

Standard of Practice:

Point of Care Testing

Introduction

The intent of this standard is to advise Members of the requirements to perform Point of Care testing safely, ethically and competently. This standard does not apply to collecting samples for the purpose of sending them to an outside laboratory.

Definitions

Point of Care Test (POCT): an in-office test conducted by a member on clinical samples such as blood, saliva or urine.

Critical Value: an abnormal test result that is significantly out of the normal range and which needs to be communicated to the patient urgently.

Clinically Significant Test Result: a result determined by the Member based on his or her clinical judgment to be one which requires follow-up with appropriate urgency.

POCT Equipment, Instruments and Supplies: equipment, devices, instruments and supplies required to perform a Point of Care test. This includes disposable and non-disposable materials.

POCT Reagents: a chemical product necessary for the reactions required to obtain a POCT result. These may include enzymes, antibodies, primers, dyes, and culture media.

Standard Operating Procedure (SOP): the processes or techniques required to conduct a Point of Care test safely, ethically and competently. This may include the manufacturer's directions for use.

1. Competency

The Member has the knowledge, skill and judgment to perform the authorized act to be delegated safely, ethically, and competently prior to delegating the act.

Performance Indicators

The Member has the knowledge, skill and judgment to perform Point of Care tests safely, ethically and competently, to be able to interpret results and to identify when further testing or referrals may be necessary.

2. Standard Operating Procedure

The Member creates a Standard Operating Procedure for the performance of all Point of Care tests.

Performance Indicators

Prior to performing a Point of Care test, the member will create, and adhere to, a Standard Operating Procedure (SOP) that contains:

- · roles and responsibilities of all health care professionals delivering Point of Care testing;
- purpose and limitations of the test;
- step-by-step instructions on how to properly complete the test and use the corresponding instruments;
- · reference ranges for results;
- · critical values;
- · date of implementation or revision;
- procedure for setting up, validating, calibrating and maintaining all POCT equipment, instruments and supplies; and
- name of individual responsible for reviewing and approving the SOP.

3. Performing Point of Care Testing

The Member ensures that Point of Care tests are performed in a safe, effective and ethical manner.

Performance Indicators

When performing point of care tests on blood samples, the Member:

- performs only the Point of Care tests authorized in the General Regulation;
- performs only the Point of Care Tests authorized in the Laboratory Specimen Collection Centre Licensing
 Act or the regulation made thereunder.

The Member performs Point of Care Testing for the purpose of:

- Assessing the patient's health status;
- Communicating a naturopathic diagnosis; or
- Monitoring or evaluating the patient's response to treatment.

Equipment, Instruments and Supplies

In addition to meeting the Standard of Practice for Performing Authorized Acts, the Member:

- uses a Class III medical device approved by Health Canada for testing on blood samples, where available;
- uses only testing equipment that has been approved for use in Canada, in accordance with the purpose intended by the manufacturer of the device and in accordance with the manufacturer's instructions;
- verifies that the POCT equipment is calibrated and is in proper working order immediately prior to performing a Point of Care test, as required by the manufacturer;
- ensures that there is sufficient space for the POCT in accordance with the manufacturer's recommendations;
- maintains an accurate and up to date inventory of all POCT equipment, instruments and supplies;
- follows a Standard Operating Procedure for setting up, validating, calibrating and maintaining all POCT equipment, instruments and supplies;
- follows a Standard Operating Procedure to properly store, handle, clean, disinfect and maintain POCT equipment, instruments and supplies;
- verifies that the POCT equipment currently being used is working properly;
- · does not reuse POCT single use devices;
- verifies that POCT supplies and reagents are not expired or deteriorated and are appropriate for use;
- promptly and properly disposes of inappropriate, expired, deteriorated and substandard POCT supplies and

reagents;

- stores POCT supplies and reagents under proper environmental conditions;
- has a protocol for addressing POCT adverse events and recalls of equipment, instruments or supplies.

Testing

In addition to meeting the Standard of Practice for Performing Authorized Acts, the Member:

- obtains informed consent from the patient prior to performing the test;
- ensures proper infection control measures are in place in order to minimize the risks to patients, self and others associated with Point of Care testing;
- adheres to instrument specific quality controls and testing procedures;
- ensures that testing is completed and analyzed within the proper time frame;
- provides the patient with appropriate preparatory instructions with regard to sample collection requirements (e.g. fasting, how to perform a clean-urine catch, etc.);
- wears appropriate personal protective equipment (which may include gloves, gowns, eye protection);
- appropriately disposes of used test supplies and patient samples.

Results

The Member is responsible for ensuring appropriate and timely communication of test results to patients.

In addition to meeting the Standard of Practice for Performing Authorized Acts, the Member, when reporting POCT results to the patient:

- verifies that the results comply with set acceptability criteria;
- interprets the results and explains them to the patient;
- makes a copy of the results available to the patient and/or designated health care professional within a reasonable time following testing, if requested;
- ensures appropriate follow-up on test results they receive;
- uses their clinical judgment to determine if it is necessary to contact other health professionals who are involved in the patient's circle of care; and
- refers as appropriate when a critical value or clinically significant result is received.

4. Record Keeping

The Member maintains records specific to Point of Care testing.

Performance Indicators

In addition to the College's Standard of Practice for Record Keeping, the Member will document in the patient chart:

- the date of the test:
- the time of the test, where applicable;
- the name and title of the individual carrying out the test; and
- the test results and interpretation.

Related Standards & Guidelines

Collecting Clinical Samples Communicating a Diagnosis Consent Infection Control Performing Authorized Acts Record Keeping

Legislative Framework

General Regulation

Naturopathy Act, 2007

Professional Misconduct Regulation

Regulated Health Professions Act, 1991

Guideline C-4:The Management of Biomedical Waste in Ontario

The ISO 15189:2007 essentials – A practical handbook for implementing the ISO 15189:2007 Standard for medical laboratories

National Standard of Canada CSA-Z22870-07: Point-of-care testing (POCT) Requirements for quality and competency

Accreditation Canada: Point-of-Care Testing Standards

Ministry of Health and Long-Term Care Point-of-Care Testing Policy and Guideline for Hospitals with a Licensed Laboratory

Disclaimer

In the event of any inconsistency between this standard and any legislation that governs the practice of Naturopathic Doctors, the legislation shall govern.