

Quality Assurance Roles and Responsibilities in HIV Rapid HIV Testing

Activity	QA Lead / Manager of Test Site	Testing Counsellor	Institute for Quality Management in Health	AIDS and Hepatitis C Programs (Ministry)	Manufacturer
Training	Ensures staff are trained appropriately (e.g., review all training materials at www.hivtestingontario.ca).	Participates in training program.		Provide resources to support staff training .	
Staff Validation/ Competency	Ensures staff have tested a certification panel successfully, before testing clients. Retain certificate for all staff.	Passes certification testing before beginning testing on clients.	Provides certification panels.	Provides Certification panels (ordered via the Inventory Management portal). Provides certificates on satisfactory completion of panel.	
Refresher Training	Ensures staff have periodic refresher training. Must document refresher training for staff.	Participates in periodic refresher training.		Provide resources to support staff training . Arranges periodic education opportunities for staff.	
Job Descriptions	Ensures responsibilities for rapid testing are indicated in job descriptions.				
Test Lot Release Program	Ensures regular QC testing of each test Lot, as specified . The Lead may request a Lot's Certificate of Analysis from the Ministry.	Runs QC specimens on each new test Lot, under the direction of the QA Lead. This must be done prior to use for client testing.		Retains the original Certificate of Analysis for each test Lot number.	Provides Certificate of Analysis for each test Lot shipped to the Government Pharmacy describing the performance of the Lot.
Parallel Testing	Reviews and compares results of POC tests to PHOL tests; compiles monthly summary report. Informs Ministry of any issues related to POC test performance (e.g., discordant results).	Records results of Rapid testing and PHOL testing in the daily log. Inform QA Lead/ supervisor of discordant results.		Follows-up with PHOL and manufacturer on any discordant results. Supports investigation if warranted.	Responds to any concerns regarding test performance.
Inventory Control	Authorizes ordering through the Inventory Management portal and ensures portal is updated regularly to reflect tests received/used.	Tracks test usage on the daily log. Orders tests and updates on-line inventory system, as directed by site's QA Lead.		Reviews and approves test orders. Monitors test usage and collects data.	Produces test kits and QC materials. Ensures a sufficient supply of kits available for Ontario.

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Internal Quality Control (QC)	<p>Review internal QC records regularly and takes corrective action, as required. This includes maintenance of the daily log, the quality control log and the incident log.</p> <p>Compiles monthly summary of kit usage and errors, and monitors kit expiry dates.</p> <p>Ensures a supply of QC controls on site.</p>	<p>Runs positive and negative QC testing of each kit Lot, as specified. Records the results in the QC log and the use of tests in the daily log; notifies QA lead of any discrepancies.</p> <p>Records kit Lot numbers for all tests in the daily log.</p> <p>Alerts QA lead/supervisor to expired kits or gap in supplies.</p>		<p>Point of contact for QC issues.</p> <p>Provides technical support as needed. Supports communication between the manufacturer, Government Pharmacy, and sites.</p> <p>Provides templates for all quality assurance reporting.</p> <p>Positive and negative QC controls available for order through the Inventory Management portal.</p>	<p>Provides positive and negative QC controls to sites. Responds to any issues related to Quality Control in consultation with sites AND the ministry.</p>
Proficiency Testing (PT)	<p>Works with ministry to ensure the site is enrolled in the PT program. Ensures all staff participate in PT on a rotating basis.</p> <p>Reviews the results of PT with staff, and takes corrective action if needed. Maintains PT records.</p>	<p>Participates in PT as required.</p>	<p>Ships PT panels to sites (no ordering required).</p> <p>Provides PT results to sites through the IQMH secure Qview portal.</p>	<p>Provides direction on PT program and tracks site participation in PT.</p> <p>Provides technical support to sites for discordant findings investigations.</p>	<p>Responds to any PT issues related to test performance.</p>
Environmental Monitoring	<p>Ensures temperature charts are maintained daily for all areas where tests are stored or used.</p> <p>Reviews data regularly, and takes corrective action, if required.</p>	<p>Completes daily temperature charts for all areas, where tests are stored or used. Notes any temperature outside the range; notifies supervisor/ QA Lead.</p>		<p>Provides template for environmental monitoring.</p>	<p>Determines appropriate storage temperatures for test kits; updates range as needed.</p>
Documents and Records	<p>Ensures all quality assurance records are stored for 10 years. See QA templates.</p>	<p>Completes all quality assurance documents for QC Lead/Supervisor review AND approval.</p>		<p>Periodically audits sites to ensure QA is appropriate.</p> <p>Provides QA templates.</p>	