# JHH Point-of-Care Testing Program

## Waived Testing Quality Control Plan

<table>
<thead>
<tr>
<th>TEST</th>
<th>QC REQUIRED</th>
<th>QC FREQUENCY</th>
<th>RATIONALE</th>
</tr>
</thead>
</table>
| Fecal Occult Blood     | **Internal Procedural Control:** Negative and Positive Performance Monitor | ● Minimally once/week on each opened box/bottle of developer  
 ● With each patient test  
 ● When opening a new box of slides or bottle of developer | ● Manufacturer’s recommendations  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| Gastric pH and Occult Blood | **pH:** External Liquid QC: 2 levels  
 ● **Occult Blood:** Internal Procedural Control: Negative and Positive Performance Monitor | **pH:**  
 ● Once/week on each opened box  
 ● When opening a new box of slides  
 **Occult Blood:**  
 ● Minimally once/week on each opened box/bottle of developer.  
 ● With each patient test  
 ● When opening a new box of slides or bottle of developer | ● Manufacturer’s recommendations  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| Glucose                | **External Liquid QC:** 2 levels                                             | ● Once every 24 hours of patient testing  
 ● Minimally once/week for low volume testing sites | ● Manufacturer’s recommendations  
 ● Joint Commission Waived Testing Standards  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| Hemoglobin             | **External Liquid QC**  
 ● **Red Control Cuvette (RCC)**                                               | ● Once every 24 hours of patient testing  
 ● Minimally once/week for low volume testing sites | ● Manufacturer’s recommendations  
 ● Joint Commission Waived Testing Standards  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| Hemoglobin A1C         | **External Liquid QC:** 2 levels                                             | ● External QC:  
 – Once every 24 hours of patient testing  
 – Minimally once/week for low volume testing sites  
 – With each new lot/shipment of test kits or controls  
 – Anytime an unexpected result is obtained | ● Manufacturer’s recommendations  
 ● Joint Commission Waived Testing Standards  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
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| pH Hydrion    | **External Liquid QC:** 2 levels | ● Once/week on each opened dispenser roll of pH paper  
 ● When opening a new dispenser roll of pH paper or bottle of pH buffer | ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| pH Nitrazine  | **External Liquid QC:** 2 levels | ● Once/week on each opened dispenser roll of pH paper  
 ● When opening a new dispenser roll of pH paper or bottle of pH buffer | ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
| Rapid HIV 1/2 | **Internal Procedural Control**  
 **External Liquid QC:** 3 levels | ● Internal QC:  
 ●   - Each test  
 ●   - External QC:  
 ●     - Once/day of patient testing (Site dependent)  
 ●     - Minimally once/week on each opened test kit box  
 ●     - With each new lot/shipment of test kits or controls  
 ●     - When two consecutive Invalid results are obtained  
 ●     - If there is a change in testing conditions (new location, temperature issues) | ● Manufacturer’s recommendations  
 ● State of Maryland Laboratory Regulations  
 ● Operational  
 ● Good laboratory practice |
| Rapid Strep A | **Internal Procedural Control**  
 **External Liquid QC:** 2 levels | ● Internal QC:  
 ●   - Each test  
 ●   - External QC:  
 ●     - Once/week on each opened test kit box  
 ●     - When a new kit box is opened  
 ●     - With each new lot/shipment of test kits or controls  
 ●     - When two consecutive Invalid results are obtained | ● Manufacturer’s recommendations  
 ● State of Maryland Laboratory Regulations  
 ● Good laboratory practice |
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| Urine Dipstick        | **External Liquid QC:** 2 levels    | • Once/week on each opened bottle of dipsticks  
                        |                                    | • When opening a new bottle of urine dipsticks                        | • State of Maryland Laboratory Regulations  
                        |                                    |                                 | • Good laboratory practice                                         |
| Urine Pregnancy       | **Internal Procedural Control**  
                        | • **External Liquid QC:** 2 levels                                        | • Internal QC:  
                        |                                    | • Each test  
                        |                                    | • External QC:  
                        |                                    | • Once/week on each opened test kit box  
                        |                                    | • When a new kit box is opened                                | • Manufacturer’s recommendations  
                        |                                    |                                 | • State of Maryland Laboratory Regulations  
                        |                                    |                                 | • Good laboratory practice                                         |

Revision: 8/11

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<tr>
<th>Revision Level</th>
<th>Reviewed By</th>
<th>Review Date</th>
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<tbody>
<tr>
<td>8/11</td>
<td>William Clarke</td>
<td>2011.08.23 12:27:15 -04'00'</td>
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</table>

Digitally signed by William Clarke
DN: cn=William Clarke, o=Johns Hopkins Medical Institutions, ou=Department of Pathology, email=wclarke@jhmi.edu, c=US
Date: 2011.08.23 12:27:15 -04'00'