



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

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 rapidly, the implementation of processes and procedures may be premature, 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.

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 (5D)-g0 G50 G00AF>4nnting0.0000092 0 62 79

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.

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.

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->