
*Unaccredited
Point-of-Care Laboratory
Testing Guideline for
Physicians*

Prepared by the Advisory Committee on Laboratory Medicine
College of Physicians & Surgeons of Alberta



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Introduction:

This guideline was prepared for non-laboratory physicians who employ or rely on point-of-care laboratory testing (POCT) for their patients. This includes the use of POCT by physicians in clinical practice, in occupational medicine and in medico-legal examinations.

POCT is laboratory testing performed at or near the site of the patient by personnel who may not be laboratory technologists and which may or may not be under the auspices of an accredited diagnostic laboratory. Much POCT involves the use of test-kits with or without hand-held devices to read samples of whole blood, saliva or urine.

The College accredits and endorses the use of POCT when it is supervised by an accredited laboratory. When physicians use unaccredited POCT, they must understand its limitations.

The small number of tests traditionally performed by physicians in their offices for their own patients are not generally of concern. Therefore, the College is NOT concerned about the accreditation status of the following:

- Urinalysis (Basic routine examination, including simple chemistry and examination of centrifuged sediment).
- Microscopic examination of smears, hair and nails for bacteria, ectoparasites, fungi or worms.
- Wet mount and/or hanging drop for *Trichomonas*.
- Pregnancy tests using standard kits.

However, newer POCT testing from which more critical decisions are made should be subject to quality standards and should be accredited. These include, but are not limited to:

- Hemoglobin measurement
- Drug testing
- Coagulation testing (e.g. D-Dimer and INR)
- Cardiac marker identification/quantitation

Training and experience are often required to achieve accurate and reliable results from POCT. That expertise starts at the choice of appropriate test procedure/kit and extends through sample collection, management of equipment and supplies, performance of the test, and interpretation of the results in each patient's context. Although the use of unaccredited POCT for screening purposes may seem to lessen the risk for patients, errors will still adversely affect detection of disease or management of those patients.

A physician must never use unaccredited POCT on anyone who is not his or her own patient.

Laboratory testing offered to others than one's own patient constitutes the operation of a diagnostic laboratory, which invokes College requirements for the accreditation of a diagnostic laboratory.

Steps and Guidelines:

1. Before selecting the tests and instrumentation for each POCT, ask:

- What is the purpose of the test?
- What is the accuracy, precision and reliability of the test?
- What are the quality control procedures?
- How simple is the device to use?
- Who will be performing the test?
- How much training is required and how will they be trained?
- How will results be recorded / reported?

2. Procedures should be written which address the following:

- principle of operation;
- purpose of the test;
- specimen collection, identification and handling;
- preparation of reagents and other materials;
- quality control procedures;
- stepwise instructions;
- reporting and documentation of results;
- special alerts to out-of-control and "critical result" values;
- limitations of the procedure;
- remedial action when out-of-control;
- reference interval ("normal values");
- reagent, test unit(s), and material storage;
- action if test system is inoperable; and
- criteria for referral of specimens to an accredited laboratory.

3. Training of personnel should be documented

4. Safety issues to be considered include:

- personal protective equipment (e.g. gloves, gowns/coats)
- Hepatitis B vaccination for workers
- evaluation and follow-up of workers after accidental exposure to blood and body fluids
- a safety training program for employees who routinely work with blood or other infectious materials
- special waste disposal considerations
- cleaning requirements for contaminated surfaces and supplies

- 5. Specimen Collection is as important as the analysis because if done improperly, it could invalidate the remainder of the process. Issues to consider include:**
- Collection of the appropriate specimen must be in accordance with the manufacturer's instructions
 - Volume, handling, and storage of samples must conform to requirements specified by the manufacturer of the test reagent and instrument.
 - Patient/Client Preparation considerations/requirements (e.g. fasting, lack of interfering drugs) should be documented.
 - A protocol should be developed to ensure that each specimen is associated with a patient/client name and patient/client identification number (ID#).
- 6. Quality Control procedures should be designed for use by the least trained of the potential users of the device.**
- Control materials should be used to monitor the integrity of the test system by comparing the analyzer's results with an expected value.
 - Quality control and/or calibration must be performed as specified by the manufacturer.
- 7. Result Reporting/Record Keeping**
- For reporting patient results, the following questions should be considered:
 - Are control results acceptable? (If not, then patient results must not be reported.)
 - Have the procedures for specimen preparation, reagent preparation, and instrument maintenance outlined in the written procedure and operators manual been followed?
 - The physician who requests a test has the responsibility to ensure there is follow up on the results.
 - POCT results must be recorded in a permanent record (which may be the patient's chart), and a mechanism established to ensure this is done. This record should clearly state that this is a POCT result.
 - The length of time that records are retained must be in compliance with CPSA guidelines
- 8. Evaluation of Proficiency**
- An external program for evaluating the accuracy of the POC testing system (equipment, reagents, and operators) is highly recommended. External proficiency testing survey programs provide "blinded" specimens containing the analyte(s) being tested. Participants receive performance evaluation against the user's peers for a given test analyte for a given test method/system. Users should refer to the CPSA proficiency testing guidelines for further information regarding proficiency testing.

9. Interpretation of Results

Pre-analytical, biological, and analytical errors and variations should be taken into account for correct interpretation of a test result.

Examples of pre-analytical errors include:

- incorrect collection site preparation (e.g., wrong disinfecting reagent);
- incorrect specimen handling and preparation;
- incorrect specimen and wrong patient/client identification;
- incorrect specimen collection procedure;
- inappropriate specimen collected (e.g., venous vs. capillary); and
- inappropriate pretest requirements (e.g., fasting requirements).

Examples of biological variation include:

- gender
- age
- patient/client diet (fasting/non-fasting)
- interference by medication.

Examples of analytical errors and variations include:

- instrument variation/device errors;
- specimens inappropriately sampled;
- inappropriate reference interval for specific test method; and
- operator errors.

References:

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4. *Physician's Office Laboratory Guidelines – Third Edition*; (Vol. 15, No. 5); POL1-T3; CLSI; 1995
5. *Physician's Office Laboratory Procedure Manual*; (Vol. 15, No. 6); POL2-T3; CLSI; 1995