This form is used to request a new test addition or to modify the indication, tier status, or other details concerning an existing Provincial Laboratory Formulary (PLF) test entry. Please complete all applicable items below and submit the completed form with all supporting documentation by email to [LabFormularyNL@gov.nl.ca](mailto:LabFormularyNL@gov.nl.ca). Applications for changes to the PLF are reviewed and approved by the Provincial Laboratory Formulary Advisory Council (PLFAC). It is advised that clinical units work together with local laboratories to prepare the application form and preliminary business case for new test additions.

|  |  |  |
| --- | --- | --- |
| **Information on Applicant** *(To whom correspondence should be addressed)* | | |
| **Name:** | **Position:** | **Program/Department/Site:** |
| **Date:** | **Telephone:** | **e-mail:** |
| **Information on Proposed Test Addition/Modification for the PLF** | | |
| **Common name(s)/alias(es) for test:** | **Recommend changes to:**  Test Name  Description or Primary Use  Reorder Interval  Availability (Tier Level)  Ordering Restrictions  Performing Laboratory/Site  Other: | |
| **Is this test already in the PLF?**  Yes – Please indicate which specific formulary categories you are recommending changes to (see column to the right) and complete **Section A,** **D,** and **E.**  No – Complete **all** sections below. |

|  |  |
| --- | --- |
| **Section A. General Information on Recommended Formulary Changes** | |
| **Briefly indicate why this test addition/modification is required** (*Indicate how the test result is used in patient management decision making; and how the test fills a unique clinical niche not filled by other less costly and/or less effective investigations. Consider impacts on patients and/or improvements to workflow. Please attach any supporting information):* | |
| **Supporting documentation provided:**  Peer-Reviewed Literature Article(s) Diagnostic Decision Tree  Letters of Support Clinical Practice Guideline | |
| **Recommended test name:** | **Proposed testing ordering restrictions (select only one):**  Tier 1 (General availability)  Tier 2 (Restricted to specialty group or indication)  Tier 3 (Laboratory mediated case by case approval) |
| **Reorder interval** (*enter minimum number of days*): |
| **Primary clinical indication for test:** | |
| **List specific ordering restrictions** (*To which specialty groups or clinical indications should the test be limited?*): | |
| **Required consultation** (*Indicate which laboratory or clinical specialist group should vet all test requests.*): | |
| **Testing laboratory/site:**  Referred Out of Province HSC/PHML (St. John’s) Regional Hospitals  Rural Community Hospitals Community Health Centres Others (please indicate): | |
| **Describe any other recommended changes:** | |

|  |  |  |
| --- | --- | --- |
| **Section B. Basic Test Information for New Test Entries** | | |
| **Is the test *Health Canada* approved?** *(Note: Only approved Health Canada tests or Laboratory Developed Tests based on CSA standards will be included in the formulary)*  Yes No Unknown | **Is test available at other Canadian Laboratories?**  Yes No Unknown | **Is this test available at reference laboratories in US?**  Yes No Unknown |
| **Purpose for test:** *(select all that apply)*  Screening Diagnosis Monitoring  Risk assessment Selection of therapy Disease staging/prognosis | | |
| **Sample type:**  Blood Urine Saliva Tissue Other: | | |
| **Patient population:**  Inpatient Outpatient Emergency | | |
| **Proposed sample collectors:**  Laboratory Staff Physicians Patients Nurses | | |
| **Proposed sample collection centre(s):**  HSC/PHML (St. John’s) Regional Hospitals Rural Community Hospitals  Community Health Centres Outpatient collection centers Others (Please indicate): | | |
| **Will collection occur during a medical Intervention (e.g.: during surgery, endoscopy, biopsy, or aspirate)?**  No Yes, specify: | | |
| **Expected turn-around time (time from order to reported result):** (*e.g.: 2 hr, 2 d, 2 w, etc.)* | **Testing modes:**  POCT Laboratory | |

|  |  |
| --- | --- |
| **Section C. Cost/Resource Assessment** *(It is recommended that this section be prepared in cooperation with the local laboratory administration team)* | |
| **Cost assessment:** *(In the space below, or in an accompanying spreadsheet, indicate the following: At which sites the test will be available; How many test systems and tests will be required per site; What is the anticipated workload by site; and what is the anticipated start-up cost?**What are the anticipated annual costs for testing supplies, training, QC and PT materials, Maintenance Contracts, Replacement Parts, and Labour?)* | |
| **Estimated cost per test:** | **Estimated total annual test number:** |
| **Are there anticipated cost savings by introducing this test?** Yes No  If Yes, describe the anticipated savings: | |
| **Will special utilization restrictions be required to control costs and workload?** Yes No  Explain: | |
| **Will new funding be required to introduce this test?** Yes No  Indicate proposed source of funding and estimate total amount: | |

|  |
| --- |
| **Section D. Other Potential Impacts** *(Complete for all applications!!)* |
| **Will changing this tests PLF status affect usage of or replace another existing PLF test?** Yes No  Explain: |
| **Will changing this tests PLF status affect usage of non-laboratory tests or services?** Yes No  Indicate departments and effects (*include any patient preparation or follow-up impacts*): |

|  |  |
| --- | --- |
| **Section E. Authorization** *(Complete for all applications!!)* | |
| **Name of Requestor:** | **Date:** |
| **Signature:** | |

|  |  |
| --- | --- |
| **Internal Office Use Only** | |
| **Date of application receipt:** | **All required documentation received?** Yes No |
| **Approved for review by PLFAC**? Yes No | **PLFAC decision:** Approve Not Approve |
| **Authorization** | |
| **Name:** | **Date:** |
| **Signature:** | |

|  |
| --- |
| **Please Return completed form to:** Provincial Laboratory Formulary Advisory Council (FAX: 709-729-4009 or [LabFormularyNL@gov.nl.ca](mailto:LabFormularyNL@gov.nl.ca). ) |