Point of Care Testing

Intent

To advise Registrants of the requirements to perform point of care testing safely, ethically and competently. This standard does not apply to collecting specimens for the purpose of sending them to an outside laboratory.

Definitions

Point of Care Test (POCT): An in-office test conducted by a Registrant on clinical specimens such as blood, saliva, or urine as authorized in section 26 of the LSCCLA (Appendix A).

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 Registrant based on their 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.

STANDARD 1

The Registrant who performs point of care testing within the context of their naturopathic practice has acquired and maintains the knowledge, skill and judgment necessary to perform the procedure safely, ethically, and competently.

A Registrant demonstrates the standard by:

- maintaining competency for performing the procedure by engaging in continuing education and/or incorporating the performance of POCT as a regular part of their practice, and
- maintaining the knowledge, skill and judgment to be able to interpret results and to identify when further testing or referrals may be necessary.

STANDARD 2

The Registrant creates standard operating procedures for the performance of all POCTs.

Prior to performing a POCT, a Registrant demonstrates the standard by:

- creating and adhering to a standard operating procedure (SOP) that contains:
    - the roles and responsibilities of all health care professionals delivering point of care testing,
    - the 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
    - the name of the individual(s) responsible for reviewing and approving the SOP.

STANDARD 3

The Registrant ensures that POCTs are performed in a safe, effective, and ethical manner.

A Registrant demonstrates the standard by:

- ensuring that when performing point of care tests on blood, urine, throat or vaginal swabs, the Registrant:
    - performs only the point of care tests authorized in the *General Regulation*,
    - performs only the point of care tests authorized in the *Laboratory and Specimen Collection Centre Licensing Act, 1990* or the regulation made thereunder.
- performing 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.
- ensuring that in addition to meeting the *Standard of Practice for Performing Authorized Acts*, the Registrant:
    - performs a POCT within the context of the naturopathic doctor-patient relationship,
    - uses a device approved for sale by Health Canada for testing on blood specimens, 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, equipment and supplies,
    - verifies that POCT supplies and reagents are not expired, contaminated or deteriorated and are appropriate for use,
    - promptly and properly disposes of inappropriate, expired, deteriorated, contaminated, and substandard POCT supplies and reagents,
    - stores POCT supplies and reagents under proper environmental conditions, as per manufacturers requirements where applicable,
    - has a protocol for addressing POCT adverse reactions, and recalls of equipment, instruments or supplies,
    - 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 specimen 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), and
    - appropriately disposes of used test supplies and patient specimens.

- when reporting POCT results to the patient:
    - ensures appropriate and timely communication of test results to patients,
    - 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.

STANDARD 4

The Registrant maintains records specific to point of care testing.

A Registrant demonstrates the standard by:

- ensuring that in addition to the College's *Standard of Practice for Record Keeping*, the Registrant 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.

APPENDIX A – POINT OF CARE TESTING

Point of Care Testing - Blood

Under the regulations made under the *Laboratory and Specimen Collection Centre Licensing Act 1990* (LSCCLA), Registrants are permitted to take blood from **their own patient in their own office** for the purposes of performing only the following seven tests **in their own office** on that blood:

1. Blood Group—ABO and RhD.
2. BTA Bioterrain Assessment.
3. Fatty acids, free.
4. Glucose.
5. Hemoglobin—A1C.
6. Live blood cell analysis.
7. Mononuclear Heterophile Antibodies (monospot).

(Reference: R.R.O. 1990, Regulation 683 (Specimen Collection Centres), section 8, paragraph 1)

Point of Care Testing – Non-blood Specimens

Under the regulations made under the LSCCLA, Registrants are permitted to take non-blood specimens from **their own patient in their own office** for the purposes of performing **only** the following ten tests **in their office** on that specimen:

Test	Specimen
Ascorbic acid (ascorbate) Vitamin C	Urine
BTA Bioterrain Assessment	Urine
Human Chorionic Gonadotropin – pregnancy test	Urine
Indican	Urine
Koenisberg	Urine
Oxidative testing	Urine
Rapid Strep Test	Throat swab/culture
Routine urinalysis by dipstick	Urine
Sulkowitch	Urine
Vaginal pH	Vaginal swab/culture

(Reference: R.R.O. 1990, Regulation 683 (Specimen Collection Centres), section 8, paragraph 2)