



HIV Viral Load and Infant Virologic Testing (VL/IVT) Scorecard

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Learning Objectives

At the end of this presentation you will be able to:

- Demonstrate how to perform an audit using the VL/IVT scorecard
- Demonstrate how to conduct an audit using the “Follow the ROAD” technique

Purpose of an Audit

- Identify areas where improvement is needed
- Measure improvements as gaps are addressed
- Develop and implement a work plan to address gaps
- Implement quality assurance elements
- Monitor quality progress
- Maintain continuous quality improvement

The goal is to ensure the client receives accurate and reliable test results!

Audit Process

- ▶ Preparation and planning –complete questions in advance.
- ▶ Conducting the audit - Have a relevant personnel present (allow 2 hrs.)
- ▶ Reporting on the audit (feedback)
- ▶ Following up to determine compliance

Standards for Audit

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HIV VIRAL LOAD AND INFANT VIROLOGIC TESTING SCORECARD

Version 1.7

HIV VIRAL LOAD AND INFANT VIROLOGIC TESTING SCORECARD

USER GUIDE

Version 1.7

Methods Used to Evaluate Test Site Operations: Follow the ROAD



Review
the VL/IVT
site
records



Observe
the VL/IVT
site
operations



Ask open-
ended
questions



Discover
the path
of a
specimen



VL/IVT Audit Stages and Requirements

Pre - Assessment

- Identify sites
- Notify sites & agree on audit dates
- Convey importance of the VL/IVT checklist
- Familiarize yourself with the checklist

Assessment

- Introduce audit team to VL/IVT testing lab
- Discuss purpose of audit
- Conduct assessment using the VL/IVT checklist

Post - Assessment

- Debrief with site management on findings & recommendations
- Agree on remedial plan

Follow the ROAD



**Review the
VL/IVT site
records**

- Quality manual, policies, Standard Operating Procedures (SOPs) and other manuals (e.g., safety manual) are complete, current, accurate, and annually reviewed
- Laboratory Records: equipment maintenance records; audit trails, incident reports, logs, personnel files, IQC records, PT records.

Follow the ROAD



Observe the
VL/IVT site
operations

- ▶ Laboratory testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of laboratory testing;
- ▶ Laboratory procedures are appropriate for the testing performed;
- ▶ Nonconformities identified are adequately investigated and resolved within the established timeframe.

Follow the ROAD



Ask open-
ended
questions
the VI/MT
site
operations

- Ask open-ended questions to clarify documentation seen and observations made
- Ask questions like, "show me how..." or "tell me about..."
- An experienced auditor can often learn to answer multiple questions through open-ended questions with the laboratory staff.

Follow the ROAD



Discover
the path of
a
specimen



- Follow a sample through the lab from collection through registration, preparation, analyzing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of laboratory operations.
- Confirm that IQC results are recorded for all IQC runs and reviewed for validation
- Confirm PT results and the results are reviewed and corrective action taken as required.
- Evaluate the quality and efficiency of supporting work areas
- Talk to clinicians to learn the user perspective on the laboratory's performance

Reporting

- Notes should be written neatly and documented
- Scorecard should be properly and fully completed
- Nonconformance forms completed and linked to the specific requirement
- Accuracy of findings verified
- Copy of the report can be given to the laboratory

Dissemination of Audit Findings

Information is provided to:

- ▶ Head of VL/IVT testing laboratory
- ▶ Quality assurance officer
- ▶ VL/IVT testing sites personnel
- ▶ VL/IVT program coordinators
- ▶ Regional/District program coordinator
- ▶ Facility managers
- ▶ Implementing partners

Follow-up to the audit

- Following the audit:
 - ✓ Provide recommendations
 - ✓ Review exit summation report
 - ✓ Plan corrective actions, if necessary
 - ✓ Develop a plan and time frame for corrections
 - ✓ Develop a report



Questions?