POLICY ON PROVINCIAL LABORATORY FORMULARY

1.0 Introduction and Background

The provincial medical laboratory test formulary was established by direction of Government through Executive Council (2013) and as part of recommendations to reform clinical laboratory services across the province. As part of this recommendation, the provincial medical laboratory formulary would establish:

1. Which lab tests are available and where;
2. The clinical circumstances under which the tests can be ordered;
3. The type of health professional who can order the test; and
4. The standardization of testing methods, including the circumstances under which tissues must be examined by a pathologist.

The Provincial Laboratory Formulary (PLF) framework adopts these functions. Information related to the first three specifications are held within the formulary test database. Tests listed in the PLF are categorized according to a tier system. The tier system defines who can order a test and under what conditions. With each test entry at tier 2 and greater, special procedures or special conditions apply which restrict access to the test. The tier system identifies three groups of tests:

- **Tier 1**: indicates tests that have no special restrictions based on medical specialty and requiring no special approval process.
- **Tier 2**: indicates tests that are restricted to subspecialties or special conditions.
- **Tier 3**: indicates tests where one time authorization is granted by designated laboratory specialist.

Development of this framework was done by a multidisciplinary team called the Advisory Group for Laboratory Formulary Development. This group consisted of experts and representative stakeholders to laboratory testing, and was comprised of clinicians, laboratory physicians and scientists, health information specialists, and Information Technology (IT) support. The main products of this work is the PLF website and the PLF database which is open for public access through the website. This work was completed in fall of 2019.

Moving forward, specific laboratory test utilization policy will be developed collaboratively with other organizations having interests in appropriate laboratory test utilization; which includes but is not limited to, Quality of Care and Choosing Wisely NL, Appropriateness of Care Initiative, Memorial University, and RHA initiated activities. On review and approval, these policies comprise the rule base on which the PLF operates.

This policy describes the governance structure and requirements for operation of the PLF.

2.0 Definitions

2.1 Department of Health and Community Services (HCS)

2.2 Listed tests – are tests that listed in the PLF database.

2.3 Minimum reorder interval policy– a laboratory test specific policy that defines the minimum amount of time that must occur between two separate orders of the same test. Test orders that violate the minimum reorder interval are usually cancelled as repeat or redundant orders, unless special conditions are met.

2.4 PLFAC communications working group – in is a working group tasked with preparation, review, and dissemination of PLF information to stakeholders.

2.5 Provincial Laboratory Formulary (PLF) - is an up to date catalogue of laboratory tests (with related information) that can be ordered by clinicians and performed at local accredited clinical laboratories, or referred out for testing through accredited reference laboratories.

2.6 Provincial Laboratory Formulary Advisory Council (PLFAC) – is a multidisciplinary team whose main role is to advise HCS on matters related to management and updating of the PLF.

2.7 Regional Health Authority (RHA).

2.8 Unlisted tests – are tests that are not listed in the PLM database.

3.0 Main Policy Statements

3.1 Department of Health and Community Services (HCS) has established the Provincial Laboratory Formulary (PLF) to operate with oversight by the office of the Director of Clinical Laboratory Services and managed through

the Provincial Laboratory Formulary Advisory Council (PLFAC) and its working groups (*Provincial Laboratory Formulary Organizational Chart*).

3.2 The PLF is established to:

3.2.1 Determine which laboratory tests are available for ordering by clinicians within the province of Newfoundland and Labrador.

3.2.2 Identify and make available tests that support current standards of practice, are supported by evidence, and important to optimizing patient health outcomes.

3.2.3 Minimize laboratory testing costs required to obtain greatest clinical usefulness.

3.2.4 Direct physicians toward ordering the most effective tests for their patients.

3.2.5 Enhance responsibility and accountability to all involved in the laboratory testing process.

3.2.6 Phase out and remove laboratory tests that are redundant and outdated, or are no longer considered useful, based on current standards of practice and evidence.

3.3 All information related to PLF policy, procedures, and Pathology and Laboratory Medicine testing requirements shall be made public through the PLF website. The PLF website is hosted within the HCS website.

3.4 The PLF website is the main forum for communication of PLF policy concerning availability of laboratory tests. The PLF website hosts the PLF test database which describes ordering privileges and conditions; and provides links to all approved test requisition forms, procedures and other

policies related to laboratory tests ordering and availability within the province.

3.5 PLFAC is a multidisciplinary team appointed by HCS to update and maintain the PLF.

3.6 PLF website, procedures, and policies shall be reviewed annually and organized through the PLFAC.

3.7 Applications for new Pathology and Laboratory Medicine diagnostic tests must be directed to PLFAC for review and approval.

3.8 New test additions or removal of unnecessary test procedures, or changes to test availability shall be completed following approval of applications through PLFAC.

3.9 All modifications to the PLF including updates to the website shall be communicated to stakeholders and clinicians through the office of the Director of Clinical Laboratory Services.

3.10 All written policies and procedures related to Pathology and Laboratory Medicine tests and services within Regional Health Authorities (RHAs) must align with PLF procedures and policy.

3.11 Only tests listed in the PLF database or organized through described authorization processes shall be made available and funded by Pathology and Laboratory Medicine Programs.

3.12 Onsite tests performed in centralized clinical laboratories must comply and be listed in the PLF.

4.0 Policy Scope

4.1 PLF policy applies to all publically funded testing performed under the auspices of RHAs and Pathology and Laboratory Medicine Programs. This includes all testing done within central laboratories, at blood collection centres, and at the point of care.

4.2 All laboratory test ordering practices must comply with PLF policy.

4.3 PLF policy does not apply to diagnostic testing paid for by private individuals and organizations, including that done for research or evaluation purposes.

5.0 Provincial Laboratory Formulary Governance and Procedure Related Policies

5.1 Provincial Laboratory Formulary Advisory Council

5.1.1 The activities related to the maintenance of a PLF shall be led by PLFAC.

5.1.2 The PLFAC is a multidisciplinary group comprised of stakeholders including: medical laboratory physicians and scientists, Vice-Presidents from four RHAs, physician members from all RHAs, Newfoundland and Labrador Centre for Health Information, and other health care stakeholders with interests in appropriate laboratory test usage.

5.1.3 Laboratory personnel from each RHA shall assist with implementation of the PLF policy, through communication from the Provincial Director of Clinical Laboratory Services. These laboratory personnel include: Directors of Laboratory Medicine, Laboratory Managers/ supervisors/ designates/scientist/physicians and technologists.

5.1.4 All new entries of funded laboratory tests to the PLF must occur through completing an application process, which shall be reviewed and approved by PLFAC.

5.2 Ordering of tests with tier-based ordering restrictions

5.2.1 Tests with tier-based restrictions must be ordered based on indicated restrictions and according to guidance given by test in the PLF database.

5.3 Ordering of tests with reorder interval-based restrictions

5.3.1 All exceptions to re-order interval-based restrictions are based on minimum reorder interval policy and typically involves placing "OVERRIDE" next to the test request or by completing a *Laboratory Test Special Authorization (LTSA) form*.

5.3.2 Minimum reorder interval policy shall be communicated through the PLF website and by test in the PLF database.

5.4 Ordering of tests that are referred out-of-province

5.4.1 The approval process for test requests for both listed and unlisted tests, that are referred out-of-province depends, on the tier status for the test and specific ordering privileges of the ordering clinician.

5.4.2 All unlisted tests shall be addressed as tier 3 tests and require one-time authorization by a designated laboratory medicine specialist.

5.4.3 When there is need for a test that is listed as tier 3, a *Laboratory Test Special Authorization (LTSA) form* must be prepared by the ordering professional. Approval of this form confirms that appropriate consultation with a laboratory medicine specialist has occurred prior to sample collection, or that necessary information is available to permit timely decisions on sample send-out.

5.4.4 Procedures for ordering referred out-of-province tests are described in the "*Procedure for referred-out tests*".

5.4.5 Criteria that shall be considered during review of an out-of-province laboratory test request shall include but shall not necessarily be limited to:

5.4.5.1 How the test will influence clinical management, treatment plan, and patient care.

5.4.5.2 Whether it is the most appropriate test for accurate diagnosis/management, or if any other tests are available and more appropriate.

5.4.5.3 If equally useful tests are readily available at lower cost.

5.4.5.4 Whether a repeat request meets the minimal retest interval.

5.4.5.5 Whether the testing lab is on the current list of acceptable referral labs (i.e. meets the RHA quality and accreditation requirements).

5.4.5.6 Consultation with other laboratory medicine specialists within or outside the organization as necessary to determine test utility.

5.4.6 If a sample is received by a laboratory for out-of-province testing listed as tier 2 or tier 3 but without a fully completed *LTSA form*, it will not be approved for referral. In such cases, the ordering professional will be requested to complete a *LTSA form* prior to the sample being sent out-of-province for testing. Where sample stability allows, non-approved samples shall be held for a maximum of two months, or until the sample storage stability limit has been reached, whichever is lower, pending submission of further information then discarded.

5.5 Urgent approval of non-formulary Tier 4 or unlisted tests

5.5.1 Approval of urgent test requests for non-formulary Tier 4 or unlisted tests shall be made on an *ad hoc* basis and involving Laboratory Medicine Physicians and Scientists.

5.5.2 All requests for urgent test requests for non-formulary Tier 4or unlisted tests shall involve approval by a Laboratory Medicine Physician or Scientist and completion of the *LTSA form* as described in the "*Procedure of referred-out tests*".

5.6 Applications for new test additions to the PLF

5.6.1 All requests for adding previously unfunded tests to the PLF requires completion of the "*Application form for Additions and*

Modifications to the Provincial Laboratory Formulary" and by the "*Procedure for adding new laboratory tests to the Provincial Laboratory Formulary".*

5.6.2 The PLFAC, uses an application process to assist with decision making activities for the addition of new not previously funded tests to the PLF.

5.6.3 All decisions for addition of new not previously funded laboratory tests to the PLF must receive endorsement from the HCS before final approval.

5.7 Applications for amendment of approved PLF tests

5.7.1 All requests for amendment of previously approved and funded PLF tests shall be considered following completion of the "*Application form for Additions and Modifications to the Provincial Laboratory Formulary*" and by the procedure outlined in "*Procedure for adding new laboratory tests to the Provincial Laboratory Formulary".*

5.8 Annual review and modification of the PLF.

5.8.1 A PLF laboratory test review shall be conducted annually and organized by the PLFAC. Smaller test specific reviews will occur at greater frequency when new information becomes available on a test that requires immediate attention. Outdated and redundant tests will be identified by the PLFAC through the PLF review process. Other formal requests for changes to the PLF will also be considered during the review process.

5.8.2 Any changes to the PLF must go through a review process with appropriate evidence provided as to why change is necessary. The process may result in deletion of redundant or outdated tests. As part of the change process, stakeholders shall be involved for review and comment prior to finalizing the change. Final approval for change shall be given by PLFAC.

5.8.3 Once approved changes in the formulary list are completed, all stakeholders must be informed of the changes.

5.9 Stakeholder Communications

5.9.1 PLF information shall be communicated to stakeholders in the form of: memos and letters of notification, newsletters, and through the PLF website.

5.9.2 All changes to PLF shall be communicated to stakeholders and according to the "*Procedure for Dissemination of Provincial Laboratory Formulary Amendments to Stakeholders*"

5.9.3 All communications for general distribution shall be approved by PLFAC. Items requiring communication include additions/deletions and other changes to the PLF and its test entries, or any other items deemed appropriate for broad communication by PLFAC.

5.9.4 All communication for general distribution shall be authorized through the office of the Director of Clinical Laboratory Services and distributed by the PLF communication working group. This committee is also responsible for control of all publicized documents.

5.9.5 The PLF website shall serve as the primary repository of PLF documents, communications, and database.

5.9.6 Dissemination of all communications for general consumption shall be directed through stakeholder organizations and offices of administrative leads representing stakeholder groups.

6.0 Related Documents

6.1.1 Application form for Additions and Modifications to the Provincial Laboratory Formulary

6.1.2 Provincial Laboratory Formulary Advisory Council Terms of Reference

6.1.3 Provincial Laboratory Formulary Organizational Chart

6.1.4 Procedure for referred-out tests.

6.1.5 Laboratory Test Special Authorization (LTSA) Form

6.1.6 Procedure for adding new laboratory tests to the Provincial Laboratory Formulary

6.1.7 Procedure for Dissemination of Provincial Laboratory Formulary Amendments to Stakeholders

7.0 Appendices

7.1 Appendix 1: Laboratory Test Special Authorization Form.
7.2 Appendix 2: Provincial Laboratory Formulary Organizational Chart
7.3 Appendix 3: Application form for Additions and Modifications to the Provincial Laboratory Formulary

Appendix 1. Laboratory Test Special Authorization Form

Newfoundland Labrador

Laboratory Test Special Authorization

HCN:
Province/Territory: Expiry: YYYY / MON / DD
Name: First Middle Surname
Date of Birth: YYYY / MON / DD Sex: ☐ M ☐ F ☐ UN
Mailing Address:
City:
Province/Territory: Postal Code:
Telephone: (Indicate Preferred) ☐ Home (___) ___-____ ☐ Work (___) ___-____
☐ Cell (___) ___-____

Ordering Provider's Name:
Clinic Name:
Mailing Address:
City:
Province/Territory: Postal Code:
Phone: (___) ___-____ Fax: (___) ___-____
Signature: Date: YYYY / MON / DD

Clinic Stamp (include fax, provider and mnemonics)

Ordering Provider's Meditech Mnemonic:
EMR Clinic Mnemonic:
COPY TO PROVIDER

Please indicate Laboratory Service area:

✔	Laboratory Division	Laboratory Professional	Fax Number
☐	Clinical Biochemistry	Biochemist on-call 697-2306	777-2442
☐	Hematology	Hematopathologist, 777-6550 or see call schedule	777-8494
☐	Public Health and Microbiology	Microbiologist on Call, contact switchboard (777-6300)	777-6362
☐	Molecular Genetics	Molecular Geneticist, 570-1088, 777-2968	777-4792
☐	Cytogenetics	Cytogeneticist, 777-4090, 777-2968	777-4792

This form can be completed electronically, printed and then faxed. If completing by hand, please be sure to write legibly.
This form is used for special authorization of laboratory tests, for out-of-province referral, restricted access tests, or for exception to the minimal retest interval.

Test(s) to be Performed	**Sample Type**

Special Protocols (Based on consultation with Laboratory Professional)

Rationale for Test Request: (Please indicate how the result will affect a patient management decision)

Is this an urgent request? ☐ Yes ☐ No If yes, has the appropriate Laboratory Professional been notified? ☐ Yes ☐ No
Anticipated collection date: YYYY / MON / DD or
For collected samples: Collection Date: YYYY / MON / DD Collection Time: Laboratory Specimen Number?
Was test pre-approved? ☐ Yes ☐ No If yes, by whom:
Laboratory Professional Authorizing:
Name: Signature: Date: YYYY / MON / DD

Clear Form Print Form

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PLF ORGANIZATION CHART