

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1082041	(X3) Date Survey Completed 01/22/2026
Name of Provider or Supplier Caldwell Memorial Hospital, Inc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	<p>An off-site follow-up survey was performed for Caldwell Memorial Hospital, INC, CLIA ID 19D10831, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories. 1 were cited.</p> <hr/> <p>A Recertification survey was performed at Caldwell Memorial Hospital, CLIA ID 19D1082041, on J. Caldwell Memorial Hospital was found not in compliance with the following CONDITION LEVEL 1 42 CFR 493.803: CONDITION: Successful Participation 42 CFR 493.1403: CONDITION: Laboratory moderate complexity testing: Laboratory Director</p>
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all recopy of the proficiency testing program report forms used by the laboratory to record proficiency test including the attestation statement provided by the PT program, signed by the analyst and the laboratory documenting that proficiency testing samples were tested in the same manner as patient specimens, for two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and proficiency testing records and interview with personnel failed to ensure the proficiency testing attestation statement for Microbiology was signed by the Laboratory Director one (1) of six (6) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Surveys" proficiency testing Vendor's attestation statement must be signed by the Laboratory Director and the laboratory performed any portion of the survey prior to submission of the results to API. 2. Review of the laboratory testing records revealed the laboratory enrolled in the American Proficiency Institute (API) proficiency testing program to verify the accuracy of Microbiology testing. 3. Further review of the laboratory's American</p>

Institute (API) proficiency testing (PT) records revealed the following documentation was not complete. Microbiology 3rd event - Laboratory Director did not sign the attestation statement 4. In interview on 1/22/26 at 12:16 pm, the Laboratory Director confirmed the identified PT event did not have a signed attestation statement.

D2016

SUCCESSFUL PARTICIPATION

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except if one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the performance by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on review of proficiency testing results from American Proficiency Institute (API) and CASPE failed to achieve a score of at least 80% for Aspartate Aminotransferase (AST) in two of three consecutive testing events in 2025, resulting in an initial unsuccessful participation as evidenced. Refer to D2096.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing results from American Proficiency Institute (API) and Casper report 155D, the laboratory failed to achieve a score of at least 80% for Aspartate Aminotransferase (AST) in two of three consecutive events in 2025 resulting in an initial unsuccessful performance. Findings: 1. Review of the laboratory's American Proficiency Institute (API) testing results and CMS Casper 155D report revealed the laboratory's unsatisfactory performance for the following two (2) of six (6) events resulting in the first unsuccessful performance for AST: * 2025 Chemistry Core 2nd event - AST received a score of 0% * 2025 Chemistry Core 3rd event - AST received a score of 60% 2. In interview on January 22, 2026 at 12:16 pm, the Laboratory Director stated the 2nd event was submitted prior to date for submission to API and the 3rd event for AST was repeated within normal time. Laboratory Director confirmed the identified testing events for AST were below 80% in two events in 2025.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS-209 form, personnel records and interview with personnel, the laboratory failed to ensure a competency assessment for personnel serving as Clinical Consultant was performed.

	<p>(1) personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Rep the laboratory has one (1) personnel serving as Clinical Consultant. 2. In interview on January 22, 20: Laboratory Director stated that he recently assumed the position of laboratory director and did not kn competency assessment for Clinical Consultant was required with new personnel taking over as labor Review of the laboratory's personnel records revealed the laboratory did not have documentation of a assessment for personnel serving as Clinical Consultant. 3. In interview on January 22, 2026 at 10:44 Director confirmed the competency assessment for the identified personnel serving as Clinical Consu performed.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the mar instructions and in a manner that provides test results within the laboratory's stated performance speci test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's package insert and laboratory policie well as interview with personnel, the laboratory failed to document the visual inspection of blood cult manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on Janu 38 am revealed the laboratory utilizes BacT/ALERT Adult Blood Culture Collection Kits. 2. Review polices revealed the laboratory does not have a policy related to the visual inspection of blood culture of the manufacturer's package insert revealed "Prior to use, examine the bottles for evidence of dama contamination. Do not use a bottle containing media which exhibits turbidity or excess gas pressure, & possible contamination". 4. Review of the laboratory's records revealed the laboratory did not perform blood culture bottles prior to patient use. 5. In interview on January 22, 2026 at 3:40 pm, the Laborat confirmed the laboratory did not document visual inspections of blood culture bottles received.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this sub overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policy and records and interview with personnel, the Laboratory Direc provide overall management and direction for the laboratory. Refer to D6016.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable 1</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records, and interview with person Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5411</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p>

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records and interview with personnel, the Lab failed to ensure proficiency testing samples are tested as required. Findings: 1. The laboratory failed to ensure proficiency testing attestation statement for Microbiology was signed by the Laboratory Director for all events reviewed. Refer to D2014. 2. The laboratory failed to achieve a score of at least 80% for Aspartate Aminotransferase (AST) in two consecutive events in 2025 resulting in an initial unsuccessful performance. Refer to D2096.

D6030 LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency; process specimens, perform test procedures and report test results promptly and proficiently, and when needed, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, personnel records and interview with personnel, the Laboratory failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209