

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0465694	<b>(X3) Date Survey Completed</b>  04/04/2018
<b>Name of Provider or Supplier</b>  Little River Memorial Hospital	<b>Street Address, City, State</b>  451 West Locke Street, Ashdown, AR	
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>	<p>On 04/03/18 at 1:00 PM, an entrance conference was conducted with Facility Representatives. The facility was informed the purpose of the visit was to conduct a complaint investigation. On 04/04/18 at 2:45 PM, an exit conference was conducted with Facility Representatives. The findings of the survey were discussed. The Representatives were given an opportunity to present additional information. No additional information was presented. The following conditions were not met: 493.1250 - Analytic Systems 493.1403 - Moderate Complexity Laboratory Director 493.1409 - Technical Consultant</p>
<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 review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy, review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, and interviews with laboratory staff, it was determined the laboratory failed to meet the Condition of analytic systems as evidenced by: D5441 - the laboratory quality control procedures failed to monitor accuracy of test performance D5783 - the laboratory failed to take and document corrective actions when controls failed to meet the labs established acceptable range D5791 - the laboratory failed to follow written policies to monitor, assess, and correct problems in the analytic systems</p>

## CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory quality control (QC) and quality assurance (QA) policies, documented QC reviews, and interviews with laboratory staff, it was determined the laboratory quality control procedures failed to monitor accuracy of test performance. Failure to monitor accuracy of tests had the potential to affect all patient testing. Survey findings include: A. The policy titled "Westgard Rules for Evaluating Out-of Control Situations" included the following Quality Control rule which monitored accuracy of test performance over time: 10: mean Ten consecutive control observations fall on the same side of the mean. This usually indicates systemic error." The policy further stated, "Corrective action must be taken for all observation exceeding the stated rules and patients must be repeated with valid control data prior to turning the results out. All corrective action and the action taken with regard to patient data must be documented." B. The QC Review document for January 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD (standard deviation), CV (coefficient of variation) good on both levels, no shifts or trends noted." C. Through a review of the QC documentation for January 2018 the Surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10: mean : ALP (alkaline phosphatase) Level 1 control was shifted below the mean all month (30 of 30 points); AST (aspartate aminotransferase) Level 2 control was shifted below the mean all month (30 of 30 points); Calcium Level 1 control was shifted below the mean all month (30 of 30 points); Glucose Level 1 and Level 2 controls both shifted below the mean all month (30 of 30 points for each level); Uric Acid Level 2 shifted below the mean 29 of 30 points; Lipase Level 1 and Level 2 Controls shifted below the mean all month (29 of 29 points); Lactase Level 2 control above the mean all month (12 of 12 points); Troponin I Level 1 control below the mean from 1/17/2018 through 1/24/2018 (18 points); Troponin I Level 2 control was shifted below the mean from 1/9/2018 through 1/27/2018 (42 of 42 points); Folate Level 1 control shifted below the mean 1/4/2018 through 1/31/2018 (20 consecutive points); Folate Level 2 control shifted below the mean 1/3/2018 through 1/31/2018 (20 consecutive points); White Blood Cell Level 2 control below mean all month (58 of 58 points); and Platelet Level 2 and 3 controls below mean all month (Level 2 58 of 58 points and Level 3 51 of 51) points. D. The QC Review document for February 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD, CV good on both levels, no shifts or trends noted." E. Through a review of the QC documentation for February 2018 the Surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10:

mean : ALP Level 1 control was shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); AST Level 2 control was shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); Calcium Level 1 control was still shifted below the mean all month which was a continuation of the shift in January (34 of 34 points); Glucose Level 1 and Level 2 controls both still shifted below the mean all month which was a continuation of the shift in January (28 of 28 points for each level); Lipase Level 1 and Level 2 Controls shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); Folate Level 1 control shifted below the mean on 15 of 16 consecutive runs which was a continuation of the shift in January; Folate Level 2 control shifted below the mean all month which was a continuation of the shift in January (16 of 16 consecutive points); Monocytes Level 2 control below mean all month (49 of 49 points); and Platelet Level 2 and 3 controls below mean all month which was a continuation of the shift in January; (Level 2 49 of 49 points and Level 3 44 of 44) points. F. The QC Review document for March 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD, CV good on both levels, no shifts or trends noted." G. Through a review of the QC documentation for March 2018 the Surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10: mean : ALP Level 1 control was shifted below the mean all month which was a continuation of the shift in January and February (43 of 43 points); ALT Level 2 control was shifted below the mean (44 of 46 points); AST Level 2 control was shifted below the mean all month which was a continuation of the shift in January and February (43 of 43 points); Calcium Level 1 control was still shifted below the mean all month which was a continuation of the shift in January and February (45 of 45 points); Lipase Level 1 and Level 2 Controls shifted below the mean all month which was a continuation of the shift in January and February (30 of 30 points); Folate Level 1 control shifted below the mean on 33 of 34 consecutive runs which was a continuation of the shift in January and February; and Troponin I Level 1 control shifted below the mean on 31 of 34 points. H. In an interview at 10:43 AM on 4/4/2018, Laboratory Employee #1, who completed the QC Reviews for January, February, and March 2018, stated she didn't know what a shift was and that she didn't really understand what to look for when doing a quality control review. When the Surveyor informed her that all of that information was in their policy and procedure manual she stated, "I guess I need to get the policy out and study up on it."

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of quality control documentation for January, February, and March of 2018, a review of patient test records, and interviews with laboratory staff, it was determined the laboratory failed to take and document corrective actions when

controls failed to meet the labs established acceptable range. Failure to take and document corrective actions for failed quality control had the potential to affect all patient results reported. Survey findings include: A. The policy titled "Westgard Rules for Evaluating Out-of Control Situations" included the following Quality Control (QC) rules: 1:3s - One control observation exceeds the mean plus or minus 3s limits. Any time a control value falls outside the 3s limits: the run is invalid and may not be reported. 2:2s Two consecutive control observations for the same level exceed the mean plus or minus 2s limit, the run is invalid and may not be reported. This rule also applies to both levels on the same run. 4:1s Four consecutive control observations exceed the same mean plus or minus 1s limit. This is an indication of systemic error; appropriate investigative action should be taken to find and correct the problem. 10: mean Ten consecutive control observations fall on the same side of the mean. This too, usually indicates systemic error." The policy further stated, "Corrective action must be taken for all observation exceeding the stated rules and patients must be repeated with valid control data prior to turning the results out. All corrective action and the action taken with regard to patient data must be documented." B. Through a review of QC documentation for January 2018 it was revealed the following tests had 10: mean failures with no corrective action documented: ALP (alkaline phosphatase); AST (aspartate aminotransferase); Calcium; Glucose; Uric Acid; Lipase; Digoxin; Lactase; Troponin I; Folate; WBC; and Platelets. C. Through a review of QC documentation for February 2018 it was revealed the following tests had 10: mean failures with no corrective action documented: ALP; AST; Calcium; Glucose; Lipase; Folate; Monocytes; and Platelets. D. Through a review of QC documentation for February 2018 and patient test records, it was revealed the following tests had 2:2s failures with no corrective action documented and patients tested: on 2/26/2018 both Level 1 and Level 2 control failed for Vitamin B12 (Patient 1167952 was reported); and on 2/27/2018 Level 1 control failed for Vitamin B12 for the second consecutive time (Patient 1171507 was reported). E. Through a review of QC documentation for February 2018 it was revealed the following tests had 10: mean failures with no corrective action documented: ALP; ALT; AST; Calcium; Lipase; Troponin I; and Folate. F. Through a review of QC documentation for March 2018 and patient test records, it was revealed the following tests had 2:2s failures with no corrective action documented and patients tested: on 3/20/2018 both Level 1 control failed for Free T4 (Patients 1190381, 1174506, 1168157, 1152332, 1199377, and 1190380 were reported); on 3/23/2018 Level 1 control failed for Free T4 (Patients 1147007, 1167565, 1190058, and 1168804 were reported); on 3/24/2018 Level 1 control failed for Free T4 (Patient 1154331 was reported); on 3/14/2018 Level 1 control failed for Vitamin B12 (Patient 1168984 was reported) and on 3/16/2018 Level 1 control failed for Vitamin B12 (Patients 1189073 and 1167587 were reported). G. In an interview on 4/4/2018 at 11:30 AM, Laboratory Employee #1 (as listed on the Employee Identification Worksheet) confirmed the quality control program in use was not flagging QC results that failed the 2:2s rule and further confirmed no corrective actions were documented for these failures or for the 10:mean failures.

**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 review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy, review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, and interviews with laboratory staff, it was determined the laboratory failed to follow written policies to monitor, assess, and correct problems in the analytic systems which had the potential to affect all patient results reported. Survey findings include: A. The Quality Assurance Policy included the following instructions: "Regular review by the Technical Consultant will include quality control data for all instruments and tests done in-house. Control data will be reviewed to ensure that the quality control policy is followed for acceptability of daily controls. The corrective actions log will be reviewed to ensure all corrective actions are documented. Control data will be reviewed for shifts and trends. Analysis of the data will be done to determine the source of the problem and corrective actions taken...All reviews and problems identified will be documented." B. The policy titled "Westgard Rules for Evaluating Out-of Control Situations" included the following Quality Control rules: "1:3s - One control observation exceeds the mean plus or minus 3s limits. Any time a control value falls outside the 3s limits: the run is invalid and may not be reported. 2:2s Two consecutive control observations for the same level exceed the mean plus or minus 2s limit, the run is invalid and may not be reported. This rule also applies to both levels on the same run. 4:1s Four consecutive control observations exceed the same mean plus or minus 1s limit. This is an indication of systemic error; appropriate investigative action should be taken to find and correct the problem. 10: mean Ten consecutive control observations fall on the same side of the mean. This too, usually indicates systemic error." The policy further stated, "Corrective action must be taken for all observation exceeding the stated rules and patients must be repeated with valid control data prior to turning the results out. All corrective action and the action taken with regard to patient data must be documented." C. The Quality Control Design Policy states, "At least monthly, all QC records will be reviewed by the area supervisor or designee. Any corrective action required will be documented. A report or summary of monthly QC data including maintenance logs will be submitted to the Laboratory Director or designee as soon as possible after the end of the month." D. In an interview, at 3:29 PM on 4/3/2018, Laboratory Employee #1 (as listed on the Personnel Identification Worksheet) stated that she had not documented a quality assurance (QA) review or quality control (QC) review since the Technical Consultant left in August of 2017. She further stated that quality assurance has not been done since the Technical Consultant and that she has not printed quality control monthly Levey-Jennings graphs since August 2017. E. The QC Review document for January 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD (standard deviation), CV (coefficient of variation) good on both levels, no shifts or trends noted." F. Through a review of the QC documentation for January 2018 the Surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10: mean : ALP (alkaline phosphatase) Level 1 control was shifted below the mean all month (30 of 30 points); AST (aspartate aminotransferase) Level 2 control was shifted below the mean all month (30 of 30 points); Calcium Level 1 control was shifted below the mean all month (30 of 30 points); Glucose Level 1 and Level 2 controls both shifted below the mean all month (30 of 30 points for each level); Uric Acid Level 2 shifted below the mean 29 of 30 points; Lipase Level 1 and Level 2 Controls shifted below the mean all month (29 of 29 points); Lactase Level 2 control above the mean all month (12 of 12 points); Troponin I Level 1 control below the mean from 1/17/2018 through 1/24/2018 (18 points); Troponin I Level 2 control

was shifted below the mean from 1/9/2018 through 1/27/2018 (42 of 42 points); Folate Level 1 control shifted below the mean 1/4/2018 through 1/31/2018 (20 consecutive points); Folate Level 2 control shifted below the mean 1/3/2018 through 1/31/2018 (20 consecutive points); White Blood Cell Level 2 control below mean all month (58 of 58 points); and Platelet Level 2 and 3 controls below mean all month (Level 2 58 of 58 points and Level 3 51 of 51) points. G. The QC Review document for February 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD, CV good on both levels, no shifts or trends noted." H. Through a review of the QC documentation for February 2018 the Surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10: mean : ALP Level 1 control was shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); AST Level 2 control was shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); Calcium Level 1 control was still shifted below the mean all month which was a continuation of the shift in January (34 of 34 points); Glucose Level 1 and Level 2 controls both still shifted below the mean all month which was a continuation of the shift in January (28 of 28 points for each level); Lipase Level 1 and Level 2 Controls shifted below the mean all month which was a continuation of the shift in January (28 of 28 points); Folate Level 1 control shifted below the mean on 15 of 16 consecutive runs which was a continuation of the shift in January; Folate Level 2 control shifted below the mean all month which was a continuation of the shift in January (16 of 16 consecutive points); Monocytes Level 2 control below mean all month (49 of 49 points); and Platelet Level 2 and 3 controls below mean all month which was a continuation of the shift in January; (Level 2 49 of 49 points and Level 3 44 of 44) points. I. The QC Review document for March 2018 included the following statement for each quantitative test in chemistry, toxicology, endocrinology, hematology, and coagulation: "Both levels within +/- 2 SD, CV good on both levels, no shifts or trends noted." J. Through a review of the QC documentation for March 2018 the surveyor identified the following tests with shifts, as defined by the laboratory quality control policy for 10: mean : ALP Level 1 control was shifted below the mean all month which was a continuation of the shift in January and February (43 of 43 points); ALT Level 2 control was shifted below the mean (44 of 46 points); AST Level 2 control was shifted below the mean all month which was a continuation of the shift in January and February (43 of 43 points); Calcium Level 1 control was still shifted below the mean all month which was a continuation of the shift in January and February (45 of 45 points); Lipase Level 1 and Level 2 Controls shifted below the mean all month which was a continuation of the shift in January and February (30 of 30 points); Folate Level 1 control shifted below the mean on 33 of 34 consecutive runs which was a continuation of the shift in January and February; and Troponin I Level 1 control shifted below the mean on 31 of 34 points. K. In an interview at 10:43 AM on 4/4/2018, Laboratory Employee #1, who completed the QC Reviews for January, February, and March 2018, stated she didn't know what a shift was and that she didn't really understand what to look for when doing a quality control review. When the Surveyor informed her that all of that information was in their policy and procedure manual she stated, "I guess I need to get the policy out and study up on it."

**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:

Based on review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy, review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, and interviews with laboratory staff, it was determined the facility failed to meet the Condition of Moderate Complexity Lab Director in that: D6020 - the laboratory director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services D6021 - the laboratory director failed to ensure quality assessment programs were maintained to assure quality of laboratory services D6025 - the laboratory director failed to ensure patient results were only reported when the system is functioning properly

**D6020**

**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 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 review of laboratory quality control (QC) and quality assurance (QA) policies, documented QC reviews, quality control documentation for January, February, and March of 2018, and interviews with laboratory staff, it was determined the Laboratory Director failed to ensure the quality control program is established and maintained to assure the quality of laboratory services. Failure to assure quality of laboratory services had the potential to affect all patient test results reported. Findings include: A. The laboratory quality control procedures failed to monitor accuracy of test performance as cited at D5441. B. The laboratory failed to take and document corrective actions when controls failed to meet the labs established acceptable range as cited at D5783.

**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 review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy,

	<p>review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, and interviews with laboratory staff, it was determined the Laboratory Director failed to ensure quality assessment programs were maintained to assure quality of laboratory services. Failure to assure quality of laboratory services had the potential to affect all patient test results reported Survey findings follow: The laboratory failed to follow written policies to monitor, assess, and correct problems in the analytic systems as cited at D5791.</p>
<p><b>D6025</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(7)</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)(7) Ensure that patient test results are reported only when the system is functioning properly.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control documentation for January, February, and March of 2018, and through interviews with laboratory staff, it was determined the Laboratory Director failed to ensure patient results were only reported when the system was functioning properly which had the potential to affect all patient testing. Survey findings include: The laboratory failed to take and document corrective actions when controls failed to meet the labs established acceptable range as cited at D5783.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy, review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, review of personnel records for the four current laboratory employees, and interviews with laboratory staff, it was determined the facility failed to meet the Condition of Technical Consultant in that: D6043 - the Technical Consultant failed to ensure remedial actions were taken when quality control did not meet the laboratory's specifications D6044 - the Technical Consultant failed to ensure patient results were not reported until corrective actions had been taken and test systems were functioning properly D6054 - the Technical Consultant failed to evaluate and document competency of personnel who performed moderate complexity testing</p>
<p><b>D6043</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(5)</p>

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:

Based on review of the Quality Assurance Policy, review of the Westgard Rules for Evaluating Out-of Control Situations, review of the Quality Control Design policy, review of documents titled "QC Review" for January, February, and March 2018, review of quality control documentation for January, February, and March 2018, and interviews with laboratory staff, it was determined the Technical Consultant failed to ensure remedial actions were taken when quality control did not meet the laboratory's specifications which could affect all patient test results. Failure to take and document remedial action had the potential to affect all patient test results reported Findings include: A. The laboratory failed to take and document corrective actions when controls failed to meet the labs established acceptable range as cited at D5783. B. The laboratory failed to follow written policies to monitor, assess, and correct problems in the analytic systems as cited at D5791.

**D6044**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on review of quality control documentation for January, February, and March of 2018, and through interviews with laboratory staff, it was determined the Technical Consultant failed to ensure patient results were not reported until corrective actions had been taken and test systems were functioning properly which could affect all patient test results reported. Failure to take and document corrective actions for failed quality control had the potential to affect all patient results reported. Findings follow: The laboratory failed to take and document corrective actions when controls failed to meet the labs established acceptable range as cited at D5783.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel records for the four current laboratory employees and an interview with laboratory staff, it was determined the Technical Consultant failed to evaluate and document competency of personnel who performed moderate complexity testing. Testing performed by personnel who are not competent could affect all patient testing. Survey findings include: A. A review of personnel records revealed three of four Laboratory Employees had not had competency documented in

2017 or 2018. B. The personnel record for Laboratory Employee #1 did not include any competency documentation after 5/21/2015. C. The personnel record for Laboratory Employee #2 did not include any competency documentation after 9/30/2016. D. The personnel record for Laboratory Employee #3 did not include any competency documentation after 7/6/2015. E. The fourth employee was a new hire who had been at the facility less than one month. F. In an interview at 2:49 PM on 4/3/2018 Employee #1 (who is the Laboratory Supervisor, and the only employee of the lab who qualifies as Technical Consultant) confirmed the lack of competency assessments for employees.