performed	☐ 8
Staff performing ART procedures undergo periodic competency assessment	☐ 9
Other method *(please specify)*:_____	☐ 10

98. How are the results of laboratory quality assurance efforts communicated? *Check all that apply.*

QA review results are **not** communicated	☐ 1
Results are presented at embryo laboratory staff meetings	☐ 2
Results are presented at Clinical staff meetings	☐ 3
Results are presented during individual staff performance review	☐ 4
Results are posted in the embryo laboratory for review	☐ 5
The embryo laboratory is represented on institutional quality assurance committee(s)	☐ 6
Results are presented at peer group presentations	☐ 7
Other methods *(please specify)*:_____	☐ 8

99. Which methods are used to validate assays or procedures that are newly implemented in the embryo laboratory? *Check all that apply*.

New assay performance compared with existing assay or known performance standards	☐ 1
New procedures are tested using animal models prior to being used on human cells (gametes, embryos, etc.)	☐ 2
Compare success rates obtained using new procedures with success rates obtained by other programs	☐ 3
Assess new assay/test performance on interlaboratory proficiency testing or performance evaluation programs.	☐ 4
Other method *(please specify)*:_____	☐ 5

100. Please indicate which of the following activities take place to ensure and improve the quality of services provided by the embryo laboratory. *Check all that apply*.

The laboratory has a written program in place for monitoring and evaluating the quality and appropriateness of patient care services	☐ 1
A written procedure is in place for detecting clerical, transcription, or analytical errors	☐ 2
A written procedure is in place for documenting problems that arise in the laboratory	☐ 3
A written procedure is in place for resolving identified problems	☐ 4
A written procedure is in place for reviewing corrective actions the appropriate individuals	☐ 5
A minimum fertilization rate or other measure of success is maintained in order to continue offering embryology services	☐ 6
Live birth rates are monitored	☐ 7
Laboratory performance thresholds adjusted annually to encourage improvement in success rates	☐ 8
Laboratory performance success rates compared to embryology laboratories	☐ 9
The laboratory director and/or supervisor participate as member(s) of quality improvement committee(s) or efforts of the facility/institution	☐ 10

Please continue on next page.