

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2074778	<b>(X3) Date Survey Completed</b> 06/25/2018
<b>Name of Provider or Supplier</b> Lodestar Diagnostic Laboratory Inc	<b>Street Address, City, State</b> 11301 Fallbrook Drive #108, Houston, TX	
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>	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of Association of Bioanalysts (AAB) proficiency testing from 2017 and 2018 and confirmed in interview, the laboratory failed to ensure that proficiency testing was performed by all personnel who performed testing. Findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 3 testing personnel. 2. Review of the 2017 and 2018 American Association of Bioanalysts (AAB) proficiency testing for Chemistry revealed all specimens for 4 of 4 PT events were tested by the same testing person (TP#1). 2017 Chemistry 1st event 2017 Chemistry 2nd event 2017 Chemistry 3rd event 2018 Chemistry 1st event 3. Review of the 2017 and 2018 American Association of Bioanalysts (AAB) proficiency testing for Hematology revealed all specimens for 4 of 4 PT events were tested by the same testing person (TP#1). 2017 Hematology 1st event 2017 Hematology 2nd event 2017 Hematology 3rd event 2018 Hematology 1st event 4. An interview with the technical consultant on 6/21/18 at 1030 hours in the office confirmed the above findings. key: CMS - Centers of Medicare and Medicaid Services</p>

<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: A review of the laboratory's Association of Bioanalysts (AAB) proficiency testing from 2017 and 2018 and confirmed in interview, the laboratory quality assessment policies and procedures failed to identify, monitor and correct problems in the general laboratory systems. Refer to D2007</p>
<p><b>D5309</b></p>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory patient records, and confirmed in interview, the laboratory failed to ensure the date and time of collection transcribed onto the laboratory information system matched the information on the patient requisition. Findings were: 1. Review of the laboratory policy Quality Plan Policy approved 11/11/15 revealed "if the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately." 2. Random sampling review of the specimens and specimen requisition (req) received in the laboratory on 06/20/18 revealed 10 of 10 samples when the collection date and time were not transcribed accurately to the laboratory information system. ID Req collection Final report date/time collection date/time 29144 06/20/18 1630 06/20/18 1836 29145 06/20/18 1000 06/20/18 1837 29146 06/20/18 1345 06/20/18 1838 29147 06/20/18 0855 06/20/18 1839 29139 06/20/18 1640 06/20/18 1750 29138 06/19/18 1500 06/20/18 1748 29136 06/20/18 1300 06/20/18 1744 29137 06/20/18 1040 06/20/18 1746 29135 06/20/18 1440 06/20/18 1743 29134 06/20/18 1500 06/20/18 1741 3. An interview with the technical consultant on 6/21/18 at 1505 hours in the laboratory confirmed the above findings. He was unaware the collection date and time were not transcribed accurately.</p>
<p><b>D5400</b></p>	<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>

This CONDITION is not met as evidenced by:  
Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to follow its own policy for reagent handling. Refer to D5415 2. The laboratory failed to ensure that expired reagents were not used to perform patient testing on the Beckman Access2. Refer to D5417A 4. The laboratory failed to follow the manufacturer's instructions for the storage and handling of Audit MicroControls linearity materials for the Olympus AU400. Refer to D5411A 5. The laboratory failed to establish the type, number, and acceptable limits for the calibration verification on the Olympus AU400. Refer to D5437 6. The laboratory failed to follow the manufacturer's instructions to establish its own mean and ranges for the quality controls on the Sysmex XT-2000i hematology analyzer. Refer to D5469 7. The laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Refer to D5783

**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:

A. Based on review of the manufacturer's instructions, surveyor observations, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for the storage and handling of Audit MicroControls linearity materials for the Olympus AU400. Findings were: 1. Review of the laboratory Audit MicroControls Linearity FD General Chemistry Beckman AU (Ref K820M-5) lot 0633A, exp 03/21/2020 package insert revealed under storage and stability: "Linearity FD General Chemistry Beckman AU is stored at 2-8C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer 's instructions and immediately returned to 2-8C. When used to monitor the precision of laboratory testing procedures for its assays, Linearity FD General Chemistry Beckman AU has a reconstituted stability of up to 3 days under the proper storage conditions. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial stability claim. Make sure the contents of the vial are well mixed before use." 2. Surveyor observations on 6/21/18 in the laboratory revealed 1 set of reconstituted Audit MicroControls Linearity FD General Chemistry Beckman AU (Ref K820M-5) lot 0633A, exp 03/21/2020 stored in the laboratory freezer with a notation 'o:11/5/17 RA' on the outside of the box. 3. Review of the 2017 and 2018 calibration verification records revealed the laboratory performed calibration verification for the Beckman AU chemistry analyzer on 5/4/17, 11/3/17, and 5/1/18 using the above lot number of Audit MicroControls Linearity. 4. An interview with testing person #1 on 6/21/18 at 1305 hours acknowledged that the laboratory used 1 set of calibration verification materials opened on 11/5/17, stored frozen, and thawed for the calibration verification performed on 5/1/18. He was unaware that it couldn't be stored frozen after reconstitution and then reused. B. Based on a review of Association of Bioanalysts

(AAB) proficiency testing from 2017 and confirmed in interview, the laboratory failed to follow the manufacturer's instructions that required an active calibration curve for testing Chemistry proficiency samples. Findings were: 1. Review of the laboratory policy Proficiency Testing Handling approved 11/11/15 revealed "all proficiency tests will be handled and tested as routine patient specimens." 2. Review of the laboratory policy for PSA, Total (prostate specific antigen) effective 06/2014 revealed under calibration "an active calibration curve is required for all tests." 3. Review of the 2017 AAB Chemistry PT events laboratory records revealed 1 of 3 events when the laboratory used an expired calibration curve when performing PSA testing. 2017 3rd event PSA-1 9.07 ng/mL CEX (curve expired) PSA-2 17.98 ng/mL CEX (curve expired) 4. An interview with the technical consultant on 6/21/18 at 1045 hours in the office confirmed the above findings. He stated that they don't run patients so did not calibrate.

**D5415**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policy, surveyor observations, and confirmed in interview, the laboratory failed to follow its own policy for reagent handling on the Olympus AU400. Findings were: 1. Review of the lab policy Reagent Policy effect 07 /2014 revealed "'date opened' must be indicated, along with the initials of the technologist when new reagents are put into use." 2. Random sampling review of the reagents on board the Olympus AU400 chemistry analyzer revealed 5 of 5 reagents with no documentation of the date opened nor the initials of the technologist on the opened reagents. Uric Acid (Ref OSR6098) lot 2523, exp 11/1/2018 Total Protein (Ref OSR6155) lot 2549, exp 5/1/19 Bicarbonate (Ref OSR6137) lot 2553, exp 12/1 /18 HDL (Ref OSR6295) lot 2514, exp 11/1/19 ALT (Ref OSR6107) lot 2525, exp 7/1 /19 The laboratory performs 40,000 chemistry tests annually. 3. An interview with the testing person #1 on 6/21/18 at 1540 hours in the laboratory confirmed the above findings. key: HDL - High-density lipoproteins ALT - Alanine transaminase

**D5417**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
A. Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to ensure that expired reagents were not used to perform patient testing on the Beckman Access2 immunoassay analyzer. Findings were: 1. Review of the instructions for use for the following Beckman Coulter reagents revealed under reagents "Stable until the expiration date stated on the

label when stored at 2 to 10C. Stable at 2 to 10C for 28 days after initial use." Access2 FT3 (Free triiodothyronine) (A33730L EN, May 2018) Access2 TSH (Thyroid-stimulating hormone) (B83033 G, June 2017) Access2 FT4 (Free thyroxine) (B01902 H, April 2018) Access2 Testosterone (A33261 M, October 2017) Access2 Estradiol (A56077 M, October 2017) Access2 FSH (Follicle-stimulating hormone) (A83734 H, August 2017) Access2 LH (Luteinizing hormone) (A83753 H, October 2017) Access2 Prolactin (A83772 G, October 2017) 2. Review of the Beckman Coulter Access Substrate instructions for use (386966 H, May 2018) revealed under stability "maximum 14 days (in use)." 3. Random sampling review of Beckman Coulter Access 2 patient printouts from January 2017 - June 2018 revealed 13 of 36 patient printouts with LEX (lot expired); PEX (pack expired); and EXS (substrate expired) flags. acc Analyte Result Access2 flag 28990 FT3 3.12 pg/mL LEX, PEX 26560 TSH 2.39 uIU/mL EXS 26560 FT4 0.68 ng/dL EXS 26449 TSH 2.81 uIU/mL EXS 26449 FT4 0.67 ng/dL EXS 26449 FT3 3.45 pg/mL EXS 26449 Testo 843 ng/dL EXS 26449 Estradiol 67 pg/mL EXS 25569 FSH 11.8 mIU/mL PEX 25046 TSH 2 uIU/mL EXS 25046 Testo 314 ng/dL EXS 25046 Estradiol 72 pg/mL PEX, EXS 25046 FSH 9.53 mIU/mL EXS 25046 LH 7.15 mIU/mL PEX, EXS 24914 Estradiol 107 pg/mL EXS 24738 Estradiol 115 pg/mL EXS 24738 Testo 1575 ng/dL EXS 24603 Estradiol 25 pg/mL EXS 24603 Testo 918 ng/dL EXS 24340 Estradiol 25 pg/mL PEX 24139 TSH 2.83 uIU/mL PEX 23666 Prolactin 9.56 ng/mL LEX, PEX 23382 FSH 1.77 mIU/mL PEX 23382 LH 2.31 mIU/mL PEX 21148 FSH 3.55 mIU/mL PEX 21148 LH 4.05 mIU/mL PEX 4. An interview with testing person #1 on 6/21/18 at 1305 hours in the laboratory confirmed the above findings. B. Based on review of laboratory policy, laboratory records, laboratory patient records, and confirmed in interview, the laboratory failed to ensure expired calibration were not used for patient testing on the Beckman Access 2 immunology analyzer. Findings were: 1. Review of the laboratory policy Quality Plan Policy approved 11/11/15 under calibration and calibration verification revealed "for each applicable test system, the lab will do the following: Perform and document calibration procedures Following the manufacturer's test system instructions, using calibration materials provided or specified and with at least the frequency recommended by the manufacturer." 2. Review of the laboratory policy for the Beckman Access 2 Immunology reagents revealed 5 of 7 assays that require "an active calibration curve is required for all tests..calibration is required every 28 days." Access hTSH (approved 06/2014) Access hFSH (approved 06/2014) Access hLH (approved 06/2014) Access Free T4 (approved 06/2014) Access Free T3 (approved 06/2014) 3. Review of the laboratory policy for the Beckman Access 2 Immunology reagents revealed 2 of 7 assays that require "an active calibration curve is required for all tests..calibration is required every 14 days." Access Testosterone (approved 06/2014) Access Estradiol (approved 06/2014) 4. Random review of the Beckman Coulter Access 2 patient printouts from 2017 and 2018 revealed 10 of 30 patient specimens which were analyzed with expired calibration (CEX). PT accession Analyte Result flag 26993 TSH 0.13 uIU/mL CEX 25728 Testo 167 ng/dL CEX 25728 Estradiol 40 pg/mL CEX 25569 FSH 11.8 mIU/mL CEX 25046 TSH 2 uIU/mL CEX 25046 Testo 314 ng/dL CEX 25046 Estradiol 72 pg/mL CEX 25046 FSH 9.53 mIU/mL CEX 25046 LH 7.15 mIU/mL CEX 24914 Estradiol 107 pg/mL CEX 24340 Testo 241 ng/dL CEX 24340 Estradiol 25 pg/mL CEX 24139 TSH 2.83 uIU/mL CEX 24139 Testo 53 ng/dL CEX 24139 Estradiol 98 pg/mL CEX 23382 FSH 1.77 mIU/mL CEX 23382 LH 2.31 mIU/mL CEX 23056 FT4 0.94 ng/dL CEX 23056 FT3 3.03 pg/mL CEX 23056 TSH 0.99 uIU/mL CEX 21148 FSH 3.55 mIU/mL CEX 21148 LH 4.05 mIU/mL CEX 21148 Testo 28 ng/dL CEX 5. An interview with testing person #1 on 6/21/18 at 1330 hours in the office confirmed the above findings. He assumed that if the controls were within acceptable range, he didn't need to recalibrate prior to testing. key: key: Testo - Testosterone LH - Luteinizing hormone FSH -

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and confirmed in interview, the laboratory failed to establish the type, number, and acceptable limits for the calibration verification on the Olympus AU400 chemistry analyzer. Findings were: 1. Review of the laboratory policy Quality Plan Policy (effective 07/2014) under calibration and calibration verification revealed no documentation of the type, number, and acceptable limits when performing calibration verification on the Olympus AU400. 2. Review of the 2017 and 2018 calibration verification records revealed the laboratory performed calibration verification with Audit MicroControls, lot 06633, exp 3/21/2020 for the Olympus AU400 chemistry analyzer on 5/4/17, 11/3/17, and 5/1/18 with no documentation of the acceptable limits for each analyte. 3. Review of the 5/4/17 calibration verification records revealed the values for each analyte from the package insert (PI) values, lab result, and peer mean for each level and each analyte. The % difference between the peer mean value and lab value revealed varying degrees of percentage from -50% to 218 %. Calibration verification 5/4/17 with Audit Microcontrols lot 06633 Level A PI lab peer % diff ALB 2.5 2.5 2.5 -0.8 ALP 21.0 8.0 16.8 -52.4 ALT 11.7 15.0 11.8 26.7 AST 12.5 31.0 14.5 113.6 TBIL 0.3 0.2 0.2 -18.7 DBIL 0.1 0.1 0.1 -15.9 BUN 4.0 2.0 4.0 -49.6 CAL 4.0 5.8 5.7 2.3 CL 66.3 73.0 74.6 2.1 CHOL 29.9 30.0 29.2 2.8 CO2 3.7 7.0 3.1 129.4 CK 17.5 19.0 17.4 9.4 CREA 0.4 0.6 0.4 49.3 GLU 14.0 47.4 14.9 218.7 HDL 14.5 18.0 17.5 2.7 MG 1.2 1.3 1.3 1.6 PHOS 1.3 1.9 1.3 46.5 K 1.6 1.6 1.5 4.2 NA 75.8 74.0 74.8 -1.0 TP 2.9 3.4 3.2 6.8 TRIG 14.0 20.0 14.8 34.9 UA 1.7 1.7 1.6 3.8 Level B PI lab peer %Diff ALB 3.8 3.8 3.8 -0.3 ALP 423.0 290.0 506.9 -42.8 ALT 133.0 144.0 146.9 -2.0 AST 294.0 288.0 323.9 -11.1 TBIL 8.5 6.9 7.3 -6.1 DBIL 4.0 3.2 3.7 -13.7 BUN 40.0 40.0 40.5 -1.3 CAL 9.0 9.5 9.6 -1.4 CL 105.0 110.0 108.6 1.3 CHOL 205.0 194.0 198.8 -2.4 CO2 11.3 16.0 11.5 38.9 CK 577.0 497.0 637.7 -22.1 CREA 8.9 8.3 8.8 -5.9 GLU 208.0 95.0 205.5 -53.8 HDL 89.5 87.0 101.2 -14.0 MG 3.2 3.4 3.3 1.5 PHOS 6.5 6.9 6.4 8.3 K 3.8 4.0 3.7 8.8 NA 106.0 106.0 106.1 -0.1 TP 5.5 5.4 5.2 4.2 TRIG 281.0 306.0 289.8 5.6 UA 8.8 8.9 9.0 -0.8 Level C PI lab peer %Diff ALB 4.9 4.8 4.9 -2.1 ALP 796.0 774.0 974.7 -20.6 ALT 241.0 250.0 269.8 -7.3 AST 545.0 551.0 600.5 -8.2 TBIL 15.2 11.0 13.5 -18.6 DBIL 6.9 4.5 6.4 -29.9 BUN 73.0 74.0 74.5 -0.6 CAL 12.0 12.7 13.1 -3.3 CL 131.0 148.0 143.5 3.1 CHOL 363.0 359.0 358.0 0.3 CO2 23.8 29.0 20.0 45.2 CK 1049.0 875.0 1170.0 -25.2 CREA 16.3 15.5 16.2 -4.3 GLU 387.0 368.0 383.0 -3.9 HDL 164.0 167.0 177.0 -5.7 MG 5.1 5.2 5.3 -1.3 PHOS 11.3 12.3 11.3 9.2 K 6.0 6.2 5.8 6.7 NA 139.0 141.0 138.0 2.0 TP 7.4 7.5 7.0 6.5 TRIG 518.0 581.0 543.0 7.0 UA 15.2 15.3 15.6 -1.7 Level D PI lab peer %Diff ALB 5.9 5.9 5.8

1.3 ALP 1156.0 1167.0 1411.0 -17.3 ALT 346.0 335.0 384.2 -12.8 AST 750.0 727.0 826.0 -12.0 TBIL 22.0 14.3 19.0 -24.8 DBIL 9.6 5.5 8.7 -36.9 BUN 104.0 104.0 106.0 -1.9 CAL 14.7 15.7 16.3 -3.8 CL 167.0 185.0 176.9 4.6 CHOL 515.0 511.0 505.8 1.0 CO2 37.5 37.0 27.9 32.7 CK 1484.0 1165.0 1645.0 -29.0 CREA 22.9 22.0 22.6 -2.7 GLU 561.0 640.0 549.7 16.4 HDL 224.0 232.0 236.9 -2.1 MG 6.4 7.0 7.0 -0.3 PHOS 15.8 18.1 15.9 13.7 K 8.2 8.6 7.9 8.6 NA 171.0 175.0 169.0 3.5 TP 9.4 9.7 8.8 10.8 TRIG 744.0 891.0 770.0 15.6 UA 21.3 21.4 21.5 0.3 Level E PI lab peer %Diff ALB 7.2 6.5 6.6 -0.8 ALP 1444.0 1441.0 1753.0 -17.8 ALT 436.0 414.0 474.3 -12.7 AST N/A 813.0 914.4 -11.1 TBIL 27.8 17.2 23.3 -26.1 DBIL N/A 6.4 10.4 -38.9 BUN 130.0 127.0 131.3 -3.3 CAL 16.7 18.1 18.8 -3.5 CL N/A 218.0 205.0 6.3 CHOL 639.0 635.0 617.4 2.9 CO2 N/A 43.0 35.2 22.2 CK 1802.0 1547.0 1982.0 -22.0 CREA 30.9 27.4 27.9 -1.7 GLU 702.0 663.0 683.3 -3.0 HDL N/A 287.0 270.4 6.1 MG N/A 8.5 8.4 1.6 PHOS 19.5 22.3 19.7 13.3 K 10.0 10.6 9.7 9.3 NA 197.0 205.0 196.0 4.4 TP 11.1 10.9 10.0 8.6 TRIG 924.0 1079.0 941.0 14.5 UA 26.2 26.6 26.0 2.4 4. An interview with the technical consultant on 6/21/18 at 1340 hours in the laboratory confirmed the above findings. He acknowledged that the laboratory policy should specify the acceptable criteria for the calibration verification. key: ALP - Alkaline Phosphatase TBIL - Total Bilirubin DBIL - Direct Bilirubin CHOL - Cholesterol CL - Chloride CAL - Calcium CK - Creatine Kinase CREA - Creatinine HDL - HDL Cholesterol MG - Magnesium PHOS - Phosphorus K - Potassium NA - Sodium TP - Total Protein TRIG - Triglycerides UA - Uric Acid GLU - Glucose ALB - Albumin

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to establish it's own mean and ranges for the quality controls on the Sysmex XT-2000i hematology analyzer. Findings were: 1. Review of the package insert for the Sysmex echeck hematology controls for Sysmex X-series (CG808126) revealed "the mean assay values for each parameter of e-Check are derived from replicate analyses on whole blood calibrated instrumentation. The mean values obtained on e-Check should be within the expected ranges. The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. These expected ranges should not be used as QC file limits." 2. Review of the laboratory QC records from 03/18 to 05/18 revealed the laboratory used the manufacturer expected range for the following QC lot numbers Level 1 80520801, exp 05/14/18 Level 2 80520802, exp 05/14/18 Level 3 80520803, exp 05/14/18 Level

1 81080801, exp 07/09/18 Level 2 81080802, exp 07/09/18 Level 3 81080803, exp 07/09/18 3. Random sampling review of the laboratory patient records from 03/2018 to 05/2018 revealed the laboratory performed patient testing. 03/22/18 26993 03/30/18 27168 05/08/18 28180 4. An interview with the testing person #1 on 06/25/18 at 1530 hours in the laboratory confirmed the above findings.

**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 a review of Olympus AU400 chemistry analyzer quality control reports for 2018, corrective action logs, patient test logs, and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Findings were: 1. Random review of the Olympus AU400 chemistry analyzer from January 2018 to April 2018 revealed 2 of 5 days when the laboratory had quality control failures and a repeat analysis and calibration were performed as corrective action. 4/17/18 lot 45771 Creatinine lab result 0.7, acceptable range 0.754 - 0.968 Magnesium lab result 0.03, acceptable range 0.849 - 1.53 lot 45772 Creatinine lab result 1.7, acceptable range 1.73 - 2.16 Magnesium lab result 1.0, acceptable range 2.17 - 3.19 lot 45773 Magnesium lab result 2.3, acceptable range 3.44 - 4.0 2/1/18 lot 45771 Glucose lab result 72, acceptable range 54.5 - 67.1 Triglyceride lab result 109, acceptable range 79.4 -105 BUN lab result 18, acceptable range 12.6 - 16.9 Albumin lab result 2.9, acceptable range 2.12 - 6.63 lot 45772 Albumin lab result 3.8, acceptable range 2.96 -3.59 BUN lab result 45, acceptable range 33.6 - 42.9 Glucose lab result 143, acceptable range 109 - 132 Triglyceride lab result 162, acceptable range 119 - 154 2. Review of the 2018 corrective action log revealed no documentation to show that patients prior to the above quality control failures back to the last successful quality control run were evaluated to ensure the accuracy of the patient results reported. 3. Review of the patient test logs from 2018 revealed no documentation of patient remediation on 04/16/18 and 01/30/18. 4/16/18 99027557 99027539 99027533 99027534 1/30/18 99025799 99025800 4. An interview with testing person #1 in the office confirmed the above findings. He stated that he was unaware that he needed to do anything with the patients that were run since the last acceptable QC. key: BUN - blood urea nitrogen

**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 laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory quality assessment policies failed to identify, monitor, and correct problems in the analytic systems as evidenced by: 1. The laboratory failed to follow its own policy for reagent handling. Refer to D5415 2. The laboratory failed to ensure that expired reagents were not used to perform patient testing on the Beckman Access2. Refer to D5417A 3. The laboratory failed to follow the manufacturer's instructions for the storage and handling of Audit MicroControls linearity materials for the Olympus AU400. Refer to D5411 4. The laboratory failed to establish the type, number, and acceptable limits for the calibration verification on the Olympus AU400. Refer to D5437 5. The laboratory failed to follow the manufacturer's instructions to establish it's own mean and ranges for the quality controls on the Sysmex XT-2000i hematology analyzer. Refer to D5469 6. The laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Refer to D5783

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
 Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems developed and used for the Olympus AU400 chemistry analyzer performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D5309, D5411, D5437, D5783

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(7)

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 all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:  
 Based on a review of Olympus AU400 chemistry analyzer quality control reports for 2018, corrective action logs, patient test logs, and confirmed in interview, the laboratory director failed to ensure the laboratory evaluated all patient test results

	<p>obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Refer to D5783</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</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 laboratory policies, testing records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. Refer to D6036, D6042</p>
<p><b>D6036</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Review of manufacturer's instructions, laboratory records, quality control records, and patient test reports, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Findings were: 1. The laboratory failed to follow the manufacturer's instructions for the storage and handling of Audit MicroControls linearity materials for the Olympus AU400. Refer to D5411 2. The laboratory failed to establish the type, number, and acceptable limits for the calibration verification on the Olympus AU400. D5437 3. The laboratory failed to ensure that expired reagents were not used to perform patient testing on the Beckman Access2. Refer to D5417 4. The laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. D5783</p>
<p><b>D6042</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control (QC) records, and confirmed in interview, the laboratory technical consultant failed to ensure that the laboratory followed the manufacturer's instructions to establish it's own mean and ranges for the quality controls on the Sysmex XT-2000i hematology analyzer. Refer to D5469</p>