HCV Rapid Antibody Initial Training and Competency Assessment Checklist: OraQuick® HCV Rapid Antibody Test

<table>
<thead>
<tr>
<th>Competency Category</th>
<th>Performance Indicator</th>
<th>Assessment Tool</th>
<th>Criteria Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>eLearning</td>
<td>New testing personnel up-to-date on eLearning quiz prior to initial training (MyLearning Completion Date: ____________________________)</td>
<td>Exam</td>
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</tbody>
</table>
| Reagent Stability and Storage | Maintains a working knowledge of Divided Pouches and QC Storage:  
  - Records open and expiration dates on Divided Pouch kits and QC boxes, as applicable.  
  - Understands expiration dates of consumables (Divided Pouches – Manufacturer’s Expiration)(QC Vials – 8 weeks at 2-8°C)  
  - Does not use expired reagents.                                                                                                                             | Direct Observation |              |                 |
| QC Performance      | Adheres to QC policies and procedures, including labeling of Developer Solution Vials:  
  - Runs appropriate QC at defined frequency (minimum weekly, opening new kits or QC, two consecutive invalid results, initial training, annually).  
  - Verifies QC is within acceptable limits.  
  - Properly interprets results and completes the QC Log (Internal QC)(QC Pass/Fail)(Dating)(Recording Results).  
  - Adheres to defined Corrective Action for out-of-range QC results.  
  - Demonstrates performance of QC, obtains acceptable results, and properly completes QC Log (see below for Initial Competency). | Direct Observation |              |                 |
| Specimen Collection | States acceptable specimen type (fingerstick whole blood or venipuncture whole blood), and collection and labeling requirements (Developer Solution Vial and Test Device labeled with two patient identifiers or QC information). | Direct Observation |              |                 |
| Routine Patient Testing | Adheres to Patient Testing procedure, as outlined in POCTW026:  
  - Developer Solution Vial and Test Device labeled properly (patient label, two patient identifiers).  
  - Maintains a working knowledge of the steps for testing patient samples (blood in Specimen Collection Loop, mix in Developer Solution, place Test Device, interpret results at 20-40 minutes with timer). | Direct Observation |              |                 |
| Factors Influencing Test Results | Interprets and evaluates test results in regards to test limitations. Refer to SOP for full list:  
  - Oral Specimens are not allowed for the OraQuick® HCV Rapid Antibody Test.  
  - Refers to unit-specific procedures for proper documentation of patient results in Epic. | Direct Observation |              |                 |
| Documentation of Patient Results | - Interprets and evaluates test results appropriately (confirms acceptability of Internal QC on each Test Device).  
  - Completes the HCV Rapid Antibody Test Patient Result Log Sheet for each patient tested.  
  - Refers to unit-specific procedures for proper documentation of patient results in Epic. | Direct Observation |              |                 |
| Problem Solving Skills | Understands interpretation and corrective action for all Invalid test results (review Corrective Action chart).  
  Understands requirement to send specimen for all Reactive test results for confirmatory testing.  
  Understands POCT Office Contact Information (5-2645 M-F; POCT Consult on CORUS; POCTGroup email). | Direct Observation |              |                 |
| Safety              | Adheres to Standard Precautions throughout testing procedures.  
  Discards biohazardous materials according to policies.                                                                                                           |                |              |                 |
| Procedure Review    | Acknowledges ongoing competency requirements (Annual successful completion of both levels of QC and passing eLearning module).  
  Locates and reads the current version of the SOP (POCTW026) – accessing through POCT website or HPO.  
  http://pathology.jhu.edu/department/staff/POCT/procedures.cfm | Direct Observation Operator Acknowledgement |              |                 |

Date: ____________________________  
Unit: ____________________________  
Operator Name: ____________________________  
JHED ID: ____________________________

Operator Initials: ____________________________
### Initial Competency

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>JHED ID</th>
<th>Test Kit</th>
<th>Controls</th>
<th>Testing</th>
<th>QC</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lot #</td>
<td>Exp Date</td>
<td>Lot #</td>
<td>Open Date</td>
<td>Exp Date</td>
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</tbody>
</table>

I have reviewed this checklist with the new operator and observed their completion of QC. POCC/ Trainer Initials signify this operator:

*Is competent to perform HCV testing using the OraQuick® HCV Rapid Antibody Test ________*

*Requires retraining before performing patient testing using the OraQuick® HCV Rapid Antibody Test ________*

Operator Signature: ___________________________ Date: ________________

Trainer Signature: ___________________________ Date: ________________