

### NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES ACCREDITATION PROGRAM

# **Accreditation Standards**

Point-of-Care Testing



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#### INTRODUCTION

Point-of-care testing (POCT) is laboratory testing which is performed at the patient bedside or near the site of patient care. POCT typically uses portable, hand-held instruments and kits. The POCT use small bench analyzers. This standard applies to the following point-of-care testing (POCT) only: hemoglobin, blood glucose, urinalysis, pregnancy testing (urine), semen examination for the presence of sperm and occult blood (stool). Portable point of care laboratory testing systems used for blood chemistry (electrolytes) analysis, coagulation testing, blood gas testing and hormone level testing requires review and accreditation with the Diagnostic Accreditation Program (DAP).

#### POC1.0 POINT-OF-CARE TESTING

POC1.1	PO	CT training and competency assessment is provided.
POC1.1.1	М	POCT is performed by personnel who have completed training and demonstrated competence. Guidance: Staff performing POCT is trained for each POCT device. The training and competency assessments are performed by qualified personnel (e.g. clinician, vendor). Training and annual competency assessments are documented. Retraining and continuing education is documented.
POC1.1.2	м	POCT devices are coded/calibrated prior to use. Guidance: Depending on the POCT device, manual coding/calibration (an adjustment made to the POCT device to match the lot number of the testing strips) of the POCT device may be needed. For POCT devices that require manual coding/calibration, either a code chip is inserted into the POCT device each time a new box of test strips is used or a button located on the POCT device is used to change the code to match the code of the test strips. If POCT devices are not manually coded/calibrated, the user manual must confirm that the POCT device performs automatic coding/calibration.
POC1.1.3	Μ	POCT device user manual is available to staff performing POCT testing.
POC1.2	Qua	ality control measures are in place for POCT.
POC1.2.1	м	Facilities performing blood chemistry (electrolytes) analysis, coagulation testing and hormone level testing are accredited by the Diagnostic Accreditation Program (DAP).

POC1.2.2	Μ	Quality control testing of the POCT device is performed in accordance with manufacturer's instructions for use. Guidance: Quality control testing refers to using a control solution (testing reagent) to determine if the POCT device is giving an accurate reading (result). Testing is performed in accordance with the POCT device manufacturer's instructions for use (frequency, testing procedures) and the results are documented in a log.
POC1.2.3	Μ	Quality control testing is documented. Guidance: The quality control testing (QC testing) log documentation includes: date of testing, test result, lot number of the test strip, lot number (if available) and expiration date of the testing reagent and signature of the staff member that completed the QC testing. The QC testing is performed by regulated health professionals who have completed training and demonstrated competence.
POC1.2.4	Μ	Quality control testing reagents are labeled with date of preparation or reconstitution, content, expiry date and storage requirements. Guidance: Many reagents used for POCT quality control testing are temperature sensitive and therefore require refrigeration. Testing reagents that are not stored in accordance with manufacturer's instructions for use and/or label may result in inaccurate readings (results).
POC1.2.5	М	Quality control testing reagents are stored in accordance with manufacturer's instructions for use. Guidance: Testing reagents that are not stored in accordance with manufacturer's instructions for use and/or label may result in inaccurate readings (results).
POC1.2.6	М	Quality control testing reagents are within their labeled expiry date. Guidance: Testing reagents used past their labeled expiry date may result in inaccurate readings (results).
POC1.2.7	Μ	POCT device strips are within their labeled expiry date. Guidance: Testing strips used past their labeled expiry date may result in inaccurate readings (results).
POC1.2.8	Μ	There are procedures for the follow-up of quality control testing results that fall outside of the expected range. Guidance: These procedures should be outlined in the facility's policy and procedures for POCT testing and may include trouble- shooting (confirming code/calibration, expiry dates, storage conditions), repeating the QC testing and removing the POCT device from service.
POC1.3	Infe	ection control measures ensure the safe use of POCT.
POC1.3.1	М	Only single-use auto-disabling finger stick devices are used. <i>Guidance: Finger stick devices are used to puncture the skin to obtain small blood specimens for testing blood glucose, hemoglobin</i> <i>and other blood components. Single-use auto-disabling finger stick devices, also knowns as "safety lancets," are devices designed to</i> <i>be used only once, after which the blade retracts, is capped or is otherwise made unusable. Reusable finger stick devices are not to be</i> <i>used. Reusable finger stick devices resemble a pen and lancet (endcap). The lancet is removed and replaced after each patient use.</i> <i>These devices are not permitted because of their link to blood-borne virus transmission and because they cannot be adequately</i> <i>cleaned. The Centers for Disease Control and Prevention website provides useful images and descriptions of appropriate single-use</i> <i>finger stick devices and reusable finger stick devices (<u>https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html</u>).</i>

POC1.3.2	Μ	POCT devices are cleaned and low-level disinfected after every use. Guidance: POCT devices, such as a glucometer, are to be cleaned and low-level disinfected (e.g. wiped down with a low-level disinfectant (LLD) wipe) after every use in accordance with manufacturer's instructions for use. The low-level disinfectant manufacturer's label must confirm that the product is a low-level disinfectant. If the POCT device manufacturer does not specify how to clean and low-level disinfect the device then it should not be used.		
POC1.4	Pat	Patient POCT results are documented and communicated.		
POC1.4.1	Μ	POCT testing that is in-progress is linked to the patient at all times. Guidance: The facility must have a process to ensure that POCT testing that is in-progress (e.g. during the time that the meter takes to display a result), is linked to the patient at all times. For example: the glucometer remains in the possession of the staff member performing the test until the result is read and documented in the patient's medical record; the pregnancy test (urine) device is labelled with the patient's identifiers.		
POC1.4.2	Μ	Reference intervals for POCT results are available to staff performing POCT testing. Guidance: Reference intervals include LifeLabs reference ranges ( <u>http://www.lifelabs.com/healthcare-providers/Pages/Reference-</u> <u>Ranges.aspx</u> ), Canadian Diabetes Association (CDA) suggested blood glucose ranges available as a general guide to refer to and identify any readings (results) that fall outside of the expected range ( <u>https://www.healthlinkbc.ca/health-topics/aa135726</u> ).		
POC1.4.3	Μ	There are procedures for the follow-up of patient POCT testing results that fall outside of the expected range. Guidance: These procedures should be outlined in the facility's policy and procedures for POCT testing of patients and may include trouble-shooting the POCT device (confirming code/calibration, expiry dates of test strips), collecting another patient sample and repeating the POCT testing and alerting the most responsible physician of the abnormal result.		
POC1.4.4	М	POCT testing result(s) documentation is complete. Guidance: POCT testing results are documented in the patient's medical record and include: date and time of the testing, the test result(s), the name of the person performing the testing (if the person making the entry in the patient's medical record is not the person that performed the POCT testing), the ordering physician (as appropriate) and any action taken to notify the most responsible physician of the result(s). If the POCT device provides a printout, the POCT testing results are to be transcribed (written) into the patient's medical record; affixing the POCT printout into the medical record is not sufficient as they fade with time and therefore do not provide a permanent record.		
POC1.5	<b>Pol</b> Inte hos	<b>Policies and procedures contain all the information necessary for the safety of patients, staff and visitors.</b> Intent: Policies and procedures ensure that activities/procedures are performed consistently and accurately by all personnel within the non-hospital facility.		
POC1.5.1	М	There is policy and procedures for point-of-care testing. Guidance: Point-of-care testing policy and procedures outline the appropriate use and frequency of POCT, who may perform POCT, education and training to perform POCT, annual competency testing of personnel authorized to perform POCT, calibration and quality control testing and recording, handing and reporting of POCT results.		



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