

HIV TESTING SITE VISIT REPORT

Site:

Date:

Assessment Team:

Major Findings:

Reacommendations:

HIV ELISA QUALITY SYSTEM VISIT CHECKLIST

Organization

Has the laboratory provided information to the hospital/clinic director about the laboratory quality systems efforts? Yes No

Has the laboratory developed quality policies/policies for the laboratory? Yes No

Has a laboratory quality officer been named? Yes No

Personnel

What is the total number of laboratory staff? _____

How many: lab scientists _____ lab techs _____ and lab assistants _____

How many personnel are trained to perform ELISA? _____

How many: lab scientists _____ lab techs _____

How often does each person perform ELISA testing per month? _____

What support staff is available to the laboratory? _____

Do you have a process in place to monitor personnel performance in performing ELISA? Yes No

What is the total laboratory workload per year? _____

How many HIV tests are performed per month? _____

Equipment

Are Pipettes calibrated? Yes No Frequency _____

Is the reader maintained? Yes No Frequency _____

Is the washer maintained? Yes No Frequency _____

Are refrigerator temperatures monitored? Yes No

Are freezer temperatures monitored? Yes No

Is the centrifuge maintained? Yes No

Purchasing and Inventory

Is refrigerator space adequate for kits? Yes No

Is an inventory control system in place? Yes No

Are you ever unable to perform testing because you do not have kits on hand? Yes No

Are you ever unable to perform testing because of equipment problems? Yes No

How frequently are you unable to perform testing? _____

Is there a policy for what to do when you are unable to perform HIV testing?

Yes No

Process Control

How often are specimens delivered to the laboratory from outside sites? _____

What are your sample acceptance criteria? (e.g. hemolysed, not properly labeled, test request form not completely filled out) _____

How do you process and store specimens prior to testing? _____

Is the testing performed exactly as described in the SOP? Yes No

Are kit controls used to check the validity of each run, and are these results monitored over time? Yes No

Do you run any controls in addition to those provided in the kit? Yes No

Does the laboratory follow the National testing algorithms for HIV rapid and ELISA testing? Yes No

Information Management

What is your data capture system?

- What is your sample registration system?
- How are the worksheets made (maintaining unique patient identification throughout)?
- What is the procedure for transferring results from the printout to the worksheet?
- What is the procedure for transferring results from the worksheet to the testing request form?

Note: Assessor should check observed run and two previous runs (data from reader, log and results sent back to clinic) to assess whether final results are accurately recorded.

Documents and Records

Does the laboratory have a Standard Operating Procedure (SOP) for HIV testing?

Yes No

Does the laboratory have a Quality Manual? Yes No

What is the process for documenting time of receipt and time of dispatch?

Are patient logs maintained in such a manner that a patient result can be tied to a run?

Yes No

Is there an equipment log book, including a record of maintenance? Yes No

Note to assessor - check worksheet for the following information: operator name, date and time of run, control results, kit and lot number, and equipment used(if there is more than one reader/washer?

Occurrence Management

How do you identify and resolve errors? _____

How do you trouble-shoot equipment problems? _____

Assessment

Has the laboratory conducted an internal audit? Yes No

What external quality assessments programs are used by the lab?

Are the results of Internal Quality Control monitored over time? Yes No

Process Improvement

Is corrective action taken for unacceptable IQC results? Yes No

Is corrective action for unacceptable EQA results? Yes No

Customer Service

What is the turnaround time for HIV testing? _____

How often does the lab perform HIV testing? _____

Does the lab have a process for actively seeking customer input? Yes No

How does the lab respond to client concerns?

Facility and Safety

Is laboratory space adequate for all testing needs? Yes No

Is the lab environment suitable for ongoing patient HIV testing (e.g. temperature, electrical supply)? Yes No

Is the laboratory space organized? Yes No

Is the laboratory space clean and safe? Yes No

Is storage adequate? Yes No

Are gloves available and used routinely? Yes No

Are hand washing supplies and sink available in testing area? Yes No

