Complete Summary

GUIDELINE TITLE

Reproductive testing. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Gronowski AM, Grenache DG, Markenson G, Weiner R, Demers LM, St. Louis P. Reproductive testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 135-48. [73 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Reproduction-related conditions, including

- Pregnancy including ectopic pregnancy
- Ovulation
- Premature rupture of membranes
- Preterm delivery
- Infertility

GUIDELINE CATEGORY

Diagnosis
Evaluation
Prevention
Risk Assessment
Technology Assessment

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT)

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To examine the clinical utility of point-of-care reproductive testing and the effect it has on patient outcomes

TARGET POPULATION

- Pregnant women including those at risk of premature rupture of membranes and preterm delivery
- Women undergoing treatment in fertility clinics

INTERVENTIONS AND PRACTICES CONSIDERED

1. Urine luteinizing hormone (LH) point-of-care test for detecting and predicting ovulation
2. Rapid fetal fibronectin (fFN) testing for identifying women at low risk of preterm delivery

Note: The following interventions were considered and recommended against: pH/nitrazine testing alone and routine fern testing alone for the detection of premature rupture of membranes.

Refer to the original guideline document for information on other tests that were considered but not recommended (e.g., human chorionic gonadotropin hormone [hCG], nonurine ovulation test).

MAJOR OUTCOMES CONSIDERED

- Patient outcomes such as number of clinic visits, length of stay in the emergency department or hospital, conception rates, use of tocolytic medications
- Utility and accuracy of reproductive diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For a specific clinical use, pertinent clinical questions were formulated and key search terms were ascertained for the literature search. Searches were conducted on MEDLINE or PubMed and were supplemented with the use of the National Guideline Clearinghouse, the Cochrane Group, or evidence-based medicine (EBM) reviews. Additionally, authors' personal article collections were used. Acceptable citations were limited to peer-reviewed articles with abstracts, those published in English, and those involving human subjects.

To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the Rating Scheme for the Strength of the Recommendations field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 2: Transcutaneous Bilirubin Testing
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 4: Coagulation
- Chapter 5: Critical care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 7: Drugs and Ethanol
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 12: Renal Function Testing

Urine/Serum Human Chorionic Gonadotropin Hormone (hCG) Testing

Does the use of urine hCG point-of-care testing (POCT) as an aid in the diagnosis of pregnancy improve outcomes (i.e., reduce clinic visits or reduce length of stay [LOS] in the emergency department or reduce number of contraindicated drugs or therapies) compared to serum core laboratory hCG? (Literature Search 95 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 171. The guideline developers note that the use of rapid urine/serum hCG devices may have utility in settings such as the emergency department or urgent care centers, but remarkably, no studies have been published that examine outcomes such as LOS, number of clinic visits, or the number of contraindicated drugs or procedures. Therefore, there is not sufficient evidence to make any recommendation for or against the use of rapid urine/serum hCG tests. The guideline developers note that the use of home urine hCG devices may have utility and reduce adverse social behaviors, but no studies have been published that examine outcomes in this setting either. Therefore, there is not sufficient evidence to make any recommendation for or against the use of home urine hCG tests.
Strength/consensus of recommendation: I
Level of evidence: III (no studies, clinical experience)

Is the diagnostic accuracy of urine hCG POCT equivalent to serum core laboratory hCG? (Literature Search 96 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 172. Early studies have indicated much brand-by-brand variation in point-of-care (POC) laboratory hCG devices. Recent studies (after 1990) have not been conducted, making a recommendation difficult. According to the published data available, caution should be used with POC hCG devices. Since new novel technologies have significantly enhanced these earlier tests, further studies are needed to determine which devices are most accurate and consistent in performance. POC hCG devices may have utility as an aid in the diagnosis of ectopic pregnancy, although this utility has not been adequately compared to the use of in-lab testing. Therefore, there is not sufficient evidence to make any recommendation for or against the use of POC urine hCG devices for the diagnosis of ectopic pregnancy. Studies also indicate brand-by-brand variation in rapid home hCG devices. However, recent studies (after 1989) have not been conducted, making a recommendation difficult. According to the published data available, caution should be used with home hCG devices. Further studies are needed to determine which devices are most accurate.
Strength/consensus of recommendation: I
Level of evidence: II (observational and retrospective cohort studies)

How early in gestation does urine hCG POCT diagnose pregnancy accurately and how does this compare to serum core laboratory hCG? (Literature Search 97 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 173. The guideline developers note that it is unclear how early all home urine hCG devices can detect pregnancy. It is clear that there are brand-by-brand differences. Recent studies (after 1989) have not been conducted, making a recommendation difficult. According to the published data available, caution should be used in interpreting home hCG devices early after missed menses. Further studies are needed to determine which newer over-the-counter devices

are best able to detect early pregnancy.
Strength/consensus of recommendation: I
Level of evidence: III (single retrospective cohort studies)

What is the diagnostic accuracy of urine hCG POCT when performed by a layperson compared to the diagnostic accuracy of serum or urine core laboratory hCG? (Literature Search 98 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 174. No studies have been published that compare the accuracy of hCG POC devices when performed by a layperson versus the accuracy of a core laboratory. Therefore, there is not sufficient evidence to make any recommendation about laypersons and the use of home urine hCG tests.
Strength/consensus of recommendation: I
Level of evidence: III (no studies, clinical experience)

What is the diagnostic accuracy of urine hCG POCT when performed by a layperson compared to the diagnostic accuracy of urine POCT in a core laboratory? (Literature Search 99 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 175. Studies have clearly shown decreased accuracy of urine POCT devices when performed by laypersons. The guideline developers recommend that manufacturers provide clear concise instructions for use and adequate (easy to interpret) quality-control measures to maximize the proper use and interpretation of these devices. The guideline developers recommend that physicians confirm results with quantitative serum hCG.
Strength/consensus of recommendation: I
Level of evidence: III (observational cohorts and blind randomized cohort)

Urine Luteinizing Hormone (LH) Ovulation Tests

Is the diagnostic accuracy of urine LH tests sufficient for detecting ovulation using progesterone or ultrasound as a gold standard for confirming ovulation? (Literature Search 100 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 176. The guideline developers note that POC tests have excellent diagnostic sensitivity for the detection of ovulation. They can strongly recommend the use of these devices when the purpose of using them is to detect ovulation.
Strength/consensus of recommendation: A
Level of evidence: II (cohort studies)

Is the diagnostic accuracy of urine LH tests sufficient for predicting ovulation using progesterone or ultrasound as a gold standard for confirming ovulation? (Literature Search 101 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 177. The guideline developers recommend the use of urine LH tests to predict ovulation within 48 h of a positive test.

Strength/consensus of recommendation: B
Level of evidence: II (cohort studies)

Does the use of urine LH tests for predicting ovulation in women not treated in a fertility clinic improve outcomes (i.e., increase conception rates, decrease number of clinic visits, or number of unwanted pregnancies) compared to no use of prediction tests? (Literature Search 102 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 178. There is insufficient evidence to make any recommendation for or against the use of home urine LH testing to improve conception rates in women not seeking fertility treatments.
Strength/consensus of recommendation: I
Level of evidence: III

Does the use of urine LH tests for predicting ovulation in women undergoing fertility treatment improve outcomes (i.e., increase conception rates, decrease number of clinic visits, number of fertility treatment cycles) compared to no use of prediction tests? (Literature Search 103 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 179. The guideline developers can make no recommendation for or against routinely providing urine LH tests to improve outcomes. There are limited data available to adequately assess the utility of the test to improve conception rates, clinic visit frequency, or fertility treatment cycles. Although these questions are certainly of considerable interest, clear-cut answers remain elusive and additional studies need to be performed.
Strength/consensus of recommendation: I
Level of evidence: I (at least 1 randomized controlled trial)

What is the diagnostic accuracy of urine LH POCT ovulation tests when performed/interpreted by a layperson as compared to the diagnostic accuracy of urine LH in a core laboratory (performed by Clinical Laboratories Improvement Act [CLIA]-approved laboratory staff)? (Literature Search 104 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 180. There is insufficient evidence to evaluate the diagnostic accuracy of results obtained from layperson- or laboratory-performed "urine" LH testing.
Strength/consensus of recommendation: I
Level of evidence: III (descriptive studies)

What is the diagnostic accuracy of urine LH POCT ovulation tests when performed/interpreted by a layperson as compared to the diagnostic accuracy of serum LH in a core laboratory (performed by CLIA-approved laboratory staff)? (Literature Search 105 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 181. There is insufficient evidence to evaluate the diagnostic accuracy of results obtained from layperson-performed urine LH tests compared to laboratory-performed "serum" LH testing.
Strength/consensus of recommendation: I
Level of evidence: III (expert opinion)

Nonurine Ovulation Tests

Is the diagnostic accuracy of nonurine POCT ovulation tests sufficient to predict ovulation using progesterone or ultrasound as a gold standard for confirming ovulation? (Literature Search 106 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 182. The guideline developers note that there is limited useful evidence to support the use of nonurine POCT for predicting ovulation, and the available evidence is generally of poor quality. They therefore can make no recommendation for or against the use of nonurine POCT for ovulation prediction.
Strength/consensus of recommendation: I
Level of evidence: III (descriptive studies)

pH/Nitrazine Tests for Premature Rupture of Membranes

Does the pH/nitrazine test accurately predict preterm premature rupture of membranes? (Literature Search 107 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 183. The guideline developers note that the evidence is insufficient to recommend for or against providing pH/nitrazine tests for the prediction of preterm premature rupture of membranes.
Strength/consensus of recommendation: I
Level of evidence: III (descriptive studies)

Does the pH/nitrazine test accurately identify women with ruptured membranes and/or women whose membranes have not ruptured? (Literature Search 108 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 184. The guideline developers note that the pH/nitrazine test is sensitive only when used in women for whom membrane status is known. When applied to patients suspected of having premature rupture of the membranes (PROM), the test does not appear to be sufficiently sensitive or specific enough for diagnostic determination of premature rupture of membranes. Accordingly, the guideline developers do not recommend the use of pH/nitrazine testing alone for the detection of premature rupture of membranes.
Strength/consensus of recommendation: C
Level of evidence: II (case-controlled studies)

Does the pH/nitrazine test improve outcomes (number of admissions, use of antibiotics, neonatal morbidity/mortality) compared to the fern test in women suspected of having PROM? (Literature Search 109 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 185. The guideline developers note that the evidence is insufficient to recommend for or against providing pH/nitrazine tests for the prediction of preterm premature rupture of membranes.
Strength/consensus of recommendation: I
Level of evidence: III (descriptive studies)

Fern Tests for Premature Rupture of Membranes

Does the fern test accurately identify women with ruptured membranes and/or women whose membranes have not ruptured? (Literature Search 110 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 186. The guideline developers note that the fern test is neither sensitive nor specific enough for diagnostic determination of premature rupture of membranes. They recommend against routinely providing fern testing alone for the detection of ruptured membranes
Strength/consensus of recommendation: C
Level of evidence: III (case-controlled studies)

Fetal Fibronectin (fFN) Testing for Premature Delivery

Does performing a single rapid fFN assay improve outcomes (such as number of patient admissions, LOS, use of tocolytic medications, cost, neonatal morbidity/mortality, maternal morbidity because of adverse effects of intervention therapy) compared to cervical dilation, Bishop score, contraction number, or cervical length by ultrasound in women with symptoms of preterm labor, intact membranes, and cervical dilation <3 cm? (Literature Search 111 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 187. There are no studies that directly compared rapid fFN to any other method to predict preterm birth. There are several noncomparison studies, but none are available that investigated the role of rapid fFN in decreasing neonatal morbidity or mortality. There are 3 outcome studies available that investigated length of maternal stay, maternal transfers to a tertiary-care facility, and need for tocolysis. Two of the 3 studies demonstrated that rapid fFN decreases the need for tocolysis and the need for maternal transfer to a tertiary-care facility. It is important to note that these studies used historical controls for comparison. The third study, the only investigation that used a randomized study design, was not powered to detect a difference in the number of maternal transfers to a tertiary-care facility (primary outcome measure) and did not demonstrate an overall difference in length of maternal hospitalization in patients with symptoms of preterm labor (secondary outcome measure). Therefore, additional well-designed studies are needed to determine the true efficacy of fFN testing.
Strength/consensus of recommendation: I
Level of evidence: II (cohort studies)

Does performing a single rapid fFN assay improve outcomes (such as number of patient admissions, LOS, use of tocolytic medications, cost, neonatal morbidity/mortality, maternal morbidity because of adverse effects of intervention therapy) compared to fFN enzyme-linked immunosorbent assay (ELISA) in women with symptoms of preterm labor, intact membranes, and cervical dilation <3 cm? (Literature Search 112 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 188. No studies performed a direct comparison of rapid fFN (rfFN) to the ELISA fFN and reported any of the outcomes of interest. Validation of this test appears to be limited to studies that looked at the sensitivity, specificity, and

negative and positive predictive values for predicting preterm birth and then compared these results to previous published results of fFN determined by an ELISA microtiter plate. No study used the same sample that was measured using the 2 different methods. Therefore, there is insufficient evidence to compare clinical outcomes between the rfFN and the ELISA fFN.
Strength/consensus of recommendation: I
Level of evidence: III (no studies)

Do repeated rapid fFN tests decrease costs and improve clinical outcomes? At what testing interval? (Literature Search 113 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 189. There were no studies available that addressed the issue of the utility of repeated rapid fFN testing. In addition, there were no studies available to determine the appropriate interval between samplings. Therefore, there is insufficient evidence to make recommendations about repeated sampling or the appropriate interval between sampling.
Strength/consensus of recommendation: I
Level of evidence: III (no studies)

What are rapid fFN positive predictive values (PPV) and negative predictive values (NPV) for preterm delivery? Does rapid fFN reliably identify women at risk of preterm delivery and/or women at no risk of preterm delivery? (Literature Search 114 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 190. The major strength of this test is the strong NPV. Studies have clearly demonstrated the high NPV of rapid fFN, with NPVs > 95% to predict preterm birth within 7 days of testing. A negative rapid fFN result in symptomatic patients is a reliable test to place women at low risk of preterm birth within 7 days of testing. However, the PPV of rapid fFN is a poor predictor of preterm birth. Therefore, a positive rapid fFN should not be used as the primary guide for therapeutic decisions related to the imminent prevention of preterm birth.
Strength/consensus of recommendation: I
Level of evidence: II (cohort studies)

Definitions:

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.

POTENTIAL HARMS

Urine luteinizing hormone (LH) test and fetal fibronectin (fFN) test can render false-positive and false-negative results.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.

- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.
- Despite the fact that POC reproductive-related testing represents a huge portion of the over-the-counter testing market and a huge portion of the decentralized hospital testing, very little outcomes-based research has been done on these devices.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Gronowski AM, Grenache DG, Markenson G, Weiner R, Demers LM, St. Louis P. Reproductive testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 135-48. [73 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.
- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 13, 2007. The information was verified by the guideline developer on September 24, 2007.

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Readers with questions regarding guideline content are directed to contact the guideline developer.

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