

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1082041	<b>(X3) Date Survey Completed</b>  05/18/2022
<b>Name of Provider or Supplier</b>  Caldwell Memorial Hospital, Inc	<b>Street Address, City, State</b>  411 Main Street, Columbia, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed on May 17, 2022 through May 18, 2022 at Caldwell Memorial Hospital, CLIA ID # 19D1082041. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, policy and procedure manual and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant was complete. Findings: 1. Review of the laboratory's policy for the Clinical Consultant revealed the laboratory did not include the frequency for performance of assessment of duties for the Clinical Consultant. 2. Review of the laboratory's personnel records revealed that Personnel 6 serves as Clinical Consultant 3. Further review of personnel records for Personnel 6 revealed a competency assessment for the duties of Clinical Consultant was not performed. 4. In interview on May 17, 2022 at 11:11 am, the Laboratory Director confirmed the Clinical Consultant policy did not include the frequency of performance of competency assessment. The Laboratory Director further confirmed that a competency assessment was not performed for the duties of the Clinical Consultant.</p>
<b>D5317</b>	<b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to establish current written instructions for providers to maintain the integrity of samples. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not include detailed written instructions for specimen requirements for outside providers. 2. In interview on May 17, 2022 at 12: 19 pm, the Laboratory Director stated the laboratory is currently in the process of updating the specimen requirements due to change of instrumentation. The Laboratory Director confirmed the policy manual did not include specimen requirements for outside providers.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on review of laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure for the BioFire Film Array system. Findings: 1. Review of the laboratory's policy and procedure revealed the laboratory did not have a written procedure to include the following: a) Detailed, written instructions for the BioFire Film Array system to include but not limited to: alternate testing when supply shortages interfere with quality control performance as required by the laboratory 2. In interview on May 17, 2022 at 2:24 pm, the Laboratory Director stated BioFire supplies were backordered and the laboratory was not able to perform quality control. The Laboratory Director further stated the BioFire has an internal control that was within acceptable limits so the laboratory did not perform external quality control due to the shortage of supplies. 3. In interview on May 17, 2022 at 2:24 pm, the Laboratory Director confirmed the above identified policy was not included.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records, patient test records and interview with personnel, the laboratory failed to perform quality control (QC) for the BioFire Torch System testing per their IQCP for one (1) of sixteen (16) months reviewed. Findings:  
1. Observation by surveyor during the laboratory tour on May 17, 2022 at 10:30 am revealed the laboratory utilizes the BioFire Filmarray Torch system for the following virology testing: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, SARS-CoV-2, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae  
2. Review of the laboratory's Individualized Quality Control Plan (IQCP) for the BioFire Torch system revealed external quality control (QC) is performed with each new kit lot number or new shipment with minimal monthly QC or every 30 days.  
3. Review of the laboratory's QC records from January 2021 through April 2022 revealed the laboratory did not perform QC at least every thirty (30) days for the following one (1) of sixteen (16) months reviewed: a) March 2022: QC performed on February 11, 2022 then again on April 1, 2022 (over monthly/every 30 days requirement by eighteen (18) days)  
4. Review of patient test records revealed the laboratory performed testing without external QC for the following five (5) patients:  
a) Sample ID 17145 performed on March 14, 2022 at 3:56 pm  
b) Sample ID 17976 performed on March 17, 2022 at 12:08 pm  
c) Sample ID 18394 performed on March 21, 2022 at 07:58 am  
d) Sample ID 18410 performed on March 21, 2022 at 09:43 am  
e) Sample ID 18681 performed on March 22, 2022 at 10:30 am  
5. In interview on May 17, 2022 at 2:44 pm, the Laboratory Director stated the laboratory did not receive supplies for the BioFire Torch system in time to meet the monthly/every 30 days IQCP requirement. The Laboratory Director further stated the laboratory performed patient testing since the BioFire Torch has internal controls that were within acceptable limits.  
6. In interview on May 17, 2022 at 2:44 pm, the Laboratory Director confirmed the laboratory did not perform external QC as required by laboratory's IQCP.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	<p>director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation by surveyor, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5317.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, patient test records and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform quality control (QC) for the BioFire Torch System testing per their IQCP for one (1) of sixteen (16) months reviewed. Refer to D5445.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultant was complete. Refer to D5209.</p>
<p><b>D6031</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure for the BioFire Film Array system. Refer to D5403.