

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1082041	<b>(X3) Date Survey Completed</b>  03/22/2018
<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 CERTIFICATION SURVEY was performed at Caldwell Memorial Hospital - CLIA # 19D1082041 on March 22, 2018. Caldwell Memorial Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing Moderate Complexity Testing, LABORATORY DIRECTOR
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection according to the manufacturer for fifteen (15) of twenty two (22) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure patient samples for Lactate are analyzed within three (3) minutes according to the manufacturer for fourteen (14) of twenty six (26) patients reviewed. Refer to D5411 II. 4. The laboratory failed to have complete performance specification studies for the Horiba ABX Pentra 400 analyzer. Refer to D5421. 5. The laboratory failed to include in-house quality control (QC) data and pertinent literature to support reduction of the</p>

frequency of QC in their Individualized Quality Control Plan (IQCP). Refer to D5445. 6. The laboratory failed to perform two (2) levels of quality control material each day of patient testing for Chloride. Refer to D5447. 7. The laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Refer to D5791.

**D5401**

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

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written detailed policies for the following: a) Performance specification to include accuracy, precision, reportable range and reference range as well as detailed instructions for how these studies are to be performed and acceptable criteria for each. b) Individualized Quality Control Plan (IQCP) c) Proficiency Testing: How to address unacceptable results as well as failed analytes or events. 2. Interview with Personnel 1 on March 22, 2018 confirmed the procedure manual did not contain the above policies.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
I. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection according to the manufacturer for fifteen (15) of twenty two (22) patients reviewed. Findings: 1. Observation by the surveyor on March 22, 2018 revealed the laboratory was performing PT/INR testing on the Abbott iSTAT Clinical Analyzers. 2. Review of the Abbott iSTAT PT/INR package insert revealed that samples for PT/INR are to be tested within three (3) minutes of collection. 3. Review of patient records from January 2018 revealed the laboratory did not document testing of patient samples for PT/INR within three (3) minutes of collection for the following fifteen (15) patients: Patient 142 - Collected January 3, 2018 at 11:37 am then Resulted January 3, 2018 at 11:43 am - three (3) minutes over the manufacturer's requirement of three (3) minutes Patient 143 - Collected January 3, 2018 at 16:02 pm then Resulted January 3, 2018 at 16:28 pm - twenty three (23) minutes over the manufacturer's requirement of three (3) minutes Patient 144 - Collected January 4, 2018 at 05:30 am then Resulted January 4, 2018 at 05:44 am - eleven (11) minutes over the manufacturer's requirement of three (3) minutes Patient 145 - Collected January 5, 2018 at 05:38 am then Resulted

January 5, 2018 at 06:19 am - thirty eight (38) minutes over the manufacturer's requirement of three (3) minutes Patient 146 - Collected January 5, 2018 at 08:23 am then Resulted January 5, 2018 at 08:33 am - seven (7) minutes over the manufacturer's requirement of three (3) minutes Patient 147 - Collected January 10, 2018 at 13:58 pm then Resulted January 10, 2018 at 14:03 pm - two (2) minutes over the manufacturer's requirement of three (3) minutes Patient 148 - Collected January 14, 2018 at 06:21 am then Resulted January 14, 2018 at 07:27 am - sixty three (63) minutes over the manufacturer's requirement of three (3) minutes Patient 150 - Collected January 18, 2018 at 12:38 pm then Resulted January 18, 2018 at 13:24 pm - forty three (43) minutes over the manufacturer's requirement of three (3) minutes Patient 154 - Collected January 22, 2018 at 06:18 am then Resulted January 22, 2018 at 06:45 am - twenty four (24) minutes over the manufacturer's requirement of three (3) minutes Patient 155 - Collected January 22, 2018 at 10:38 am then Resulted January 22, 2018 at 15:07 pm - four hours sixteen minutes (4 hr 16min) minutes over the manufacturer's requirement of three (3) minutes Patient 156 - Collected January 23, 2018 at 11:49 am then Resulted January 23, 2018 at 11:58 am - six (6) minutes over the manufacturer's requirement of three (3) minutes Patient 157 - Collected January 24, 2018 at 11:23 am then Resulted January 24, 2018 at 11:29 am - three (3) minutes over the manufacturer's requirement of three (3) minutes Patient 158 - Collected January 29, 2018 at 10:50 am then Resulted January 29, 2018 at 11:06 am - thirteen (13) minutes over the manufacturer's requirement of three (3) minutes Patient 159 - Collected January 29, 2018 at 12:15 pm then Resulted January 29, 2018 at 13:03 pm - forty five (45) minutes over the manufacturer's requirement of three (3) minutes Patient 160 - Collected January 30, 2018 at 12:06 pm then Resulted January 30, 2018 at 12:16 pm - seven (7) minutes over the manufacturer's requirement of three (3) minutes 4. In interview on March 22, 2018, Personnel 1 confirmed the above patients were not analyzed within three (3) minutes according to the manufacturer's requirements. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs five hundred (500) PT/INR tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Lactate are analyzed within three (3) minutes according to the manufacturer for fourteen (14) of twenty six (26) patients reviewed. Findings: 1. Observation by the surveyors on March 22, 2018 revealed the laboratory was performing Lactate testing on the Abbott iSTAT Clinical Analyzer. 2. Review of the Abbott iSTAT Lactate package insert revealed that patient samples are to be tested within three (3) minutes of collection. 3. Review of patient records from September 1, 2017 through March 21, 2018 revealed the laboratory did not document testing of patient samples for Lactate within three (3) minutes of collection for the following fourteen (14) patients: Patient 165 - Collected November 26, 2017 at 10:58 am then resulted November 26, 2017 at 13:07 pm - six (6) minutes over the manufacturer's requirement of three (3) minutes Patient 166 - Collected February 9, 2018 at 12:17 pm then resulted February 9, 2018 at 12:28 pm - eight (8) minutes over the manufacturer's requirement of three (3) minutes Patient 167 - Collected September 28, 2017 at 09:26 am then resulted September 28, 2017 at 09:33 am - four (4) minutes over the manufacturer's requirement of three (3) minutes Patient 168 - Collected November 16, 2017 at 11:52 am then resulted November 16, 2017 at 12:03 pm - eight (8) minutes over the manufacturer's requirement of three (3) minutes Patient 169 - Collected December 5, 2017 at 11:23 am then resulted December 5, 2017 at 11:32 am - six (6) minutes over the manufacturer's requirement of three (3) minutes Patient 170 - Collected December 14, 2017 at 11:30 am then resulted December 14, 2017 at 11:34 pm - one (1) minutes over the manufacturer's requirement of three (3) minutes Patient 171 - Collected December 26, 2017 at 15:18 pm then resulted December 26, 2017 at 15:23 pm - two (2) minutes over the manufacturer's requirement of three (3) minutes Patient 172 -

Collected December 27, 2017 at 09:04 am then resulted December 27, 2017 at 09:08 am - one (1) minutes over the manufacturer's requirement of three (3) minutes Patient 173 - Collected January 3, 2018 at 10:02 am then resulted January 3, 2018 at 10:09 am - four (4) minutes over the manufacturer's requirement of three (3) minutes Patient 174 - Collected January 24, 2018 at 16:09 pm then resulted January 24, 2018 at 16:18 pm - six (6) minutes over the manufacturer's requirement of three (3) minutes Patient 175 - Collected January 29, 2018 at 11:20 am then resulted January 29, 2018 at 11:25 am - two (2) minutes over the manufacturer's requirement of three (3) minutes Patient 174 - Collected February 20, 2018 at 11:08 am then resulted February 20, 2018 at 11:12 am - one (1) minutes over the manufacturer's requirement of three (3) minutes Patient 177 - Collected February 26, 2018 at 08:28 am then resulted February 26, 2018 at 08:36 am - five (5) minutes over the manufacturer's requirement of three (3) minutes Patient 178 - Collected March 5, 2018 at 12:20 pm then resulted March 5, 2018 at 12:30 pm - seven (7) minutes over the manufacturer's requirement of three (3) minutes 4. In interview on March 22, 2018, Personnel 1 confirmed the above patients were not analyzed within three (3) minutes according to the manufacturer's requirements. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs fifty (50) Lactate tests annually.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on observation, record review and interview with personnel, the laboratory failed to have complete performance specification studies for the Horiba ABX Pentra 400 analyzer. Findings: 1. Observation by surveyors during laboratory tour on March 22, 2018 revealed the laboratory utilizes a Horiba ABX Pentra 400 analyzer for chemistry testing to include the following tests: \*Complete Metabolic Panel (CMP) - Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium, Chloride, Carbon Dioxide (CO2), Creatinine, Glucose, Sodium, Potassium, Total Bilirubin, Total Protein \*Lipid Panel - Cholesterol (CHOL), Triglyceride (TRIG), High Density Lipoprotein (HDL) \*Amylase, Lipase, C-Reactive Protein (CRP), Magnesium, Uric Acid 2. Review of the laboratory's data revealed the following studies performed: a) Accuracy b) Simple Precision c) Linearities for Reportable Range 3. Review of the laboratory's data revealed the following information was not included: a) Complete Precision: day to day and operator variance b) Reference Range: data to support reference ranges in use 4. In interview on March 22, 2018 at 1030 am, Personnel 1 confirmed the above findings. 5. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs thirteen thousand (13,000) tests annually on the Horiba ABX Pentra 400.

**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, record review, and interview with personnel, the laboratory failed to include in-house quality control (QC) data and pertinent literature to support reduction of the frequency of QC in their Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyors during the laboratory tour on March 22, 2018 revealed the laboratory utilizes the Abbott i-STAT 1 for testing of the following analytes: pH, pCO<sub>2</sub>, pO<sub>2</sub>, Lactate, Troponin (cTnI), Prothrombin Time/International Normalized Ratio (PT/INR), and Brain Natriuretic Peptide (BNP). 2. Review of the IQCP Risk Assessment revealed the laboratory did not include the in-house quality control data and pertinent literature to support the reduction of performing QC to that of the manufacturer. 3. In interview on March 22, 2018, Personnel 1 confirmed the laboratory did not include the in-house data and literature supporting the QC reduction in the IQCP. 4. Review of the Task 1 & 3 form provided to surveyors revealed the laboratory performs the following test volumes annually: a) pH - fifty (50) b) pCO<sub>2</sub> - fifty (50) c) pO<sub>2</sub> - fifty (50) d) Lactate - fifty (50) e) cTnI - six hundred (600) f) PT /INR - five hundred (500) g) BNP - five hundred (500)

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to perform two (2) levels of quality control material each day of patient testing for Chloride. Findings: 1. Observation by surveyors during laboratory tour on March 22, 2018 revealed the laboratory utilizes the Horiba ABX Pentra 400 analyzer with ABX Pentra Clinical Chemistry controls for Chloride testing. 2. Review of the laboratory's Policy and Procedure Manual revealed a policy that stated the laboratory is to run two (2) levels of Quality Controls (QC) daily. 3. Review of QC records from January 1, 2017 through March 22, 2018 revealed the laboratory did not perform two (2) levels of QC prior to patient testing on February 19, 2018. QC was documented on February 18, 2018 at 06:31 am and then on February 19, 2018 at 18:07 pm. 4. Review of the patient records revealed the laboratory performed Chloride testing on the following twenty seven (27) of forty eight (48) patients reviewed: Patient 28 - resulted February 19, 2018 at 06:44 am Patient 29 - resulted February 19, 2018 at 06:48 am Patient 30 - resulted February 19, 2018 at 06:50 am Patient 31 - resulted February 19,

2018 at 06:52 am Patient 32 - resulted February 19, 2018 at 06:54 am Patient 33 - resulted February 19, 2018 at 08:40 am Patient 34 - resulted February 19, 2018 at 09:01 am Patient 35 - resulted February 19, 2018 at 10:12 am Patient 36 - resulted February 19, 2018 at 10:24 am Patient 37 - resulted February 19, 2018 at 10:33 am Patient 38 - resulted February 19, 2018 at 10:37 am Patient 39 - resulted February 19, 2018 at 10:40 am Patient 40 - resulted February 19, 2018 at 11:07 am Patient 41 - resulted February 19, 2018 at 11:09 am Patient 42 - resulted February 19, 2018 at 11:14 am Patient 43 - resulted February 19, 2018 at 11:17 am Patient 44 - resulted February 19, 2018 at 11:46 am Patient 45 - resulted February 19, 2018 at 11:51 am Patient 46 - resulted February 19, 2018 at 11:59 am Patient 47 - resulted February 19, 2018 at 12:10 pm Patient 48 - resulted February 19, 2018 at 12:18 pm Patient 49 - resulted February 19, 2018 at 12:21 pm Patient 50 - resulted February 19, 2018 at 12:29 pm Patient 51 - resulted February 19, 2018 at 12:42 pm Patient 52 - resulted February 19, 2018 at 12:45 pm Patient 53 - resulted February 19, 2018 at 13:26 pm 5. In interview on March 22, 2018 at 3:32 pm, Personnel 1 stated that she was unaware two (2) levels of QC was not performed. Personnel 1 confirmed the above patients were resulted without QC performed.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection according to the manufacturer for fifteen (15) of twenty two (22) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure patient samples for Lactate are analyzed within three (3) minutes according to the manufacturer for fourteen (14) of twenty six (26) patients reviewed. Refer to D5411 II. 4. The laboratory failed to have complete performance specification studies for the Horiba ABX Pentra 400 analyzer. Refer to D5421. 5. The laboratory failed to include in-house quality control (QC) data and pertinent literature to support reduction of the frequency of QC in their Individualized Quality Control Plan (IQCP). Refer to D5445. 6. The laboratory failed to perform two (2) levels of quality control material each day of patient testing for Chloride. Refer to D5447.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

	<p>Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</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)(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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure that patient samples for Prothrombin Time (PT)/ International Normalized Ratio (INR) testing are analyzed within three (3) minutes of collection according to the manufacturer for fifteen (15) of twenty two (22) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure patient samples for Lactate are analyzed within three (3) minutes according to the manufacturer for fourteen (14) of twenty six (26) patients reviewed. Refer to D5411 II.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to include in-house quality control (QC) data and pertinent literature to support reduction of the frequency of QC in their Individualized Quality Control Plan (IQCP). Refer to D5445. 2. The laboratory failed to perform two (2) levels of quality control material each day of patient testing for Chloride. Refer to D5447.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.