Mock CLIA Survey	Mark if satisfactory
I. General Administrative & Personnel	
1. Has a CLIA certificate been obtained? If not, has an application been submitted?	✓
2. Does the laboratory's classification accurately reflect testing done i.e. waived, moderate complexity or high complexity?	✓
3. Have all personnel (director, clinical consultant, technical consultant{general/technical supervisor if high complexity} and testing personnel) been listed on the CLIA application form?	✓
4. Are all personnel qualified by CLIA regulations for the duties they perform in the laboratory?	✓
5. Is documentation available for education, experience and special training for all positions covered by the regulations as listed above?	✓
6. Is there a written job description detailing the responsibilities of all personnel in the laboratory?	✓
7. Are there sufficient appropriate personnel to perform the testing workload?	✓
8. Is a system in place and a written procedure available for initial and continued evaluation of the competence of laboratory personnel?	✓
9. Are the Director and Technical Consultant available as required for consultation?	✓
II. Facility and Safety	
10. Is the size and location of the area used for testing appropriate to the testing being done?	✓
11. Is there sufficient work and storage areas for testing to be performed properly and safely?	✓
12. Is there an Exposure Control Plan for Bloodborne Pathogens for the laboratory?	✓
13. Is it readily available to employees and have they been familiarized with its contents?	✓
14. Are universal precautions used in the laboratory?	✓
15. Is appropriate personal protective equipment readily available?	✓
16. Have the staff been trained in their application and use?	✓
17. Is there a Chemical Hygiene Plan for hazardous materials, if needed?	✓
18. Is it readily available to employees and have they been familiarized with its contents?	✓
19. Are Material Safety Data Sheets available for all hazardous materials used in the laboratory?	✓
20. Are all hazardous materials stored appropriately e.g. flammables cabinets, acids and alkali stored separately, etc. and labeled properly?	✓

21. Are all disposable sharps discarded in an appropriate sharps container?	✓
22. Are "red-bag" containers and sharps containers readily available?	✓
23. Is eating, drinking, smoking, application of cosmetics and handling of contact lenses strictly forbidden in laboratory areas?	✓
24. Are pipetting devices available to avoid mouth pipetting?	✓
25. Are refrigerators used for food separate and apart from those used for specimens i.e. no storage of food in laboratory refrigerators or laboratory areas?	✓
26. Are all electrical equipment or appliances up to generally accepted standards of electrical safety?	✓
27. Are fire extinguishers available and in proper working order?	✓
28. Do staff personnel know how to use them?	✓
29. Are laboratory personnel familiar with alternate routes of escape?	✓
III. Patient Test Management	
30. Are all tests requested in writing?	✓
31. If a test is ordered orally, is it followed with a written request within 30 days?	✓
Does the written requisition contain	✓
32. The patient's name and/or other unique identifier?	✓
33. The name or other identifier of the person requesting the test?	✓
34. The test to be performed?	✓
35. The date (and time, if appropriate) of specimen collection?	✓
36. Any additional information to assure accurate and timely testing and reporting of results?	✓
Does the laboratory have and follow written procedures for	✓
37. preparation of the patient?	✓
38. Collection of the specimen?	✓
39. Labeling of the specimen?	✓
40. Preservation and/or transportation of the specimen?	✓
41. Processing of the specimen?	✓

Do laboratory records show	
42. Patient's name or other unique identifier through all phases of testing?	✓
43. Date and time specimen was received in the laboratory?	✓
44. Condition of unacceptable specimen and disposition thereof?	✓
45. Date that all testing was performed?	✓
46. Identity of all personnel performing testing?	✓
Are the results of laboratory testing	
47. released only to authorized persons?	✓
48. reported in timely fashion?	✓
Does the laboratory report contain	
49. the name and address of the laboratory?	✓
50. the test performed?	✓
51. the result?	✓
52. the unit of measurement?	✓
53. the pertinent "normal range" for the test?	✓
54. Does the laboratory have and follow written procedures for reporting imminently life-threatening results?	✓
55. Does laboratory policy prohibit reporting results which exceed the reportable range for the instrument or system?	✓
56. Are test reports maintained in a manner which permits ready identification and timely accessibility?	✓
57. Does the laboratory notify the appropriate person of any errors?	✓
58. Is a corrected report issued?	✓
Are the following records maintained for two years?	✓
59. test requisitions?	✓
60. test reports, including instrument printouts and worksheets, and reports from reference laboratories?	✓

61. corrected reports?	✓
62. documentation of all quality control activities?	✓
63. documentation of all quality assurance activities?	✓
64. Are immunohematology reports (including those from reference laboratories) maintained for five years?	✓
65. Are pathology and Pap smear reports (including those from reference laboratories) maintained for ten years?	✓
IV. Proficiency Testing	
66. Is the laboratory registered with an approved PT provider?	✓
67. Are all regulated assays proficiency tested?	✓
Are PT specimens handled exactly the same way as patient specimens?	✓
68. Introduced into the normal work flow?	✓
69. Assayed same number of replicates as patients?	✓
70. Assayed by same testing personnel as patients?	✓
71. Reported in the same manner as patient specimens i.e. > or < etc.	✓
72. Are copies of PT submissions filed together with applicable instrument printouts to facilitate QA followup?	✓
73. Are PT results reviewed by the director?	✓
74. Are deficiencies investigated and remediation instituted if indicated based on this review?	✓
V. Instrument maintenance	
75. Is an instrument log maintained for each instrument used in the laboratory?	✓
Is the following recorded in the instrument log:	✓
76. Daily and periodic maintenance: procedure and log?	✓
77. Function checks: procedure and log?	✓
78. Scheduled and unscheduled manufacturer's preventive maintenance?	✓
79. Instrument problems and attempts to rectify?	✓
80. Are automatic or semi-automatic pipets checked regularly for accuracy?	✓

81. Are all moderate complexity procedures calibrated or calibration verified every six months?	✓
Is recalibration performed	
82. when quality control shows out of control values, shifts or trends?	✓
83. when a complete change of reagents occurs?	✓
84. after major preventive maintenance procedures?	✓
85. after a critical part of the instrument is changed?	✓
86. more often than every six months if required by the manufacturer?	✓
VI. Procedure manual	
87. Does the laboratory have a procedure manual?	✓
88. Does it contain all procedures performed in the laboratory?	✓
89. Is it accessible and understandable to testing personnel?	✓
90. Do procedures accurately reflect actual laboratory practice?	✓
91. Is the procedure manual reviewed and signed by the director?	✓
92. Are all new procedures or changes in procedure signed by the director?	✓
Does each procedure contain	
93. procedure for obtaining specimens for the test?	✓
94. any special instructions to the patient which may be required?	✓
95. procedure for handling, preservation and storage?	✓
96. criteria for rejection of unacceptable specimens?	✓
97. directions for preparation of reagents, standards, controls, etc. for the test?	✓
98. directions for storing and storage stability of these prepared components?	✓
99. directions for performing the test?	✓
100. special procedural notes or cautions?	✓
101. calculations or other manipulations necessary to obtain the result?	✓
102. normal or expected ranges for the test, panic values, etc.?	✓

103. procedure to follow if quality control is out of range?	✓
104. limits of the procedure, including hemolysis, lipemia, and other preanalytical variables such as drug or disease interferences?	✓
105. linearity or calibration limits?	✓
106. procedure to follow if linearity is exceeded?	✓
107. lowest detectable concentration?	✓
108. literature references?	✓
109. sample handling in the event of instrument or system malfunction?	✓
110. Is each procedure reviewed and signed annually by the director?	✓
111. Are discontinued procedures maintained for two years?	✓
VII. Quality Control	
112. Is a quality control program maintained for all analytes?	✓
Does the QC program specify	✓
113. which controls to assay?	✓
114. how often the controls are run?	✓
115. how acceptable limits are derived?	✓
116. procedures to follow if limits are exceeded?	✓
117. Are temperature controlled spaces monitored each day of use?	✓
118. For room temperature tests, is room temperature monitored?	✓
119. Are acceptable ranges defined for temperature controlled spaces?	✓
120. for room temperature?	✓
121. Are thermometers checked regularly for accuracy?	✓
122. Are timers checked regularly for accuracy?	✓
123. Are controls run in the same manner as patients?	✓
124. Are control values verified as in range prior to commencing patient testing?	✓
125. If not, are patient specimens since the last successful control rerun in case of control failure?	✓

126. Are quality control results reviewed by the director?	
127. Are mean, standard deviation and coefficient of variation calculated regularly for quantitative assays?	✓
128. Are Levy-Jennings or other graphs generated regularly for quantitative assays?	✓
129. Are prepared controls, standards, reagents, stains, etc, labeled as to content, preparation date, storage requirements and expiration date?	✓
130. Are all expired materials discarded on or before the expiration date?	✓
Microbiology:	
145. Are media inspected visually for defects before use?	✓
146. Are sterility and growth support checks performed?	✓
147. If performed by manufacturer to NCCLS standards, are these checks documented for each batch of media?	✓
148. Are results of cultures reported only according to the manufacturer's directions?	✓
149. If identification (definitive) is performed, are catalase, coagulase, oxidase, etc. reagents checked daily for positive and negative reactivity with appropriate control organisms?	✓
For antibiotic sensitivity testing:	
150. Is the concentration of organisms in the inoculum standardized?	N/A
151. Is each new batch of media or discs checked for reactivity prior to use?	N/A
152. Are zones of inhibition sizes checked each day with appropriate control organisms?	N/A
VIII. Quality Assurance	
153. Does the laboratory have a written quality assurance program?	✓
154. Are the effectiveness of policies and procedures periodically evaluated?	✓
155. Does the evaluation identify problems and suggest solutions?	✓
156. Are the solutions monitored to ensure their effectiveness?	✓
157. Are the results of the evaluations discussed with the laboratory staff?	✓
158. Are breakdowns in communications between physicians and laboratory personnel recorded?	✓
159. Are corrective actions taken to remedy these breakdowns?	✓
160. Does the laboratory have a procedure for documenting, investigating and correcting	

complaints about the laboratory?	✓
161. Are regular QA meetings held with laboratory staff?	✓
162. When tests are run on more than one system, is a system in place to evaluate their correlation twice yearly?	✓

Performed By

KWADWO OWUSU-OPORI

LAB OPERATIONS MANAGER