

Frequently Asked Questions – Test Review Process

What is the purpose of the new Test Review Committee?

The Test Review Committee (TRC) replaces previous structures and is designed to support the Laboratory Services Act by making evidence-based recommendations about publicly insured clinical laboratory benefits. The Laboratory Services Act replaces the Medicare Protection Act and the Hospital Insurance Act as the authority for insured laboratory benefits. BC's Agency for Pathology and Laboratory Medicine (Agency) has developed and implemented new test review processes to support the Minister on the administration and provision of insured laboratory benefits to British Columbians.

The test review process makes the inclusion (or elimination) of clinical laboratory tests on BC's publicly funded clinical laboratory test menu more efficient and transparent and is based on the best medical and scientific evidence. This is achieved through the involvement of clinical subject matter experts in all test review processes. All clinical laboratory tests (new, existing, replacement, out-of-province, inpatient and outpatient) are open for review and subject to the same process.

What is the test review process?

The TRC, a standing operating unit reporting to the new Agency, reviews, evaluates and makes evidence-based recommendations on the introduction, replacement and/or elimination of publicly-funded clinical laboratory tests (including inpatient, outpatient and out-of province tests). The Committee's recommendations are reported to the Agency and forwarded to the Ministry of Health for decision. Underlying this framework is the TRC's goal to ensure evidence-based, fair and transparent laboratory test review processes. The major phases of the review process are:

1. Intake (applicant submits materials)
2. Triage (TRC Triage team)
3. TRC Review
4. TRC Recommendation (sent to Agency and then to Ministry of Health)
5. Decision (Ministry of Health)

Who is on the Test Review Committee?

The structure of the TRC consists of 6 standing voting members, the Chair and four ex-officio members (one from the Agency Leadership, one from the Ministry of Health and two Agency support staff). All voting members have expertise and experience in pathology and clinical laboratory medicine with a minimum of 5 years' experience practicing in British Columbia.

How are applications assessed?

The TRC assesses applications on the basis of medical and scientific evidence, clinical practice guidelines, expert consultation, available provincial test utilization information, economic considerations and with medical and scientific input from both local and, when necessary, out of province clinical and diagnostic experts. The decision-making

processes are grounded on ethical principles, address legal and social concerns, involve stringent evaluation criteria and adhere to conflict of interest rules.

The review criteria include, but are not limited to, the following categories:

- Impact on patient care;
- Impact on health care system;
- Economic assessment, with focus on clinical outcomes;
- Analytical validity, and;
- Ethical, legal and social considerations.

Who can apply?

The requester must be an employee and/or authorized agent of a laboratory provider, health authority, the BC's Agency for Pathology and Laboratory Medicine and/or the Ministry of Health. The requester must hold relevant qualification(s) in clinical laboratory medicine. Physicians in good standing with the College of Physicians and Surgeons of British Columbia or referring practitioners enrolled under the Medicare Protection Act may apply as co-applicants. All applications must be approved by the senior administrator of the requesting organization. The organization must identify the senior administrator responsible for authorizing test review applications.

When should an application be brought forward to the Test Review Committee?

Applications should be made to the TRC for additions, changes and/or removal of BC publicly funded tests as insured benefits payable under the Laboratory Services Outpatient Payment Schedule and/or the core budgets of publicly funded laboratories (hospital or health authority). Requests that have an overall resource impact to the laboratory service provider will require an application to the TRC. Changes to existing clinical laboratory tests that do not impact the overall resource allocation of the laboratory service provider and are aligned with the overall strategic goals of the Ministry of Health and the Agency will continue as operational decisions of the laboratory service provider.

What do I need to include in my application to the Test Review Committee?

All applications MUST include:

- Letter of Intent (maximum 2 pages) which outlines:
 - Proposed change/addition/removal/replacement of clinical laboratory test,
 - Clinical impact and benefits for patients and the BC healthcare system,
 - Overview of utilization and cost impacts (business case should be included as an appendix, if applicable),
 - Impact on downstream clinical practice,
 - Additional clinical and/or scientific relevant supporting evidence,
 - Proposed implementation plan.
- Intake Form: Application for Clinical Laboratory Test Review.
- Clinical Laboratory Test Costing, if available.

Supporting documents may include:

- Peer reviewed medical and/or scientific journal articles that demonstrate the relevance and significant clinical benefit of the proposed laboratory test.
- Support letter(s) from clinical associations and/or clinical subject matter experts.



- Support letter(s) from operations and medical leaders of impacted test site(s).
- Budget quotes for instrumentation and disposables/consumables costing.

Do I need to submit an application if my organization has already submitted a request about a test to the Ministry of Health?

The TRC is in the process of reviewing a backlog of applications submitted to the Ministry of Health (MoH) under the Tariff/Medical Services Commission process. If you have already submitted a request to the MoH you may be contacted to submit a formal application to the TRC, but no action is needed until you have been contacted to do so. All new requesters must submit an application under the TRC process. If your organization has been notified that your submission is being reviewed, you do not need to submit another application.

How can I find out if another organization has already submitted a request for the same test?

Please contact testreview@phsa.ca. The Agency is assessing the privacy considerations of making this information available on the Agency website, currently under development.

How long will it take to find out if an application has been approved?

The timeline will vary and will depend on the complexity of the clinical laboratory test and associated dependencies. The process involves assessing the submitted material, supporting evidence, test costing information, and a number of factors that will take time to review and validate. The processes are being formalized and the support infrastructure within the Agency is under development. The timing of the review process will also be affected by the volume of applications received.

Will I be informed of the recommendation that the TRC is making to the Lab Agency and the Ministry of Health?

The Agency will inform the requester once a decision has been made by the Ministry of Health.

Who do I contact if I have questions about the intake form or application process?

Please contact testreview@phsa.ca and your request will be forwarded to the Research Coordinator, Test Review Committee.