



College of Physicians and Surgeons of British Columbia

Position Statement

DAP Accreditation of Genetic Testing Laboratories and Direct-to-consumer Testing

DETAILS

Department/program: Diagnostic Accreditation Program

Date: June 13, 2018

PURPOSE

Position statements from the College provide background information and express or clarify the College's intent on a particular matter. They are intended as guidance for stakeholders in areas where events are evolving or changing, the implementation of processes and procedures may be premature, the implementation of a guideline or standard may not be necessary, another credible body (e.g. professional association) has already established guidelines or standards, or it is timely to communicate the College's broad intent before or as policies and procedures are developed.

This document addresses DAP accreditation of genetic testing laboratories in general, and direct-to-consumer (DTC) testing specifically.

BACKGROUND

The primary interest of the College and the DAP on the issue of genetic testing is the protection of the public. The DAP is prepared to accredit bona fide laboratories that perform genetic testing provided that they meet the DAP accreditation standards. These standards were developed following a well-established process using experts to draft the standards and an expert advisory committee to review, revise and endorse them.

The following from the Canadian College of Medical Geneticists (CCMG) outlines the responsibilities of the ordering health-care provider:

"The medical professional ordering a test has an obligation to: obtain informed consent prior to ordering testing, interpret the result(s), support the individual with respect to the psychosocial and biological implications of the result(s), and access available health care to modify the natural history of a predisposition or a diagnosis. This includes, but is not limited to, educating an individual about the test and its various implications, such as what the results predict about the individual's future health and that of family members, the potential for insurance discrimination, the possibility of receiving difficult to interpret results or misinterpreted results. Involving the professional in accessing medically significant testing also provides an important

safeguard to our society. The professional assumes responsibility for ensuring that testing is sought autonomously.”

The DAP accreditation standards for laboratories reflects this fundamental principle. In this way, the safety of the public is supported by having their health-care professional as an integral part of the testing process.

POSITION

The College believes, and supports through its accreditation program, that testing laboratories and personnel must be accredited, maintain a quality management system specific to the laboratory, and participate in recognized proficiency testing programs or other ways of monitoring data quality. The laboratory staff performing testing, analysis and interpretation must be trained and certified by appropriate governing bodies for the provision of medically-related genetic testing and must undergo regular competency assessments.

The College at this point is not in a position to accredit any laboratories providing direct-to-consumer testing (DTC). DTC testing does not meet the fundamental principles and standards for diagnostic testing by accredited laboratory facilities; requests for tests with medically-significant implications should only be accepted from a medical professional (which may also include nurse practitioners and midwives) on behalf of the individual to be tested.

Through appropriate standards to accredit laboratories, the interest of the public can be a priority in this emerging field where the scale of the lab-based genetic testing industry is dwarfed by the DTC industry with all of its potential pitfalls. Educating the public on involving their health-care practitioner and accessing testing at accredited laboratories can mitigate the impact of DTC testing.

REFERENCES

1. CCMG Ethics and Public Policy Committee. “CCMG Statement on Direct-to-Consumer Genetic Testing.” Practice Guidelines, Position Statements, Surveys and Reports, <http://www.ccmg-ccgm.org/publications/practice-guidelines-position-statements-and-reports.html>.

CONTACT

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