
 <b>American Association for Clinical Chemistry                      Certified Point of Care Testing Professional (CPCTP)                      Detailed Content Outline</b>		<b>Total</b>
<b>1.</b>	<b>Test Selection</b>	<b>40</b>
	<ol style="list-style-type: none"> <li>1. Develop an approval process for new POC testing requests</li> <li>2. Design a POC test method verification study</li> <li>3. Design a POC testing program for managing acutely-ill patients</li> <li>4. Determine the analytical performance of a POC test</li> <li>5. Select a glucose meter technology for the POC measurement of glucose</li> <li>6. Develop a strategy for:                             <ol style="list-style-type: none"> <li>a. POC urinalysis</li> <li>b. POC urine drug testing</li> <li>c. the diagnosis of bacterial vaginosis</li> <li>d. the POC detection of fecal occult blood</li> <li>e. the POC detection of influenza infection</li> <li>f. the POC detection of pregnancy</li> <li>g. the POC detection of Streptococcal infections</li> <li>h. the POC measurement of blood gases, electrolytes, and metabolites</li> <li>i. the POC measurement of cardiac biomarkers</li> <li>j. the POC measurement of coagulation parameters</li> <li>k. the POC measurement of hemoglobin A1c (HbA1c)</li> <li>l. the POC measurement of lipids</li> <li>m. the POC screening of renal dysfunction</li> </ol> </li> </ol>	
<b>2.</b>	<b>Quality Management</b>	<b>80</b>
	<ol style="list-style-type: none"> <li>1. Educate healthcare providers about limitations of POC testing</li> <li>2. Establish a standard operating procedure for a POC test</li> <li>3. Establish components of POC testing report</li> <li>4. Evaluate data to monitor performance of a POC test in comparison to a central laboratory reference method</li> <li>5. Evaluate POC operators for color-blindness</li> <li>6. Implement a document control process for POC testing policies and procedures</li> <li>7. Maintain a controlled testing environment</li> <li>8. Produce utilization reports from the middleware system</li> <li>9. Provide consultation regarding POC results discrepant with clinical signs and symptoms</li> <li>10. Provide consultation to POC operators regarding results that are discrepant from lab values</li> <li>11. Provide initial training to POC operators</li> <li>12. Restore POC operator privileges that have been suspended due to failure to follow procedure</li> <li>13. Review documentation of corrective actions related to quality control (QC) testing failures</li> </ol>	

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<ol style="list-style-type: none"> <li>14. Review proficiency testing results and summaries</li> <li>15. Review quality control testing summary statistics</li> <li>16. Set up a new POC operator profile in middleware to allow for access to POC device</li> <li>17. Assess POC operator competency</li> <li>18. Determine criteria for quality control (QC) lockout</li> <li>19. Develop:             <ol style="list-style-type: none"> <li>a. a corrective action plan to manage POC testing incidents</li> <li>b. a lot management plan</li> <li>c. a plan for critical value reporting</li> <li>d. a POC testing total quality management plan</li> <li>e. an Individualized Quality Control Plan (IQCP) for a POC test</li> <li>f. documentation for POC test results</li> </ol> </li> </ol>	
<b>3. Regulatory Compliance and Safety</b>	<b>30</b>
<ol style="list-style-type: none"> <li>1. Design internal auditing process for inspection readiness</li> <li>2. Develop a biological and chemical exposure plan</li> <li>3. Enroll in a Proficiency Testing (PT) program</li> <li>4. Establish required documentation for off-label use of a POC device</li> <li>5. Identify the complexity of a POC test</li> <li>6. Provide consultation on regulatory requirements for opening a new testing location</li> <li>7. Report device-related adverse events to the FDA</li> <li>8. Respond to vendor/equipment alerts, recalls, and safety bulletins</li> <li>9. Select CLIA-qualified POC laboratory personnel</li> <li>10. Train POC operators on proper instrument cleaning and disinfection procedures</li> <li>11. Update documentation of POC program with the Centers for Medicare and Medicaid Services</li> <li>12. Update POC testing policies and procedures for consistency with Safety Data Sheet</li> </ol>	
<b>Total</b>	<b>150</b>