QASI®-VL EQA Program

EXTERNAL QUALITY ASSESSMENT FOR HIV VIRAL LOAD TESTING

QASI-VL is managed and operated by the National HIV and Retrovirology Laboratories of the Public Health Agency of Canada. It is located at the JC Wilt Infectious Diseases Research Centre in Winnipeg, Canada.

Our mission is to ensure accurate and reliable results for quantitative HIV viral load (VL) testing are consistently obtained and reported by laboratories and point-of-care testing (POCT) sites in countries where external quality assessment (EQA) services are limited or unavailable.

QASI-VL provides EQA through administration of proficiency testing (PT) schemes for both conventional laboratory and point-of-care devices using nucleic acid amplification testing (NAAT) technologies. Comprehensive corrective action is also provided to those sites requiring assistance in maintaining quality testing standards.

We work closely with the World Health Organization, the Centres for Disease Control and Prevention, Ministries of Health, National Reference Laboratories and external funding partners to foster sustainable partnerships and collaborations that focus on improving and maintaining quality testing practices for HIV VL testing, particularly in emerging POCT networks.

The success of our program is dependent on reliable open lines of communication between QASI-VL Administration and identified Coordinators and EQA Coordinating Centre(s) within a country. Typically, Coordinators are individuals from a National Reference Laboratory or organization tasked with providing EQA in the country. The roles and responsibilities of QASI-VL Administration and the in-country EQA Coordinating Centre are outlined below.

Roles and Responsibilities

QASI-VL Administration Provides:

- Proficiency testing scheme for quantitative HIV VL using NAAT-based platforms, including but not limited to;
    - Abbott m-PIMA (formerly Alere q)
    - Abbott m2000 RealTime
    - Cepheid GeneXpert
    - Roche COBAS AmpliPrep/Taqman
    - Additional platforms to be added according to demand
- Proficiency testing panels shipped bi-annually in March and September;
    - Annual calendar outlines important dates / deadlines for each session

- 3 blinded specimens per panel;
    - Plasma-like specimens consisting of Tris-EDTA buffer spiked with a clinically relevant amount of inactivated HIV
    - Identified by a unique QASI-VL number
- International shipment to an in-country EQA Coordinating Centre;
    - Preferred international courier is FedEx
        - Alternate courier can be requested if required
    - Panels shipped as non-infectious biologicals
    - Cold packs are used for international shipment, but cold-chain is *not* required to maintain sample integrity
    - Shipments do *not* require additional import licences *nor* special handling for dangerous goods
- Panel shipments complete with;
    - Duplicate number of panels, such that each participating testing site receives a back-up panel for repeat testing, if required
    - Single-use transfer pipettes included for loading the m-PIMA cartridge
    - Guidelines and instructions for Coordinators
    - Instructions and coded Data Submission Forms specific to each participating testing site
- QASI-VL website; https://qasi.canada.ca/vl
    - A secure online database accessible only to registered Coordinators and designated lab member(s) at participating testing sites
        - Assigned username and confidential password required for access
    - Used for enrolment of participating testing sites
        - Testing sites may include national or regional laboratories, hospitals, clinics, mobile clinics or POCT sites; collectively referred to as "*testing sites*"
    - An alphanumeric "Lab Code" assigned to each unique combination of testing platform and testing site
    - Online interface for result submission, data storage, and downloadable participant performance reports and program history
    - Coordinators have secured access to the PT data of all testing sites in their designated group
    - Designated lab member(s) may be granted secured access only to their own testing site's data
- At the end of each session, an Assessment Report emailed to Coordinators and designated stakeholders that includes;
    - Comprehensive data analysis and performance summary for all participating sites in country/group
    - Description of non-conformances identified
    - Corrective action recommendations as required
- A Performance Report for each participating testing site available for download from the QASI-VL website includes;
    - Performance summary of the corresponding testing site in the current session
    - A blinded summary of performance of all testing sites in the current session
    - Performance history of the corresponding testing site over previous 4 sessions

- Ongoing dialogue to assist Coordinators in the provision of corrective action;
    - Assistance in resolving performance issues
    - Training materials and protocols available upon request
- Annual Certificates;
    - *Certificate of Participation* for each testing site that participated in *both* sessions in the year
    - *Certificate of Achievement* for the Coordinator or EQA Coordinating Centre
- Skills and knowledge transfer workshops for EQA Coordinating Centres interested in developing and launching their own national or regional EQA scheme for HIV VL testing;
    - Offered at the JC Wilt Infectious Diseases Research Centre in Winnipeg, Canada
    - Consideration will be given for workshops on-site in-country
    - Further information can be provided upon request
- All our services, documentation and website as described above are available in English and French

EQA Coordinating Centre / Coordinator(s) Roles and Responsibilities:

- Serve as an essential liaison between QASI-VL and participating testing sites;
    - Reliable email communication with QASI-VL Administration is critical
    - Coordinator contact information must be kept up-to-date
    - At least 2 designated Coordinators are preferred
- Knowledge of the QASI-VL procedures and policies outlined in this document
- Provide enrollment information for testing sites that includes at a minimum;
    - The name of the institution, hospital, laboratory, clinic or POCT site
    - The city or region of country where the testing site is located
    - *Optional:* The names and emails of lab members and/or designated contacts at the testing site who require access to the website for direct data submission
- Respond to “Invitations to Participate” in a QASI-VL Session on behalf of enrolled testing sites;
    - Confirm with testing sites that they have the necessary reagents (kits and/or cartridges), functioning equipment, and trained personnel available *before* accepting an invitation
- Provide an up-to-date shipping address for receipt of panels
- Collect panels from customs in a timely manner;
    - Take actions to expedite the delivery and release of packages that are delayed
- Re-distribute panels promptly to participating testing sites throughout the country;
    - Ensure testing sites receive panels in a timely manner
    - Ensure panels include instructions and the Data Submission Form that is coded specifically for the corresponding testing site and instrument/device in use
- Assist personnel at the testing sites with any questions or concerns regarding the QASI-VL EQA program and PT panel instructions
- Collect results from participating testing sites;
    - Completed Data Submission Forms must be received before the indicated deadline

  - Remind testing sites to provide the instrument-generated Test Report to mitigate non-conformances and corrective actions
    - Acceptable as a paper copy, picture/sms, .pdf or .csv file
  - Remind testing sites of pending deadlines for testing and result submission
- Enter results to the QASI-VL website using a secure Coordinator account prior to the session deadline;
  - Upload instrument-generated test reports
  - Contact testing sites to account for any missing or unclear information
  - Complete valid submissions for all testing sites that accepted the Invitation to Participate
    - A valid submission includes data submissions ***as well as*** those that report "Unable to Report" along with an explanation of unforeseen challenges experienced during the session
- Upon completion of a session, review the Assessment Report and Cover Letter provided by QASI-VL Administration;
  - Discuss corrective and preventative actions with personnel at those testing sites identified with non-conformances as soon as possible to mitigate potential negative impact on patient testing
  - Provide feedback on corrective action to QASI-VL Administration before the indicated deadline
  - Request assistance with corrective action as required

Associated Costs:

The QASI-VL EQA program is designed to reduce the cost burden on participants while still enabling growth and sustainability of the program to provide essential quality assurance services.

- There is **no** enrollment fee
- There is **no** annual fee
- There are **no** hidden costs
- The EQA Coordinating Centre is responsible for any costs that may be incurred for any of the following;
  - Duties or import taxes charged at the port of entry
    - These fees are country specific and will be determined at the port of entry
  - Re-distribution of panels within the country
    - No cold chain required
  - Collection of results from participants, electronically or via courier
  - Provision of testing reagents/kits/cartridges

Policies:

- QASI-VL panels are only to be used for proficiency testing purposes by enrolled testing sites
- QASI-VL specimens must be handled as potentially infectious material and disposed of appropriately
- Coordinators are expected to represent testing sites honestly and to the best of their abilities;
    - Results must be unaltered and submitted to the QASI-VL website site as they were reported by the corresponding testing site
    - All data entries must be independently verified before final submission to ensure there are no transcription errors
- An Invitation to Participate must only be accepted once it has been confirmed with the testing site that reagents are in stock, instrument is functioning and trained personnel are available for testing;
    - A valid submission is expected for all testing sites that have accepted an Invitation to Participate in a QASI-VL Session
    - A valid submission includes either data/test results or "Unable to Report" with a valid reason as to why no results are available
- Testing sites that fail to participate in 2 consecutive sessions will be made *Inactive* in the QASI-VL database until further confirmation is provided to QASI-VL Administration that corrective action measures have been taken and the site is now ready to resume participation.
- No Extensions;
    - Reminder email will be sent to Coordinator(s) one week before a pending deadline
    - Deadlines include;
        - Invitation to Participate RSVP
        - Testing Deadline / Data Submission Forms due to Coordinators
        - Data Submission Deadline / Session Closing
        - Corrective Action Response
- Corrective action, when required, must be carried out diligently and promptly to ensure that clinical testing results and patient outcomes are not negatively affected
- Performance Reports for each session must be provided confidentially to each participating testing site
- *Certificates of Participation* will only be awarded to testing sites that participated in *both* sessions in a given year;
    - Participation is tracked by data entry for each testing site on the QASI-VL website
    - Certificate is not a reflection of performance, but rather an acknowledgement of an ongoing commitment to participating in an EQA program

Thank you for your interest in QASI-VL

QASI-VL is committed to ensuring the quality of HIV VL testing through our continuous pursuit of excellence in delivering an EQA scheme that fulfils the needs of our stakeholders and fosters long-lasting relationships and collaborations.

QASI-VL

National HIV and Retrovirology Laboratories

JC Wilt Infectious Diseases Research Centre

National Microbiology Laboratory

Public Health Agency of Canada

Winnipeg, Canada

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