# Complete Summary

## GUIDELINE TITLE

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

## BIBLIOGRAPHIC SOURCE(S)

Foran Melanson S, Petersen J, Lewandrowski KB. Occult blood. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 95-104. [75 references]

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Colorectal cancer (CRC)
- Gastric cancer
- Other causes of gastrointestinal bleeding

### GUIDELINE CATEGORY

Prevention
Screening
Technology Assessment

### CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Gastroenterology
Geriatrics
Internal Medicine
Oncology
Preventive Medicine

## 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 summarize the review of the literature on fecal occult blood and gastric occult blood and to address the use of fecal occult blood tests (FOBT) for detecting colorectal neoplasia and other gastrointestinal lesions, as well as to review data concerning the preferred methodology for FOBT in outpatient and inpatient settings

## TARGET POPULATION

- Asymptomatic individuals older than 50 years
- Patients with gastrointestinal bleeding

## INTERVENTIONS AND PRACTICES CONSIDERED

Annual or biennial guaiac-based fecal occult blood testing (FOBT) (in average risk, asymptomatic men and women beginning at age 50 to reduce mortality from colorectal cancer [CRC])

**Note**: The following interventions were considered but not recommended: FOBT in asymptomatic population to reduce the incidence of CRC, FOBT in symptomatic patients to differentiate bleeding caused by upper gastrointestinal lesions from bleeding caused by lower gastrointestinal lesions, FOBT in patients receiving anticoagulation to predict the risk of gastrointestinal bleeding, and Gastroccult testing of gastric fluid in intensive care unit patients receiving antacid prophylaxis.

### MAJOR OUTCOMES CONSIDERED

- Patient outcomes such as incidence of colorectal cancer (CRC) and mortality rate from CRC
- Sensitivity, specificity, and positive predictive value of various fecal occult blood test (FOBT) methods
- Utility of FOBT in combination with sigmoidoscopy

## 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.

The literature search performed for occult blood testing is seen in Literature Search 61 in Appendix B (see the "Availability of Companion Documents" field).

### 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

Review of Published Meta-Analyses
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

The guideline developers reviewed published cost analyses (see original guideline document for details).

### 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 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 12: Renal Function Testing
- Chapter 13: Reproductive Testing

Does annual or biennial guaiac-based fecal occult blood test (FOBT), in the average-risk asymptomatic outpatient population older than 50 years (no family history or other risk factors for colorectal cancer [CRC]), reduce mortality from colorectal cancer compared to no FOBT screening?

**Guideline 134**. The guideline developers strongly recommend that clinicians routinely provide guaiac-based FOBT for asymptomatic individuals older than 50 years at least biennially to reduce mortality from colorectal cancer. Three large randomized controlled trials have illustrated a 15% to 33% reduction in mortality from annual or biennial FOBT. FOBT is easy and inexpensive and poses no risk to the patient.
**Strength/consensus of recommendation: A**
**Level of evidence: I and II** (randomized controlled trials and case-control studies)

Does annual or biennial guaiac-based FOBT, in the asymptomatic population older than 50 years, significantly decrease the incidence of CRC?

**Guideline 135**. The guideline developers cannot currently recommend for or against the use of guaiac-based FOBT to reduce the incidence of CRC. Randomized control studies addressing this question are conflicting; however, the differences in length of follow-up make it difficult to draw direct comparisons. More studies need to be performed to resolve this question.
**Strength/consensus of recommendation: I**
**Level of evidence: I and II** (randomized controlled trials and case-control studies)

Should FOBT be performed in the central laboratory or at the point of care for asymptomatic patients who require screening for CRC?

**Guideline 136**. The guideline developers cannot recommend for or against FOBT performed in the central laboratory or at the point of care to screen for CRC in asymptomatic patients. Experts suggest that home collection of specimens with analysis either in the physician office or laboratory is recommended over traditional point-of-care testing (POCT) for occult blood by digital rectal examination (DRE). In addition, the randomized controlled trials illustrating CRC mortality reduction used the central laboratory to perform FOBT. However, no trials have compared these methodologies and addressed the benefits of POCT, which include convenience and an increase in compliance.
**Strength/consensus of recommendation: I**
**Level of evidence: III** (retrospective trial, expert opinion)

Which FOBT method, guaiac-based, heme-porphyrin assay, or immunological, is the most accurate (sensitivity, specificity, positive predictive value [PPV]) in an outpatient setting for the detection of CRC in asymptomatic individuals older than 50 years?

**Guideline 137**. The guideline developers cannot currently recommend an ideal fecal occult blood method for the detection of CRC according to the current literature and available methodology. Although guaiac-based testing is not extremely sensitive, it is reasonably specific, cheap, and easy to use and poses no risk to the patient. In addition, 3 large randomized controlled trials used guaiac-

based methods to illustrate a reduction in CRC mortality. Although guaiac-based methods are widely used in the United States, there is insufficient evidence to recommend guaiac-based methods over other types of assays.
**Strength/consensus of recommendation: I**
**Level of evidence: II and III** (prospective comparative trials, descriptive studies, and opinion)

Is FOBT useful in symptomatic patients to differentiate bleeding caused by upper gastrointestinal lesions (including gastroesophageal cancer) from bleeding caused by lower gastrointestinal lesions?

**Guideline 138**. The guideline developers cannot currently recommend FOBT to differentiate upper from lower sources of gastrointestinal bleeding. A limited number of cohort and case-control studies have demonstrated that FOBT can detect bleeding caused by upper gastrointestinal lesions, but there is no evidence to support that guaiac-based FOBT can determine the origin of bleeding.
**Strength/consensus of recommendation: I**
**Level of evidence: II** (case-control and cohort studies)

Can guaiac-based FOBT be used in patients receiving therapeutic anticoagulation to predict whether a patient is at high risk for gastrointestinal bleeding?

**Guideline 139**. The guideline developers cannot currently recommend for or against the use of guaiac-based FOBT to predict gastrointestinal bleeding in patients receiving anticoagulation. Although the current literature is sparse, it suggests that positive fecal occult blood results do not correlate with the level of anticoagulation. From these data, it can be extrapolated that FOBT would not be predictive of bleeding risk. More studies need to be done to directly address this issue.
**Strength/consensus of recommendation: I**
**Level of evidence: II and III** (prospective trials and expert opinion)

Can Gastroccult testing of gastric fluid from a nasogastric tube be used to detect gastrointestinal bleeding in high-risk intensive care unit (ICU) patients receiving antacid prophylaxis?

**Guideline 140**. The guideline developers cannot currently recommend for or against the use of Gastroccult to detect gastric bleeding in ICU patients receiving antacid prophylaxis. Only 1 study to their knowledge has indirectly addressed this issue. No randomized controlled trials have been performed.
**Strength/consensus of recommendation: I**
**Level of evidence: III** (small study and clinical evidence)

**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.

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

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### 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.
- Annual or biennial guaiac-based fecal occult blood test (FOBT) in asymptomatic individuals older than 50 years have shown a 15% to 33% reduction in mortality from colorectal cancer.

### POTENTIAL HARMS

Fecal occult blood test (FOBT) can render false-positive or 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.

## 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)

Foran Melanson S, Petersen J, Lewandrowski KB. Occult blood. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 95-104. [75 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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