**Attachment Q**

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| Personnel Responsibilities | |
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| The personnel designated below are responsible for the specified QA duties listed at [Insert Site Name Here]. | |
| **Personnel Responsible for QA** | |
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| **Responsibilities** | **Conducted By (Staff Person)** |
| Develop and update site QA plan | [Insert Name Here] |
| Final approval of site QA plan | [Insert Name Here] |
| Conduct or assign QA tasks, including external control processes, test kit storage, and control unit storage | [Insert Name Here] |
| Provide for test kit distribution and inventory processes | [Insert Name Here] |
| Initial review of QA documentation | [Insert Name Here] |
| Final review of QA documentation | [Insert Name Here] |
| Oversee testing process | [Insert Name Here] |
| Ensure personnel are qualified for assigned duties | [Insert Name Here] |
| Conduct periodic competency evaluation | [Insert Name Here] |
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| **Test Kit Storage** | |
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| [Describe test kit storage location (for example, cabinet 3 in room 102) and storage conditions (for example, cabinet is to be locked or room is to be locked; which personnel have key, or where is key located; where in cabinet thermometer is to be located, etc.)] | |
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| [If a primary site will store test kits for distribution to other satellite sites, describe that process here, including how frequently test kits will be distributed, who is responsible for distribution, and processes for returning test kits to primary site, if any; describe and account for this arrangement in inventory procedures, as well.] | |
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| **Monitoring Test Kit Inventory** | |
| [Describe process for monitoring inventory here, including who will receive deliveries, how they will be documented, how you will track/reconcile tests used with tests remaining, etc. Depending upon inventory control procedures, you shall want to break this down into several distinct responsibilities (see below).] | |
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| **Receive Test Kit Delivery** | |
| Responsibilities | [Describe actions here (e.g., receives boxes, records on inventory log with initials, writes delivery date on box, stores in cabinet, etc.)] |
| When | [Describe when shipment arrives.] |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe problem-solving action here – e.g., if delivery doesn’t match order, if units are expired, etc. – refuse delivery? Contract supervisor? Contact manufacturer?] |
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| **Next Inventory Process Item** | |
| Responsibilities | Inventory and reconcile inventory to Rapid HIV Test Daily Log |
| When | Weekly |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe problem solving action here.] |
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| **Monitoring Test Kit Storage Area Temperature** | |
| Storage area for test kits shall be equipped with an accurate thermometer. A “Test Kit Storage Temperature Log” (see **Attachment L**) shall be posted on storage unit. Test kit storage area shall be continuously maintained within temperature range specified by manufacturer in the package insert. | |
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| **Test Kit Temperature Monitoring** | |
| Responsibilities | Record temperature from thermometer in test kit storage space onto temperature control log. |
| When | 9:00 a.m., Monday through Friday |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here (e.g., report to supervisor, adjust temperature, run controls, etc.) and specify the person responsible.] |
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| **Monitoring Control Unit Storage Area Temperature** | |
| Refrigerated storage area for control units shall be equipped with an accurate thermometer. A “Test Kit Control Storage Temperature Log” shall be posted on storage unit (see **Attachment K**). Control unit storage area shall be continuously maintained within temperature range specified by manufacturer in the package insert. | |
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| **Control Unit Temperature Monitoring** | |
| Responsibilities | Record temperature from thermometer in control unit refrigerator onto temperature control log. |
| When | 9:00 a.m., Monday through Friday |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here and specify the person responsible.] |
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| **Running External Quality Controls** | |
| External quality controls will be run according to the manufacturer’s instructions. Results will be recorded on the “External Kit Control Log” (**Attachment M**). | |
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| **External Controls: New Setting/Change of Conditions** | |
| Responsibilities | Run controls and record results on external quality control log. |
| When | Each new lot of testing kits, new control kits, invalid test results, temperature falls outside the allowable range for storage of test kit device or controls, discordant test results, or if room temperature is outside of allowable range. Conduct external controls every 25 rapid tests. |
| By Whom | Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here (e.g., report to supervisor, do not begin testing, etc.] |
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| **External Controls: New Shipment/Lot** | |
| Responsibilities | Document problem, run controls, and record results on external quality control log. |
| When | When shipment arrives or later, before using the new stock. If later, make sure inventory process includes a step in which arriving boxes are marked to indicate whether controls have been run. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **External Controls: Test Storage Out of Temperature Range** | |
| Responsibilities | Run external controls when maximum/minimum thermometer registers below 35 degrees or above 80 degrees. Suspend rapid HIV testing until controls are run. |
| When | As Needed |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.] |
|  |  |
| **External Controls: Periodic Intervals** | |
| Responsibilities | Run controls every 25 tests based on Rapid Test Daily Log and record on external quality control log. |
| When | Every 25 rapid tests |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.] |
|  | |
| **External Controls: Suspected Test Kit Failure** | |
| Responsibilities | Document problem, run controls, and record results on external quality control log. |
| When | Whenever two invalid tests, more than two positive results in one week, or other event that leads you to believe test kits are not working. Also, see comments in “Out of Temperature Range” chart above. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here - e.g., if controls fail, discontinue client testing, report to supervisor, enter actions taken in troubleshooting log for each step to resolution, etc.] |
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| **Storage** | |
| Current training documentation will remain in personnel files until separation. Other documentation, including QA documents and logs, will be stored for five years. Lab forms and patient records will be stored for 10 years. | |
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| **Review of QA Documentation** | |
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| **Initial Review of QA Documentation** | |
| Responsibilities | Review of all QA logs |
| When | Monthly |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here (for example, follow-up with personnel responsible for documenting QA, document explanation in troubleshooting log, if necessary revise procedures, etc.] |
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| **Final Review of QA Documentation** | |
| Responsibilities | Review all QA logs |
| When | Quarterly |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Updating QA Plan** | |
| QA plan will be updated on an annual basis to ensure compliance with new requirements, and to review and improve existing problems. | |
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| **Update QA Plan** | |
| Responsibilities | Review product package insert for changes in requirements; incorporate changes into policies and procedures; include changes to correct problems for difficulties. |
| When | Annually in December |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Review Update QA Plan** | |
| Responsibilities | Review updated QA plan for compliance with any changes in requirements. |
| When | By January 30 of each year |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Rapid HIV Test Activities Skills Inventory** | |
| Responsibilities | Observe Rapid HIV Test testing techniques |
| When | Rapid HIV testing personnel will be observed at least twice a year conducting rapid HIV test. Each rapid HIV testing personnel will conduct CDC proficiency testing at least once a year. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Safety** | |
| All appropriate safety measures will be observed, in compliance with the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) standards for blood borne pathogens, and Universal Precautions, as outlined by the CDC. | |
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| **OSHA Bloodborne Pathogen Training** | |
| Responsibilities | OSHA training of all staff persons on bloodborne pathogens. Each testing site is required to have an OSHA card or book. |
| When | By January 30 of each year |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **HIPAA Training** | |
| Responsibilities | HIPAA training |
| When | By January 30 of each year |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Biohazard Waste Management Disposal** | |
| Responsibilities | Dispose of biohazard materials (in biohazard trash bags) at medical facility where testing or [insert name of contract agency.] |
| When | When biohazard container is full or as needed. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Exposure Control Plan at Each Testing Site** | |
| Responsibilities | Ensure that a completed copy of the Exposure Control Plan is located at each testing site and that each testing counselor signs an acknowledgement that they receive a personal copy of the Exposure Control Plan. |
| When | Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |
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| **Hepatitis B Vaccine** | |
| Responsibilities | All HIV testing personnel receive the hepatitis B vaccine. Employees who initially decline the hepatitis B vaccination and later decide to accept the vaccination, while still covered under the standard, shall receive the vaccination. All employees who decline the hepatitis B vaccination offered shall sign the OSHA-required waiver indicating their refusal. |
| When | Before testing begins at each site, and counselors shall receive a copy before initiating their first rapid test. |
| By Whom | [Insert name and/or position here of the person responsible for this activity.] |
| Corrective Action(s) | [Describe corrective action here.] |