Guidelines to Patriate Genetic and Genomic Tests

Laboratories applying to introduce a publically-funded test to BC must show that:

a. The proposed test(s) address an important and defined clinical need with the written support of relevant subject matter experts and clinical users.

b. The laboratory/facility is accredited by the Diagnostic Accreditation Program, meeting both general standard requirements and discipline specific standards.

c. The laboratory professionals providing the testing:
    i. Have formal clinical certification with the requisite training and expertise to oversee the development, when applicable, and implementation of the clinical test, and ensure its ongoing quality performance.
    ii. Ensure that the laboratory adheres to Canadian and/or International clinical laboratory best practices established by professional organizations including, but not limited to: data generation, result interpretation, report format and report mechanisms.

d. In developing the assay and testing algorithm, and in comparison to other options (if applicable), the laboratory/facility has evaluated:
    i. All applicable aspects of patient care
    ii. Compliance with BC healthcare system approved sample collection standards
    iii. Appropriate validation of test sample types with the methodology
    iv. Reporting validated results
    v. Analytical sensitivity
    vi. Analytical specificity
    vii. Reproducibility
    viii. Accuracy
    ix. Positive and negative predictive values
    x. If applicable: analysis pipelines focused on providing results of high diagnostic value while reducing impact of uncertain results on patients, family and the clinical system.

e. The cost is less than or approximately equivalent to other testing options, if applicable, taking into account other patient management costs related to the underlying condition.

f. Relevant clinical users and subject matter experts for the test have been consulted and provided perspective on:
    i. System stewardship, including but not limited to clinically appropriate indications for testing and health practitioner access to testing
    ii. Clinical utility including patient management
    iii. Barriers to patient access
    iv. Impact of turnaround time on patient care

Along with the parameters above, overall benefits to British Columbia, including the health care system and academic community, will be considered.