510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
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Establishment Registration Number:1034569
Proprietary Name: ABS2000
Common Name: Automated blood bank laboratory analyzer

Class of Device: Class II
1. Classification Name: System, Test, Automated Blood Grouping and Antibody
2. Classification Number: 81KSZ

The major components which make up the system functionally have the following classification panel names/number codes:

Microtitration plate Reader: Colorimeter, photometer, spectrophotometer for clinical use- 75JJQ- CFR ß862.2300- class I
Microtitration plate Washer: Microtiter diluting and dispensing device- 83JTC- CFR ß866.2500- Class I (note exempt from 510(k) notification)
Dispenser: Station, pipetting and diluting, for clinical use- 75JQW- CFR ß862.2750- Class I
Incubator: Incubator for clinical use- 75JRH
Centrifuge: Centrifuge, Blood Bank For In-Vitro Diagnostic Use- 81 KSO- ß862.9275- Class I;
or Centrifuge, General- 88 KDR -Class I.

Substantial Equivalence: The ABS2000 Blood Bank Analyzer whose different components are functionally equivalent to the following blood bank laboratory instruments used to perform serological tests.

Pipeting and sample handling instruments:
Hamilton MicroLab AT
Inverness Blood Grouping System Ltd. Liquid Handler

Microtitration plate washers:
SLT 96-well plate washer
BioTek EL403 and EL404 plate washer
Tricontinent Multiwash Plus and CSW100

Microtitration plate reader:
Inverness Blood Grouping System Ltd. Multireader Plus

Centrifuge:
Hettich Universal and EBA12 centrifuges
Sorval GLC2B general purpose centrifuge

Similarity to other devices: The ABS2000 hardware incorporates features which are similar to those in other automated in-vitro diagnostic systems and component devices as follows:
1. Optical reading system is similar to that used in the Bio-Tek ELs 1000, K933548/S1.
2. Sample and reagent pipeting system is similar to that used in the Bio-Tek ELs 1000, K933548/S1.
3. Incubator system is similar to that used in the Bio-Tek ELs 1000, K933548/S1.

4. Microwell wash system is similar to that used in the Bio-Tek ELs 1000, K933548/S1.
5. Scanning of the microwells is similar to that used in the Bio-Tek CERES 900C K942923/S1
6. Centrifuge similar to current laboratory centrifuges
7. Reagents and disposable components used by the ABS2000:

Immucor Monoclonal Blood Grouping Reagents: Anti-A Series 1, -B Series 1, and -A,B Series 1 are the same as approved for Slide, Tube and Microplate methods.

Immucor Monoclonal Blood Grouping Reagent: Anti-D Series 4 and -CDE Series 4 product license supplement pending approval by Center for Biologic Evaluation and Review (94-0822 and 94-0823)

Immucor Monoclonal Blood Grouping Reagent: Anti-D Series 5 product license supplement to be submitted to Center for Biologics Evaluation and Review at time of this notification.

Immucor Reagent Red Cells: A1 Red Cells, A2 Red Cells and B Red Cell for Serum Grouping are the same as approved for tube and microplate testing (Immucor trademark Referencells A1, A2 and B)

Immucor Capture Reagents: Capture-R Ready Indicator Red Cells and Capture LISS previously reviewed under 89-0420, dated 6/22/90, except that the dye used in Capture LISS has been changed from violet dye No. 1 (a potential carcinogen) to bromcresol purple. The Capture LISS with the bromcresol purple dye was used in the clinical evaluations of the ABS2000. Laboratory tests demonstrate no differences in Capture assays using Capture LISS manufactured with either dye.

Immucor Capture-R Ready Screen (4) Microwells: reviewed under 94-0553, dated 2/14/95.

Immucor Modified Capture-R: polystyrene microwell strips are similar to Capture-R (I and II) and (Pooled Cells) polystyrene 96-well plates reviewed under 87-0077, dated 6/6/88. Modified Capture-R 510(k) notification is submitted at time of this notification.

Immucor Capture-R Control Cells: are similar to IgG-coated red cells (also known as Coombs Control Cells) for the control of the antiglobulin test. Capture-R Control Cells are supplied at a concentration of less than 2 % and are intended for use on the ABS2000 only. Capture-R Control Cells 510(k) notification is submitted at time of this notification.

Immucor ABS QC Test System and ABS QC Test System Plus: are intended for the daily QC of routine blood bank reagents and components on the ABS2000 only. The ABS QC Test System and the ABS QC Test System Plus are similar to corQC Test System for the daily evaluation of routine blood bank reagents. corQC was reviewed under 84-0024, dated 11/8/84.

Immucor Hemagglutination/Dilution Strips: are similar to microwells coated with human serum or plasma to prevent the adherence of red cells (AABB Technical Manual 11th ed.,1993:619). Hemagglutination/Dilution Strips 510(k) notification is submitted at time of this notification.

The reagents and solid phase assay system described above can be used in manual assays or the steps of each test procedure may be semiautomated. The loading the microwells with samples and reagents can be performed by semiautomated pipetting systems (e.g. IBG, Inverness Blood Grouping Ltd., sample and reagent pipetting system, Olympus PK7200, Hamilton MicroLab AT). The washing of nonreacted material from microplate wells can be performed using semiautomated wash systems. Reading the endpoint reaction can be performed using semiautomated microplate spectraphotometric systems (e.g. IBG, Inverness Blood Grouping Ltd., Multireader Plus, Olympus PK7200, Hamilton MicroLab AT). Alternatively the manual and

semiautomated steps can be performed by an automated instrument, such as the ABS2000 that performs all of the steps of each assay system without user intervention.

Device Description and Intended Use: The ABS2000 is a table top automated analyzer designed to perform routine blood bank tests. The ABS2000 is intended for the ABO blood grouping and Rh typing of human blood, for the detection of unexpected IgG blood group antibodies in human plasma, for the confirmation of ABO blood group and Rh type of donor red cells and for the detection of IgG incompatibility between donor red cells and patient plasma in the compatibility test.

Summary of Clinical Trials:
The ABS2000 was evaluated at six clinical sites located in the Pacific, East, Southeast, Southwest and Midwest United States. Samples tested were derived from the following:

Hospital/Clinic
- Prenatal patients
- Elective surgical patients
- Hematology/Oncology Patients
- Geriatric Patients
- Pediatric patients

Donor pilot samples

The ABS2000 handles all processes, including logging of reagent and samples, daily Q C of reagents, transferring specimens, preparing cell suspensions, adding reagents, incubating, washing, centrifugation, shaking, reading, recording, interpreting data, validating accuracy of test results, validating crossmatch pairings, preparing test records and transferring data to a data management system. In clinical trials, samples were tested by manual tube test and ABS2000 methods.

Donor Confirmation	total samples 3779
ABO confirmation test	99.84 % agreement
Rh confirmation test	98.73 % agreement
Patient Typing	total samples 7580
ABO Typing	100 % agreement
Rh typing	99.68 % agreement
Patient Antibody Screen	total samples 7510
Antibody Screen	96.7 % agreement
Patient/Donor Crossmatch	total samples 7392
Crossmatch	98.8 % agreement

The initial NTD rates for the ABS2000 were; donor ABO - 3.04%, patient ABO - 4.59%, patient Rh - 0.22%).

Nonparametric analysis of differences between manual tube test and automated antibody screening and crossmatching indicated that the differences found were not enough to exclude the possibility that the differences were due to sampling variability; that there was not a statistically significant difference..

Hazard Analysis:
Potential system hazards (FMEA) were classified as those that could affect the functionality of the system and those that could affect user safety. The primary system function hazards which were reviewed and addressed were:

Hazard Analysis (FMEA):

Two Failure Mode Effect Analysis sessions were conducted and documented for the device based on previous systems hardware experience, and the method of operation. The ABS 2000 incorporates features to prevent utilizing data which could lead to believable but false results.

Failure Mode Effects Analysis (FMEA) for Hardware

A failure mode effects analysis was conducted on the hardware design in order to identify potential design inadequacies that could effect user safety or performance to specification.

The analysis was conducted via a "bottoms up" method which assumes basic defects at the component level and then determines the effects at higher levels of assembly. The analysis was conducted with knowledge of previous products with similar features. Failure modes were analytically induced for each component and failure effects were then evaluated and noted. Appropriate corrective actions are taken as necessary to correct the observed design deficiencies.

Each assembly was analyzed to determine the components which could affect safety or effectiveness using FMEA worksheets. The worksheets contained the following information: Component, Failure Mode, Local Effect, System Effect, How Detected (Alarm Code), Category/Action, Planned Method of Detection, and Planned Corrective Action. Failure mode effect analysis was conducted on the following major systems:

1. Arm
2. Large Syringe
3. Small Syringe
4. Track
5. Reader
6. Probe
7. Rinse Station
8. Washer
9. Waste Fluid Evacuation System
10. Vacuum/Pressure System
11. Door Locks and Sensors
12. Computer/Printed Circuit Boards
13. Power Supplies
14. Centrifuge
15. Carrousel

A summary of the safeguards incorporated into the operational features of the device based on the FMEA and knowledge of operation of ELISA systems, such as the ELs1000 are:

ARM:

Verify that the arm did not lose steps. Do verification once per strip during dispense into well A of each strip.

LARGE SYRINGE:

Verify that syringe did not lose steps. Do verifications at the end of each dispense cycle during the probe rinse.

SMALL SYRINGE:

Verify that syringe did not lose steps. Do verifications at the end of each dispense cycle during the probe rinse.

TRACK:

1. Verify that track did not lose steps. Do verification at the end of each dispense cycle during the probe rinse.

2. Monitor temperature continuously by sensors to ensure proper operation.

READER:

1. Verify that the signal in the system is within acceptable range for every filter used in the assay. Do this during calibration of the reader.
2. Verify that every filter location has either filter or a plug in place and no false home is created. Do this as part of filter homing routine.
3. Verify that filter wheel did not lose steps. Do this at end of reading a strip.
4. Verify that reader head did not lose steps. Do this at the end of reading a strip.
5. Verify that track window did not become obstructed during the run as a result of a spill. Do this once per run.
6. Check values for reference channel in the reader against set limits.

PROBE:

1. Verify that the probe did not lose steps. Do this during movement home out of rinse cup.
2. To verify integrity; of the level sensor compare dry reference value with factory default value.
3. To avoid short sample verify transition from wet to dry on the way out of a sample.

RINSE SYSTEM:

1. Verify that rinse fluid is being delivered using dispense of rinse solution with peripump into dilution strip and level sensing in the dilution strip. Do this twice per run.
2. Monitor the status of the rinse container presence micro switch during the run.

WASHER:

1. Verify that the washer did not lose steps during every move down to dispense height from the priming trough.
2. Verify that both buffer valves dispense out of every tube twice per run using dilution strip.
3. Verify that all 8 tubes evacuate the wells using dilution strip. Do this twice per run.
4. Monitor the status of the buffer containers presence micro switches during the run.

WASTE FLUID EVACUATION SYSTEM:

1. Verify that wasted fluid is being evacuated out of a rinse station by level sensing in the dump site of the rinse station. Do this for every trip to the dump site.
2. Verify that vacuum pump is operational by monitoring pressure range continuously throughout the run.
3. A float valve is installed in the intermediate vacuum vessel to prevent waste from entering vacuum filter.
4. Monitor the status of the waste container presence micro switch continuously throughout the run

VACUUM/PRESSURE SYSTEM:

1. Verify that waste fluid is being evacuated out of a rinse station by level sensing in the dump site of the rinse station. Do this once per trip to the dump site.
2. Verify that vacuum pump is operational by monitoring pressure range.

DOOR LOCKS AND SENSORS:

1. Monitor status of the doors during the run. Terminate the run if the door had been opened when not allowed.

COMPUTER/PRINTED CIRCUIT BOARDS:

1. Use of DOS assures monitoring of disk drive failures.
2. Report failure of communication with motor driver boards.

POWER SUPPLIES:

1. Monitor 24 V supply on motor driver boards.

CENTRIFUGE:

1. Verify the speed of the centrifuge. Do this per run.
2. Verify the amplitude of the shake. Do this per run.
3. Verify the balance of the centrifuge to make sure the strip was picked up.

4. Verify that lift action did not lose steps during up/down motion. Do this once per pick-up cycle.
CARROUSEL:
1. Verify that the carrousel did not lose steps. Do this once per run.
2. Carrousel positions FMEA safeguards for proper bar-code read.
All of the above FMEA steps were incorporated into the design. Validation of the device included confirmation that the FMEA steps were properly functioning.

User Safety and Environmental Compatibility:
User Safety Considerations:
The device has been designed to meet the user safety requirements of the following:
1. Underwriters Laboratories Standard UL1262, third edition "Laboratory Equipment"; Canadian Standards Association CAN/CSA C22.2 No. 151-M1986 "Laboratory Equipment"
2. IEC 1010-1 (1990) "Safety requirements for electronic equipment for measurement, control and laboratory use. Part 1 General requirements"
3. The device has been type tested to the above requirements and bears the ETL Mark for safety. ETL is a Nationally Recognized Test Laboratory (NRTL) per OSHA.
4. Electromagnetic Compatibility (Interference and Susceptibility) Testing:
EC Directive 89/336/EEC
5. EN 55011 "Specification for Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment"
The device has been type tested by an independent testing laboratory per the requirements of EC Directive 89/336/EEC and VDE 0871/CISPR 11:1990 for Radiated Emissions and Line Conducted Emissions. Verification was to the limits and methods of EN 55011 and VDE 0876/0877. The device is classified as EN 55011 Group I, Class A.
FCC Subpart J
6. Meeting the above requirements also allows us to prove compliance with FCC Subpart J for Radio Frequency Emissions type testing and allow us to apply the FCC Class A label to the device and also declare conformity to the Canadian Department of Communications regulations for Emissions.
7. EN 50082-1 "Electromagnetic compatibility- Generic immunity standard Part 1. Residential, commercial and light industry"
8. The device has also been tested per the European requirements for Electrostatic Discharge Susceptibility, Radiated Susceptibility, and Fast Transient Burst Susceptibility. Verification of compliance has been conducted to the limits and methods of EN 50082-1:1992; IEC 801-2:1984; IEC 801-3:1984; and 801-4:1988.
9. The device has met all of the above requirements which allows us to apply the CE Mark to the product for European EMC acceptability.

Environmental compatibility: The device has been tested to and meets the requirements of the European EMC Directive 89/336/EEC through the following tests:
1. EN 55011 Meets VDE 0871/CISPR 11:1990 for Radiated Emissions and Line Conducted Emissions. Verification was to the limits and methods of EN 55011 and VDE 0876/0877. The device is classified as EN 55011 Group I, Class A.
2. FCC Subpart J Meeting the above requirements also allows us to prove compliance with FCC Subpart J
3. EN 50082-1 The device meets these requirements through type testing to: IEC 801-2 Electrostatic Discharge Susceptibility, 1984; IEC 801-3:1984 Radiated Susceptibility; and 801-4:1988 Fast Transient Bursts.

Potential user hazards:

The device has been designed to meet the user safety requirements of the following and bears the ETL Certification mark for:

1. Underwriters Laboratories Standard UL 1262, third edition "Laboratory Equipment";
2. Canadian Standards Association CAN/CSA C22.2 No. 151-M1986 "Laboratory Equipment"
3. IEC 1010-1 (1990) "Safety requirements for electronic equipment for measurement, control and laboratory use. Part 1 General requirements"