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

Shirley Lecher
CDC
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

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

- 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

- 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.

Observe the VL/IVT site operations
Follow the ROAD

- 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

- 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?