ALBERTA PRECISION LABORATORIES

Leaders in Laboratory Medicine

Lab Formulary Intake Request

Complete this form to **request a new test, expand or limit indications for an existing test**, *(i.e. appropriateness, utilization initiative or request an appropriateness of assessment of a test)*. The form must be completed and signed as outlined in the instructions below and contain all supporting documentation *(as applicable)*.

The following must be submitted via email to Lab.Formulary@ahs.ca

☐ The completed and signed form

☐ All supporting documentation required

Note - The preference is to have all fields in the form completed. However, the Lab Formulary Committee understands that depending on the development stage of a test/technology not all detailed information or only limited data is available; and that missing information will be generated in collaboration with the Lab Formulary Committee over time. If the request is of sufficient value to be considered for potential adoption to the formulary.

Requestor Information		
Name	**Position**	**Program/Organization**
Phone	**e-mail**	

Requested Test Information *(N/A if unknown)*	
Name of test	**Test manufacturer**

Is test Health Canada approved?
☐ Yes ☐ No

Reason for test request and appropriateness *(attach relevant documentation to support request)*

Clinical question*(s)* **addressed by the test** *(e.g. new standard of practice, cost savings, include relevant reference(s))*

Target population
☐ Broadest Target Population
☐ Subpopulations *(please specify)* _____

Purpose of test *(check all that apply)*
☐ Risk assessment ☐ Screening ☐ Diagnosis ☐ Surveillance
☐ Staging and prognosis ☐ Therapy selection ☐ Monitoring

What is the impact on current practice *(e.g., better outcomes, cost savings, quality)*

Diagnostic Specimen
☐ Blood ☐ Urine ☐ Tissue *(specify Tissue type)* _____
☐ Other *(specify)* _____

Specimen Collection Process/Location

In-Hospital
☐ Under anesthetic ☐ Ward ☐ During surgery
☐ Biopsy ☐ Needle aspirate ☐ Endoscopy
☐ Other _____

Outside Hospital
☐ Community collection location *(specify)*
_____
☐ Doctor's office
☐ Home collection

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Specimen collected by whom
☐ Nurse ☐ Laboratory Staff ☐ Physician ☐ Patient

Where is test performed
☐ Point of care setting ☐ Laboratory

What technology is used for analysis

☐ In situ hybridization
☐ Immuno-histo-chemistry
☐ Immunoassays
☐ Mass spectrometry
☐ Elisa
☐ Polymerase Chain Reaction *(PCR)*

Chips and Microarrays
☐ RNA ☐ miRNA
☐ cDNA ☐ DNA
☐ SNPs ☐ proteins

Whole Genome Sequencing
☐ Platform? *(specify)*
_____

Exome Sequencing Platform? *(specify)*
_____

☐ Other *(specify)*

Supporting infrastructure required
☐ Pathology Dept. ☐ Point of Care ☐ Sequencers ☐ Bioinformatics ☐ Freezers
☐ Couriers ☐ Other *(specify)*_____
☐ unknown

Rationale for supporting infrastructure

By whom are results analyzed
☐ Informatician ☐ Pathologist/Clinical Doctoral Scientist ☐ Nurse ☐ Clinician
☐ Patient *(e.g., pregnancy/diabetes)* ☐ Lab Staff
☐ Other *(specify)* _____
☐ Unknown

Expected Business Model
☐ Point of Care ☐ Dx service ☐ Device/Kit ☐ Software/Algorithm
☐ Other *(explain)* _____

Expected cost of Test	**Expected/targeted Return on Investment**

Is there anything else you would like to tell us about your technology?

If Lab test is still under development complete the following page otherwise proceed to the authorization section on page 3

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Complete if Lab test is still under development

Stage of Development

☐ Discovery - research ongoing
☐ Proof of concept
☐ Pre-clinical validation in process
☐ Pre-clinical validation completed
☐ Clinical validation in progress
☐ Clinical validation completed

Available data on

☐ Receiver Operating Characteristic Curve
☐ Sensitivity – positive and negative predictive values
☐ Specificity

Expected regulatory pathway in each target market based on Device Classification *(e.g., US)*
(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm)

☐ Classification of In Vitro Diagnostic Device *(IVD)*
☐ Medical Specialty
☐ Class *(I / II / III)*
☐ Premarket Notification *(510k)* to demonstrate that the device to be marketed is at least as safe and effective
(i.e., substantially equivalent, to a legally marketed device that is not subject to PMA)
☐ Premarket Approval *(PMA)* is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.
☐ Class I / II Exemption
☐ Humanitarian Device Exemption

Stage of regulatory approval ***(if any)***	**Expected time to regulatory approval**
Stage_____ Date *(dd-Mon-yyyy)*	

Status and ownership of Intellectual Property

☐ Patent filing strategy
☐ Patents filed/priority date/ publication date
☐ Patents granted/priority date
☐ Other intellectual property protection *(e.g., proprietary database/registered copyright/trademark)*

Declaration of Conflict of Interest

☐ I have no conflicts of interest to declare related to my Lab Formulary Intake Request at this time.

☐ I have interests to declare which may actually, potentially, or be perceived to conflict with my Lab Formulary Intake Request.

NOTE: If you have a conflict of interest to declare, the Lab Formulary Committee will follow-up with you to obtain additional information.

Authorization

Signature	**Date(*dd-Mon-yyyy*)**