Provider-performed Microscopy

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KEYWORDS

• Point-of-care testing • Provider-performed microscopy
• Fecal leukocytes • Fern test • Seminal fluid

Point-of-care testing (POCT) is defined as analytic testing performed outside the central laboratory using a device or devices that can be easily transported to the vicinity of the patient.[1] Chemical analysis at the patient bedside or in ward side rooms was described in London, England, in 1883.[2,3] This definition emphasizes the semiquantitative or quantitative nature of the data obtained. This emphasis is consistent with physiologic parameters, such as temperature, respiratory rate, or blood pressure, that are determined by health care professionals at the bedside or by using computer-interfaced devices. Errors in the examination of hypertensive patients made when using the indirect method of blood pressure measurement (cuff and sphygmomanometer) can be attributable to technique, equipment used, and random variability.[4–6] Training testers to follow published guidelines improved performance.[4] These findings emphasize the need for teamwork[7,8] and knowledge of published guidelines[7–12] to improve the quality of testing at the bedside. Some procedures at the bedside, however, require the evaluation of color, odor, consistency, or a semiqualitative reagent strip reaction.[13,14] For example, the location of a nasogastric tube may be evaluated by observing the color and pH of the aspirated contents.[14] Not all bedside testing results in a numerical endpoint.

Rules and regulations related to POCT are undergoing evolution, and changes should be anticipated. In general, federal law, as described by the Health Care Financing Administration in the Clinical Laboratory Improvement Amendments of 1998 (CLIA), provides the framework for most POCT standards and guidelines.[7,10] These federal regulations, using well-defined criteria, classify laboratory procedures based on their test complexity: waived, moderately complex, highly complex, and provider-performed microscopy (PPM). Certificates are issued by the Health Care Financing Administration depending on the complexity of the tests performed at the testing site (**Table 1**). **Table 2** reviews the types of laboratories enrolled in the CLIA program.

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Table 1
CLIA number categories

Categories	Certificates (Biannual Fees)
1	Certificate of moderate complexity, volume-dependent ($150–$7,940)
2	CLIA waiver certificate for tests, granted status under HCFA ($150, waived)
3	CLIA certificate for provider-performed microscopy procedures ($200)

Health Care Financing Administration data from July 1999.
Abbreviation: HCFA, Health Care Financing Administration.

Bright-field or phase-contrast microscopy of labile specimens has traditionally been performed by the patient's physician at or near the point of care. Because specimen lability could compromise test accuracy, a unique regulatory approach for this testing was defined in the *Federal Register* of April 25, 1995, and revised on October 1, 1998. The following summary covers the criteria for PPM procedures:

1. The examination must be personally performed by a practitioner.
2. The procedure must be categorized as moderately complex.
3. The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.
4. The specimen is labile or delay in performing the test could compromise the accuracy of the test result.
5. Control materials are not available to monitor the entire testing process.
6. Limited specimen handling or processing is required.

PPM procedures are performed using specimens that include body fluids and skin scrapings. The following list includes the procedures in this category[15] as of July, 1998:

1. Wet mounts, including preparation of vaginal, cervical, or skin specimens (Q0111)
2. All potassium hydroxide preparations (Q0112)
3. Pinworm examinations (Q0113)
4. Fern test (Q0114)
5. Postcoital direct, qualitative examinations of vaginal or cervical mucus (Q0015)
6. Urine sediment examinations (CPT-4 81015; for urinalysis with microscopy, use 81000, or for urinalysis performed using an automated dipstick urinalysis instrument, approved as waived, use 81001.)

Table 2
CLIA registration

Laboratory Characteristics	No. of Laboratories	No. of Laboratories in Physician Offices
Total laboratories in nonexempt states	162,044	93,872
Total laboratories in CLIA-exempt states (New York, Oregon, Washington)	7,514	—
Application type		
Compliance (HCFA surveys)	26,045 (16%)	17,703 (19%)
Waiver	84,217 (53%)	39,633 (42%)
PPM	34,782 (21%)	29,501 (31%)
Accreditation	17,000 (10%)	7,030 (8%)

Health Care Financing Administration data from July 1999.
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