

## Quality Assurance Roles and Responsibilities in Rapid HIV Testing

Activity	QA Lead / Management of Test Sites	Testing Counsellor	Institute for Quality Management in Health (IQMH)	HIV and Hepatitis C Program (Ministry)	Manufacturer
Training	Ensures staff are trained appropriately.	Participates in training program.		Provide <a href="#">resources to support staff training</a> .	
Staff Validation/ Competency	Ensures staff have tested a certification panel successfully, before testing clients. Retain certification records for all staff.	Passes certification testing before beginning testing on clients.	Prepares certification panels.	Provides Certification panels (ordered via the <a href="#">Inventory Management portal</a> ). 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 <a href="#">resources to support staff training</a> . Arranges periodic education opportunities for staff.	
Job Descriptions	Ensures responsibilities for rapid testing are delineated in job descriptions.				
Test Lot Release Program	Ensures regular QC testing of each test lot, <a href="#">as specified</a> . The Lead may request 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 tests.		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, as determined by an independent laboratory.
Parallel Testing	Reviews results of parallel testing regularly, comparing standard tests to POC outcomes; compiles monthly summary report. Informs Ministry of any issues related to test performance.	Records results of Rapid testing and PHOL testing in the daily log. Inform QA Lead/ supervisor of discordant results.		Provides annual summaries of parallel testing results by site and provincially. Notes any trends in performance outside of manufacturer's specifications.	Responds to any concerns regarding test performance.
Inventory Control	Ensures the site participates in the inventory control program. Authorizes ordering through the Inventory Management portal and ensures system is updated regularly to reflect tests received.	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 working with Government Pharmacy. Monitors test usage and collects/provides data compares with PHOL data.	Produces test kits and QC materials; performs initial quality control. Ensures a sufficient supply of kits available for Ontario needs.

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Internal Quality Control (QC)	<p>Review and approve 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 an adequate supply of quality controls on site.</p>	<p>Runs positive and negative QC testing of each kit lot, <a href="#">as specified</a> and directed by QA Lead. Records the results in the QC log and the use of tests in the daily log; notifies supervisor/ 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 <a href="#">templates</a> for all quality assurance reporting.</p> <p>Positive and negative controls available for order through <a href="#">the Inventory Management portal</a>.</p>	<p>Provides positive and negative controls to sites. Responds to any issues related to Quality Control in consultation with sites AND the AIDS Bureau.</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>Prepares and ships PT panels for sites on a regular basis.</p> <p>Makes results of PT testing available to sites and the Ministry through the 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 documentation is appropriately completed, filed and stored for 10 years. See <a href="#">QA templates</a>.</p>	<p>Completes all quality assurance documentation as required for QC Lead/Supervisor review AND approval.</p>		<p>Periodically audits sites to ensure QA is appropriate.</p> <p>Provides <a href="#">QA templates</a>.</p>	