



MOLECULAR GENETICS DIAGNOSTIC LABORATORY: DNA Quality Task Force Review

December 5, 2011

Key Messages for Health Care Providers

CONTEXT

- The Molecular Genetics Diagnostic Laboratory, as part of the Eastern Ontario Regional Genetics Program, offers testing for 27 heritable conditions, serving as a reference laboratory for the Eastern Ontario region, as well as receiving samples from across Ontario, Canada and North America. The Laboratory also offers short-term DNA storage and "send-out" services, when appropriate.
- To ensure consistency in the generation of quality DNA within the Molecular Genetics Diagnostic Laboratory, a Task Force was struck to review practices and establish guidelines related to sample receipt, DNA extraction and DNA storage. 36 recommendations were put forward by the Task Force and external review (for further background see page 2).

HOW DOES THIS REVIEW IMPACT YOU AS A HEALTH CARE PROVIDER?

- **PLEASE SEND BLOOD SAMPLES - NOT BANKED DNA:** Health care providers are encouraged to send peripheral blood samples to referral laboratories whenever possible, in lieu of banked DNA. This practice provides the referral laboratory with back-up samples should they be required and does not compromise testing optimized for specific DNA extraction protocols in those laboratories.
- **PLEASE FOLLOW CUT-OFF TIMES FOR SPECIMEN RECEIPT:** Ensure that samples are received by the Laboratory by **2:00 pm on Fridays**. Samples received after this time cannot be processed until Monday (unless urgent), which can have an effect on DNA quality.
- **PLEASE BE AWARE OF SPECIMEN ACCEPTANCE & REJECTION CRITERIA:** New specimen acceptance and rejection criteria have been developed - see attached document for details. These changes will be made available in the CHEO ward manuals and on the CHEO website. The laboratory requisition form is in the process of being updated to reflect these changes.
- **PLEASE BE AWARE THAT YOU WILL RECEIVE A REPORT FOR REJECTED OR SUB-OPTIMAL SAMPLES:** The Laboratory will implement the practice of issuing a report for all rejected or "sub-optimal" specimens that clearly indicates the condition observed and whether an additional sample is required.

Lastly, for your information, the Laboratory will request copies of reports for all referred out specimens sent to external laboratories so that we can monitor quality, and identify any potential problems. This new process does not require any changes to requisition entry on the part of the health care provider requesting the DNA send-out.

DNA Quality Task Force Review

RATIONALE

- Despite efforts to ensure quality in DNA extraction procedures, over the last few years the Laboratory has experienced a number of incidences requiring investigations of DNA quality.
- Previous investigations have resulted in the implementation of recommended changes to improve DNA send-out service, as well as quality control and assurance improvements to the DNA extraction process.
- Despite implemented improvements, the Laboratory was notified of additional test failures involving DNA extracted and shipped by the Laboratory to an external facility.
- As a result, a Task Force chaired by Dr. Elizabeth McCreedy (Clinical Laboratory Scientist) was formed to investigate the most recent incidents of DNA degradation.

PROCESS

The review methodology consisted of several steps, including:

- Retrospective investigation of reported or observed suboptimal DNA extractions
- Overview of DNA extraction process
- DNA quality focus group with laboratory staff
- Literature search
- Review of protocol related to ArchivePure Manual DNA extraction procedure
- Evaluation of reagents used during extraction processes
- Evaluation of acceptance/rejection criteria
- Evaluation of DNA storage conditions
- Evaluation of QA/QC processes
- Evaluation of DNA send-out follow-up procedures
- External review conducted by Dr. Martin Somerville, Director of Medical Genetics Laboratories for the Alberta Laboratory Services