Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2066157	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medlogic, Llc	340 East Parker Street, Baton Rouge, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Complaint Survey # LA00049879 was performed at Medlogic, LLC-CLIA ID # 19D2066157 on October 30 , 2018 through November 1, 2018. Medlogic, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patients serviced by the laboratory: 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1290 CONDITION: Postanalytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant 42 CFR 493.1771 CONDITION: Inspection Requirements
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place to retain test records. Findings: 1. Observation by surveyors during survey October 30, 2018 through November 1, 2018 revealed the laboratory was unable to provide requested instrument printouts. 2. In interview on October 31, 2018 at 11:47 am, Personnel 4 stated she was unable to locate the requested instrument printouts.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic

	system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. The laboratory failed to obtain a written request from the physician for Chemistry testing for three (3) of ten (10) patients reviewed. Refer to D5301. 2. The laboratory failed to ensure test requisitions included all tests performed at the laboratory. Refer to D5305 I. 3. The laboratory failed to ensure test requisitions included the collection date. Refer to D5305 II. 4. The laboratory failed to ensure patient blood samples for Chemistry and Hematology testing are stored and preserved per manufacturer requirements. Refer to D5311. 5. The laboratory failed to document the date and/or time specimens are received into the laboratory. Refer to 5313. 6. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 7. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to obtain a written request from the physician for Chemistry testing for three (3) of ten (10) patients reviewed. Findings: 1. Review of random selection of patient test requisitions and final test reports for September 2018 and October 2018 revealed the laboratory reported analytes that did not have a written request for the following three (3) patients: Patient 18: Test requisition: Tests selected: Hematology (Complete Blood counts (CBC): manual diff), CRP, and Metabolic panel (includes: BUN, Creatinine, eGFR, Sodium, Potassium, Anion Gap, Chloride, CO2, Calcium, Phosphorus, Magnesium, ALT, AST, ALP, Albumin, Total Bilirubin, Direct Bilirubin, Total Protein, Amylase, Lipase, Ferritin, Folate, Vitamin B12, Vitamin D, and Iron). Patient Final Test Report: Included results for analytes included in the Diabetes Prevention Panel (includes: Glucose, Hemoglobin A1C, Insulin, Growth Hormone, Cortisol, C-peptide), Cardiovascular Panel (includes: HDL, LDL, Cholesterol, Triglycerides, Lipoprotein, Apo A, Apo B) and Hormone Panel (includes: Testosterone, DHEA-S, SHBG, Cortisol, LH, FSH, Growth Hormone, Free T3, Prolactin, Beta hCG, Estradiol, Progesterone, TSH, Total T3, Total T4, and PSA). Patient 111: Test requisition: Tests selected: CBC, Manual Diff, Metabolic panel (includes: BUN, Creatinine, eGFR, Sodium, Potassium, Anion Gap, Chloride, CO2, Calcium, Phosphorus, Magnesium, ALT, AST, ALP, Albumin, Total Bilirubin, Direct Bilirubin, Total Protein, Amylase, Lipase, Ferritin, Folate, Vitamin B12, Vitamin D, and Iron), Diabetes Prevention Panel (includes: Glucose, Hemoglobin A1C, Insulin, Growth Hormone, Cortisol, C-peptide), and Hormone Panel (includes: Testosterone,

	DHEA-S, SHBG, Cortisol, LH, FSH, Growth Hormone, Free T3, Prolactin, Beta hCG, Estradiol, Progesterone, TSH, Total T3, Total T4, and PSA). Patient Final Test Report: Included results for Cardiovascular Panel (includes: HDL, LDL, Cholesterol, Triglycerides, Lipoprotein, Apo A, Apo B) , Homocysteine, and automated differential for CBC. The laboratory did not have documentation that a manual differential for CBC was performed. Patient 116: Reported GGT and N-MID Osteocalcin without test request 2. In interview on October 30, 2018 at 11:50 am, Personnel 3 stated physicians order specific tests. Personnel 3 further stated all samples are not tested for all analytes, Wellness Panel, unless ordered. Wellness Panel includes: Hematology Panel, Inflammation (CRP and Homocysteine), Metabolic Panel, Diabetes Prevention Panel, Cardiovascular Panel, and Hormone Panel.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure test requisitions included all tests performed at the laboratory. Findings: 1. Review of the laboratory's test requisitions revealed the following tests were not included: GGT,TIBC, Transferrin. 2. In interview on October 31, 2018 at 1:07 pm, Personnel 2 stated the laboratory performs GGT and TIBC testing. Personnel 2 further stated the laboratory's requisition forms need to be updated to include GGT and TIBC. II. Based on record review and interview with personnel, the laboratory failed to ensure test requistions included the collection date. Findings: 1. Review of random selection of patient test requisitions revealed the collection date was not included for the following two (2) patients: Patient 17 Patient 110 2. In interview on October 31, 2018, Personnel 4 stated the collection date should be documented on all requisitions.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure patient blood samples for Chemistry and Hematology testing are stored and preserved per manufacturer requirements. Findings: 1. Observation by surveyor on October 31, 2018 at 10:33 am revealed the laboratory receives blood samples via United Parcel Service (UPS) in a styrofoam cooler with ice packs. Further observation revealed laboratory personnel taking the temperature of the styrofoam container once opened; however, this temperature was not documented. 2. Review of the Chemistry and Hematology package inserts revealed the following: a) Beckman Coulter Access 2 for testing of Insulin, Growth Hormone, Cortisol, Testosterone, DHEA-sulfate, SHBG, Luteinizing Hormone, FSH, Free T3, Prolactin, Beta-hCG, Estradiol, Progesterone, TSH, Total T3, Total T4, PSA, Ferritin, Folate, Vitamin B12, Vitamin D: "If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." b) AU 480: b1) Creatinine: serum stable for 24 hours at refrigerated temperature and several months when frozen at -20 degrees Celsius. b2) Direct Bilirubin: should be analyzed within two (2) hours of collection if kept at room temperature in the dark and within twelve (12) hours if kept refrigerated (2-8 degrees Celsius) and protected from light. Bilirubin in serum is stable for three (3) months frozen (-20 degrees Celsius) and protected from light. b3) Total Bilirubin: should be analyzed within two (2) hours of collection if kept at room temperature in the dark and within twelve (12) hours if kept refrigerated (2-8 degrees Celsius) and protected from light. Bilirubin in serum is stable for three (3) months frozen (-20 degrees Celsius) and protected from light. b4) Magnesium: use fresh , unhemolyzed serum or heparinzed plasma b5) Lipoprotein (a): after sampling, the test should be performed without delay. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20 degrees Celsius or below. b6) Homocysteine: place all specimens (serum and plasma on ice after collection and prior to processing. All specimens may be kept on ice for up to 6 hours prior to separation by centrifugation. Separate red blood cells from serum of plasma by centrifugation and transfer to a sample cup or other clean container. Specimens not placed on ice immediately may exhibit a 10-20 % increase in homocysteine concentration. If the assay will be performed within 2 weeks after collected, the specimen should be stored at 2-8 degrees Celsius. If the testing will be delayed more than 2 weeks, should be stored frozen at -20 degrees Celsius or colder. c)Medonic M-series (CBC): "Stable at room temperature for 48 hours." 4. The laboratory did not provide surveyors with reagent inserts for the following analytes: Sodium, Potassium, Chloride 5. Further observation by surveyor on October 31, 2018 at 10:51 am revealed Personnel 3 received the following seven (7) samples: Patients 39-45 (collection dates: 10/30/18; tests ordered Complete Wellness Panel includes CBC). Surveyor observed Personnel 3 place the identified seven (7) samples in the refrigerator after accessioning was complete. 6. In interview on October 31, 2018 at 10:38 am, Personnel 3 stated all specimens should be received at 2-8 degrees Celsius, no other handling requirements were used for specimen acceptability. Personnel 3 further stated the laboratory does not document the temperature of samples upon receipt. 7. Observation by surveyor on November 1, 2018 at 11:40 am revealed the identified seven (7) samples in the refrigerator, exceeding the stated manufacturer stated sample handling requirements. 9. Review of the laboratory's Task 1 and 3 forms revealed the laboratory did not include the annual volumes for each.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)

	The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to document the date and/or time specimens are received into the laboratory. Findings: 1. Observation by surveyor on October 31, 2018 at 10:33 am, revealed shipments of blood samples are received in the laboratory via United Parcel Service (UPS) from outside providers. 2. Review of random patient test requisitions from September 2018 to October 2018 revealed the laboratory did not have documentation of the date and/or time of specimen receipt for the following patients: Patient 11 Patient 13 Patients 17-21 Patients 33 Patient 39 Patient 120 Patient 122 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for receipt of specimens. 4. In interview on October 31, 2018 at 10:33 am, Personnel 3 stated the laboratory labels requisitions with the date of sample receipt. Personnel 3 confirmed the laboratory does not document the time of sample receipt.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes the following instruments for Chemistry and Hematology testing: a) AU 480: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C Reactive Protein (CRP), Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). b) Access 2: Insulin, Growth Hormone, Cortisol, Testosterone, DHEA-sulfate, SHBG, Luteinizing Hormone, FSH, Free T3, Prolactin, Beta-hCG, Estradiol, Progesterone, TSH, Total T3, Total T4, PSA, Ferritin, Folate, Vitamin B12, Vitamin D. c) Medonic M Series: Complete Blood Counts (CBC) 2. Review of the "Specimen Collection and Preparation" document revealed the following information was not included for each instrument used for Chemistry and Hematology patient testing: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. 3. In interview on October 30, 2018, Personnel 3 stated the laboratory provides clients the "Specimen Collection and Preparation" document.

D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a Quality Assurance Policy to identify any of the deficiencies identified with the preanalytic system. 2. The laboratory failed to obtain a written request from the physician for Chemistry testing for three (3) of ten (10) patients reviewed. Refer to D5301. 3. The laboratory failed to ensure test requisitions included all tests performed at the laboratory. Refer to D5305 I. 4. The laboratory failed to ensure test requisitions included the collection date. Refer to D5305 II. 5. The laboratory failed to ensure patient blood samples for Chemistry and Hematology testing are stored and preserved per manufacturer requirements. Refer to D5311. 6. The laboratory failed to document the date and/or time specimens are received into the laboratory. Refer to 5313. 7. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to address flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Refer to D5411 I. 4. The laboratory failed to address flags appearing on Chemistry results per manufacturer requirements. Refer to D5411 II. 5. The laboratory failed to address flags appearing on Endocrinology results per manufacturer requirements. Refer to D5411 III. 6. The laboratory failed to ensure patient samples for Chemistry were tested per manufacturer's requirements. Refer to D5411 IV. 7. The laboratory failed to ensure patient samples for Hematology were tested per manufacturer's requirements. Refer to D5411 V. 8. the laboratory failed to mix Hematology controls per manufacturer requirements. Refer to D5411 VI. 9. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 10. The laboratory failed to have complete performance verification studies for Chemistry testing. Refer

	to D5421 I. 11. The laboratory failed to have complete performance verification studies for Hematology testing. Refer to D5421 II. 12. The laboratory failed to establish calibration procedures for Hematology testing. Refer to D5425 I. 13. The laboratory failed to establish calibration procedures for Sodium, Potassium, and Chloride testing. Refer to D5425 II. 14. The laboratory failed to establish quality control procedures that monitor accuracy and precision for Chemistry testing to detect immediate errors. Refer to D5441. 15. the laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by manufacturer. Refer to D5469. 16. The laboratory failed to perform corrective action when quality control was unacceptable for Hematology testing. Refer to D5783 I. 17. The laboratory failed to perform corrective action when quality control was unacceptable for Chemistry testing. Refer to D5783 II. 18. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. 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 establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory did not have written policies and procedures that included: a) Complete Blood Counts (CBC) flagging issues that occur on the Medonic M-series instrument, to include what alternate methods/actions are required b) Complaints to include how to address, document and handle complaints or problems reported to the laboratory 2. In interview on October 31, 2018 at approximately 1:00 pm, Personnel 2 stated the laboratory's policies were being updated.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory did not have written policies for Chemistry (AU 480 and Access 2) and Hematology testing that included the following: a) Detailed policies and procedures for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection that meet manufacturer requirements for each specialty and/or instrument b) Calibration and calibration verification procedures for each specialty and/or instrument c) Quality Control for each specialty and/or instrument to include: The establishing of means and ranges for quality control material, to include but not limited to: How to establish ranges for quality control material and/or verification of quality control material; who is to monitor and how changes are to be made to the ranges of quality control material; and that the correct means and ranges are available to testing personnel. d) Corrective Action throughout all phases of testing e) Reference Ranges for all analytes tested f) Critical values, to include defining of laboratory's critical alert values and how to report critical/panic values for each specialty and/or instrument 2. In interview on October 31, 2018 at approximately 1:00 pm, Personnel 2 stated the policies were being updated.
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 address flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on October 30, 2018 revealed the laboratory utilizes a Medonic M-series instrument for measuring Complete Blood Counts (CBC). 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy to address instrument flags. 3. Review of the Medonic M-series procedure manual revealed the following messages and instructions for flags appearing on patient test reports: a) BD: Indicator: High interference between WBC populations. Do Manual Diff. b) OM Indicator: Only one WBC population found. Do Manual Diff 4. Review of random selection of patient instrument printouts from September and October 2018 revealed the following nine (9) patients were reported without addressing flags per manufacturer's instructions: September 19, 2018: Patients 1 and 2 OM flags Patient 110: OM flags September 20, 2018: Patients 3 and 4: OM flags Patient 5: BD flag Patient 6: OM flag Patient 7: BD flag Patient 8: OM flag October 6, 2018: Patient 9: OM flag 5. In interview on October 30, 2018 at 11:50 am, Personnel 3 stated manual differentials are sent out. 6. In further interview on October 31, 2018 at 3:30 pm, Personnel 3 restated CBC results that have slide reviews advised are sent out for

manual differentials; however, no documentation that the identified patients had any further actions performed was found. II. Based on observation, record review, and interview with personnel, the laboratory failed to address flags appearing on Chemistry results per manufacturer requirements. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes the AU 480 for testing of the following Chemistry analytes: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C Reactive Protein (CRP), Homocysteine, Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). 2. In interview on October 31, 2018 at 1:07 pm, Personnel 2 stated the laboratory no longer performs eGFR and C-peptide testing. Personnel 2 did not provide surveyors with the date testing was discontinued. 3. Review of the AU 480's instrument manual's "Summary of Error Flags" section revealed the following flags: a) (: Shortage of wash solution for contamination parameters b) ba: Calibration expired c) !: Unable to calculate concentration d) F: Result is higher than the dynamic range e) ph: Result is higher than upper panic value f) /: Test pending or not analyzed g) r: Data transmitted to host h) #: Insufficient sample 4. Review of random selection of patient instrument printouts from September 2018 and October 2018 revealed the following ten (10) patients were reported without instrument flags addressed: September 15, 2018: Patient 17: Lipoprotein (Lp(a)): / Patients 23-30: Lp(a): / September 28, 2018 Patient 110: "/" flag: Hemoglobin A1C, Lp(a), and Homocysteine. The laboratory reported results as "QNS." Further review revealed a total of twelve (12) patients were reported with "/" flag for Hemoglobin A1C, Lp(a), and Homocysteine. October 12, 2018: Patient 16: "(" for all analytes except Lipase and Triglycerides. Additional flags: "ph"flag : Potassium and Sodium. "ba" flag: Lipoprotein. "/" flag : Lipase and Triglycerides. "F" flag: Sodium. "!" flag: Apoprotein B. Patient 19: "(" for all analytes except Lipase and Triglycerides. Additional flags: "ph" flag: Potassium and Sodium. "ba" flag: Lipoprotein. "/" flag: Lipase and Triglycerides. "F" flag: CO2 and Sodium. "!" flag: Apoprotein B. Patient 20: "/" flag: AST, CRP, HDL, Homocysteine, Transferrin, Calcium, Direct Bilirubin, GGT, Magnesium, Lipase, Triglyceride, CO2, Total Bilirubin, Iron, Phosphorus, Apo A, amylase, Cholesterol, BUN, Total Protein, Apo B. "(" flag: Albumin, Glucose, Potassium, ALT, Chloride, Alkaline Phosphatase, Lipoprotein, Hemoglobin A1c, and Sodium. "ph" flag: Potassium and Sodium. "F" flag: Sodium Patients 31-34: "(, !, ba, ph, and F" flags present 5. In interview on November 1, 2018 a 11:40 pm, Personnel 3 stated the "r" flags meant the results were reprinted. III. Based on observation, record review, and interview with personnel, the laboratory failed to address flags appearing on Endocrinology results per manufacturer requirements. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes the Access 2 for testing of the following analytes: Progesterone, FSH, LH, Cortisol, Ferritin, Prolactin, Total T4, Folate, Total T3, Vitamin B12, Vitamin D, Testosterone, free T3, Growth Hormone, DHEA-S, Estradiol, hCG, and TSH. 2. In interview on October 31, 2018 at 1:07 pm, Personnel 2 stated the laboratory no longer performs Cortisol and Growth Hormone testing. Personnel 2 did not provide surveyors with the date testing was discontinued. 3. Review of the Access 2's instrument manual under "Troubleshooting" section revealed the following flags and corrective actions: a) CLT: An obstruction was detected. Corrective Action: Review the Event Log and troubleshoot according to the error events with a similar date and time to this event.

Repeat the test. If the problem persists, contact Technical Support. b) QNS: The sample volume is insufficient. Additional tests will not be scheduled for this sample. Tests already scheduled will be completed. Corrective Action: Follow the troubleshooting instructions for the QNS even in the Event Log. Repeat the test(s). If the problem persists, contact Technical Support. c) SYS: A device error occurred during processing. Corrective Action: Review the Event Log and troubleshoot according to the error events with a similar date and time to this event. Repeat the test (s). If the problem persists, contact Technical Support. d) IND: For sandwich assays, the result is at the low end of the analyte concentration curve. The result cannot be distinguished from a system failure because the RLU reading or concentration is too low. For competitive assays, the result is either the high or low end of the analyte concentration curve. The result cannot be be distinguished from a system failure because the RLU reading or concentration is either too high or too low. Corrective Action: Review the Event Log for error events with a similar date and time to this event. If event s occurred, troubleshoot. Run controls, then repeat the test. If the controls are not in range, troubleshoot. If you have questions about the result, or if the problem persists, contact Technical Support. e) QSD: Insufficient reagent volume was dispensed into an RV. Corrective Actions: review the Event Log and troubleshoot according to the error events with a similar date and time to this event. Run cancelled tests again. If the problem persists, contact Technical Support. 4. Review of random selection of patient instrument printouts and final reports revealed the following three (3) patients were reported without instrument flags addressed per manufacturer requirements: October 11, 2018: Patient 20: CLT flag for all analytes except hCG. SYS flag for hCG. The laboratory reported the results on 10/18/18 as "QNS." Patient 21: IND flag for Vitamin D. The laboratory reported on 10/16/18 a value for Estradiol and "QNS" for all other analytes. October 12, 2018: Patient 117: QSD flag for Free T3. The laboratory reported on 10/25/18; however, the Free T3 test was not included. 5. In interview on October 30, 2018 at 2:38 pm, Personnel 3 stated the laboratory only utilizes "QNS" for samples that quantity was insufficient. IV. Based on observation, record review, and interview with personnel, the laboratory failed to ensure patient samples for Chemistry were tested per manufacturer's requirements. Findings: 1. Observation by surveyors during laboratory tour revealed the laboratory utilizes the following analyzers for Chemistry testing: a) AU 480: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C Reactive Protein (CRP), Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). b) Access 2: Progesterone, FSH, LH, Cortisol, Ferritin, Prolactin, Total T4, Folate, Total T3, Vitamin B12, Vitamin D, Testosterone, free T3, Growth Hormone, DHEA-S, Estradiol, hCG, and TSH. 2. In interview on October 30, 2018 at 12:00 pm, Personnel 3 stated samples are tested when they are received. Personnel 3 stated the laboratory does not batch test. 3. Observation by surveyor on October 31, 2018 at 10:33 am revealed the laboratory receives blood samples via United Parcel Service (UPS) in a styrofoam cooler with ice packs. 4. Further observation by surveyor on October 31, 2018 at 10:51 am revealed Personnel 3 placed the following seven (7) samples in the refrigerator after accessioning was complete: Patients 39-45 Documented collection date: 10/30/18, Tests ordered Complete Wellness Panel, includes all Chemistry analytes. 5. In interview on October 31, 2018 at 10:51 am, Personnel 3 stated samples were being stored in the refrigerator as she was waiting for a shipment of CBC

controls. 6. In interview on November 1, 2018 at 10:09 am, Personnel 2 and Personnel 3 stated the laboratory utilizes Pointe Scientific reagents for the AU 480 and Beckman Coulter reagents for the Access 2. 7. Review of the Pointe Scientific reagent package inserts revealed the following: a) Creatinine: serum stable for 24 hours at refrigerated temperature and several months when frozen at -20 degrees Celsius. b) Direct Bilirubin: should be analyzed within two (2) hours of collection if kept at room temperature in the dark and within twelve (12) hours if kept refrigerated (2-8 degrees Celsius) and protected from light. Bilirubin in serum is stable for three (3) months frozen (-20 degrees Celsius) and protected from light. c) Total Bilirubin: should be analyzed within two (2) hours of collection if kept at room temperature in the dark and within twelve (12) hours if kept refrigerated (2-8 degrees Celsius) and protected from light. Bilirubin in serum is stable for three (3) months frozen (-20 degrees Celsius) and protected from light. d) Magnesium: use fresh , unhemolyzed serum or heparinzed plasma e) Lipoprotein (a): after sampling, the test should be performed without delay. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20 degrees Celsius or below. 8. Review of the Beckman Coulter Access reagent package inserts revealed " If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20 degrees Celsius or colder." 9. In interview on November 1, 2018 at 12:18 pm, Personnel 3 stated the identified seven (7) patients were still stored in the refrigerator as controls were not received as of yet. 10. Review of random selection of patient test records from September 2018 and October 2018 revealed the following patients were tested outside of the manufacturer's requirements: Patient 18: Collection date:9/ /18 (Date of Service: 9/13/18, Instrument printout AU 480: 09/15/18 Patient 19: Collection date: 10 /05/18, Instrument test date for the AU 480: 10/18/18 Patient 33: Collection date: 10 /05/18, Instrument test date for the Access 2: 10/11/18 Patient 71: Collection date: 10 /04/18. Instrument test date for the Access 2: 10/10/18 Patient 117: Collection date: 10 /10/18, Instrument test date for the Access 2: 10/12/18 V. Based on observation, record review, and interview with personnel, the laboratory failed to ensure patient samples for Hematology were tested per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory tour on October 30, 2018 revealed the laboratory utilizes a Medonic M-series instrument for measuring Complete Blood Counts (CBC). 2. Review of the Medonic user's manual revealed the following: "Stable at room temperature for 48 hours. For optimum results, the sample should be gently mixed for 10-15 minutes on a mixer, and should be analyzed between 15 minutes and 6 hours stored at room temperature." 3. Observation by surveyor on October 31, 2018 at 10:51 am revealed Personnel 3 placed the following seven (7) samples in the refrigerator after accessioning was complete: Patients 39-45 Documented collection date: 10/30/18, Tests ordered Complete Wellness Panel, includes CBC. 4. In interview on October 31, 2018 at 10:51 am, Personnel 3 stated samples were being stored in the refrigerator as she was waiting for a shipment of CBC controls. 5. In interview on November 1, 2018 at 12:18 pm, Personnel 3 stated the patients were still stored in the refrigerator as the controls were not received as of yet. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory did not include the annual volumes for each test. VI. Based on observation, record review and interview with personnel, the laboratory failed to mix Hematology controls per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on October 30, 2018 revealed Complete Blood Counts (CBC) controls were on mechanical rocker. 2. Review of the Boule Con-Diff Tri-Level package insert under "Instructions For Use" section revealed : a) "Remove Boule Con-Diff Hematology control from refrigeration and allow to warm to room temperature for 30 minutes before mixing. b) Mix by hand as follows: b1) Roll the tube or vial slowly between the palms of the hands 15-20 seconds in an upright position b2) Invert the tube and

	slowly roll it back and forth for another 15-20 seconds b3) DO NOT MIX MECHANICALLY b4) Continue to mix in this manner until all cells are completely suspended. Tubes stored for a long time may require extra mixing b5) Gently invert the tube 8 times immediately before sampling. 3. In interview on October 30, 2018, Personnel 3 confirmed CBC controls are placed on the mechanical rocker.
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: Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on October 30, 2018 revealed the following expired items: a) BD Vacutainer SST blood collection tubes, Lot # 7265894, Expiration date: 2018-09-30, Quantity: eleven (11) tubes b) BD Vacutainer SST blood collection tubes, Lot # 7242599, Expiration date: 2018-08-31, Quantity: seven (7) tubes c) BD Vacutainer Push Button Blood Collection Set, Lot # 6265883, Expiration date: 2018-09-30, Quantity: one (1) box d) Boule MPA Micropipettes, Lot # 1531503, Expiration date: 2018-05, Quantity: one (1) vial 2. In interview on October 30, 2018 at 12:04 pm, Personnel 3 stated she did not know how long the identified blood collection tubes had been stored in the drawer. Personnel 3 stated samples are not collected in-house, the laboratory ships blood collection supplies to their clients. 3. In further interview on October 30, 2018 at 12:15 pm, Personnel 3 stated the laboratory does not use the Boule Micropipettes.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on October 30, 2018 revealed the laboratory utilizes the following instruments for Chemistry testing: a) AU 480: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C

	Reactive Protein (CRP), Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). b) Access 2: Progesterone, FSH, LH, Cortisol, Ferritin, Prolactin, Total T4, Folate, Total T3, Vitamin B12, Vitamin D, Testosterone, free T3, Growth Hormone, DHEA-S, Estradiol, hCG, and TSH. 2. In interview on October 31, 2018 at 1:07 pm, Personnel 2 stated the laboratory no longer performs eGFR, C-peptide, Cortisol, and Growth Hormone testing. Personnel 2 did not provide surveyors with the date testing was discontinued. 3. In interview on October 30, 2018, Personnel 3 stated she was unsure of the date that patient testing began. 4. In interview on October 31, 2018, Personnel 6 stated she thinks patient testing began September 19, 2018. Personnel 6 further stated that Personnel 3 should be able to provide the exact date patient testing began. Laboratory personnel did not provide surveyors with the date patient testing began. 5. Review of the laboratory's method validation records revealed the following information was not included: a) AU 480: Precision, to include run-to-run, day-to-day, within- run, and operator variance, reportable range, acceptability criteria, and Laboratory Director approval/signature b) Access 2: accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as, operator variance), reportable and reference ranges, acceptability criteria, and Laboratory Director approval/signature 6. In interview on October 30, 2018 at 11:44 am, Personnel 3 stated the laboratory performed patient comparison studies with two (2) local laboratories. Personnel 3 further stated the comparison studies were completed the beginning of October. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Hematology testing. Findings: 1. Observation by surveyors during the laboratory tour on October 30, 2018 revealed the laboratory utilizes the Medonic M-series analyzer for Complete Blood Counts. 2. In interview on October 30, 2018, Personnel 3 stated she was unsure of the date that patient testing began. 3. In interview on October 30, 2018 at 11:44 am, Personnel 3 stated the laboratory performed patient comparison studies with two (2) local laboratories. Personnel 3 further stated the comparison studies were completed the beginning of October. 4. In interview on October 31, 2018, Personnel 6 stated she thinks patient testing began September 19, 2018. Personnel 6 further stated that Personnel 3 should be able to provide the exact date patient testing began. Laboratory personnel did not provide surveyors with the date patient testing began. 5. Review of the laboratory's method validation records revealed the following information was not included: a) Accuracy, precision (to include run-to-run, day-to-day, within- run, and operator variance), reportable range, reference range, acceptability criteria, and Laboratory Director approval/signature
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to establish calibration procedures for Hematology testing. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes a Medonic M-series instrument for measuring Complete Blood Counts (CBC). 2. Review of the Medonic M-series user manual under "Calibration" section revealed "The frequency of calibration is every 6 months." 3. Review of the

	laboratory's policy and and procedure manual revealed calibration procedures (including frequency) for Hematology testing were not included. 4. In interview on October 31, 2018 at approximately 1:00 pm, Personnel 2 stated the laboratory's policies were being updated. II. Based on observation, record review, and interview with personnel, the laboratory failed to establish calibration procedures for Sodium, Potassium, and Chloride testing. Findings: 1. Observation by surveyors during the laboratory tour on October 30, 2018 revealed the laboratory utilizes the AU 480 for testing of Sodium, Potassium, and Chloride. 2. Review of the laboratory's policy and procedure manual revealed a calibration procedure for the Ion Selective Electrode (ISE), which includes Sodium, Potassium, and Chloride, was not included. 3. In interview on October 31, 2018 at approximately 1:00 pm, Personnel 2 stated the laboratory's policies were being updated.
D5441	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 observation, record review, and interview with personnel, the laboratory failed to establish quality control procedures that monitor accuracy and precision for Chemistry and Hematology testing to detect immediate errors. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes the following instruments for Chemistry testing: a) AU 480: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C Reactive Protein (CRP), Homocysteine, Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). b) Access 2: Insulin, Growth Hormone, Cortisol, Testosterone, DHEA-sulfate, SHBG, Luteinizing Hormone, FSH, Free T3, Prolactin, Beta-hCG, Estradiol, Progesterone, TSH, Total T3, Total T4, PSA, Ferritin, Folate, Vitamin B12, Vitamin D. c) Medonic M-Series: Complete Blood Counts (CBC) 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy related to Quality Control acceptability criteria. 3. In interview on October 31, 2018 at 4:30 pm, for the AU 480 the QC parameters were set-up by the service representative. Personnel 3 further stated the QC parameters were from Pointe Scientific. 4. In interview on November 1, 2018 at 3:30 pm,

	Personnel 3 stated for the Au 480 instrument she did not know if the mean and Standard Deviation (SD) came from the package insert or the QC acceptability criteria.
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 observation, record review, and interview with personnel, the laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by manufacturer. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 and review of QC records revealed the laboratory utilizes the following instruments and quality control material for Chemistry testing: a) AU 480: Pointe Scientific QC material utilized b) Access 2: Bio Rad QC material utilized 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for the establishment of QC means, ranges, or acceptability criteria. 3. In interview on October 30, 2018 at 11: 52 am, Personnel 3 stated the laboratory runs twenty (20) samples of Quality Control (QC) and establishes their own ranges. Surveyors were not provided QC establishment data. 4. In interview on October 31, 2018 at 4:30 pm, Personnel 3 for the AU 480 the QC parameters were set-up by the service representative. Personnel 3 further stated the QC parameters were from Pointe Scientific. Personnel 3 stated Personnel 2 calculates the QC means and ranges. 5. In interview on November 1, 2018 at 3:30 pm, Personnel 3 stated the laboratory did not establish their own QC ranges for the AU 480. Personnel 3 stated the Pointe Scientific representative entered the parameters. Personnel 3 stated she did not know if the mean and Standard Deviation (SD) came from the package insert or the QC acceptability criteria. 6. Review of the manufactuers' package inserts revealed: a) Pointe Scientific: "It is recommended that each laboratory establish its own mean and precision parameters." b) BioRad: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 7. The laboratory was unable to provide surveyors documentation of where in-use QC ranges for the two (2) identified analyzers came from. 8. Review of the laboratory's Task 1 and 3 forms revealed the laboratory did not include the control material utilized and annual test volumes.
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:
I. Based on observation, record review, and interview with personnel, the laboratory failed to perform corrective action when quality control was unacceptable for Hematology testing. Findings: 1. Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory utilizes a Medonic M-series instrument for measuring Complete Blood Counts (CBC). 2. In interview on November 1, 2018 at 11: 40 am, Personnel 3 stated the laboratory uses the manufacturer ranges for the Medonic's Quality Control (QC) acceptability. 3. Review of the laboratory's Quality Control records from September 19, 2018 through October 19, 2018 revealed the laboratory did not take corrective action when QC was not acceptable for the following nine (9) dates: September 20, 2018: High Lymphocytes reported value 11.0 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) September 21, 2018: High Lymphocytes reported value 11.3 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) September 22, 2018: High White Blood Cells (WBC) 18.4 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L) and High Lymphocytes reported value 11.2 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) October 6, 2018: High WBC reported value 18.2 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L) and High Lymphocytes reported value 10.8 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) October 15, 2018: High WBC reported value 18.1 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L), High Lymphocytes reported value 10.5 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L), High Lymphocytes % reported value 58.2 % (acceptable value 58.6-68.6 %), and RDW % reported value 18.0 % (acceptable value 9.2-17.2 %) October 16, 2018: High WBC reported value 18.3 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L) and High Lymphocytes reported value 10.8 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) October 17, 2018: Normal WBC reported value 7.6 x 10 9/L (acceptable value: 7.9-9.1 x 10 9/L) and High Lymphocytes reported value 10.8 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) October 18, 2018: High WBC reported value 18.3 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L) and High Lymphocytes reported value 11.0 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) October 19, 2018: High WBC reported value 18.2 x 10 9/L (acceptable value: 18.5-22.1 x 10 9/L) and High Lymphocytes reported value 10.5 x 10 9/L (acceptable value: 11.4-14.4 x 10 9/L) 4. Review of patient test records for CBC revealed the following sixty three (63) patients were reported without acceptable QC: September 20, 2018: Unknown (Laboratory unable to provide patients tested) September 21, 2018: Unknown (Laboratory unable to provide patients tested) September 22, 2018: Patients 46-61 October 6, 2018: Patients 9, 62-74 October 15, 2018: Patients 75-78 October 16, 2018: Patients 79-85 October 17, 2018: Patients 83, 86-94 October 18, 2018: Patients 95-103 October 19, 2018: Patients 104-107 5. In interview on November 1, 2018 at 12:11 pm, Personnel 4 stated there was a problem retrieving QC data from the Medonics prior to September 29, 2018. 6. In interview on November 1, 2018 at 12:49 pm, Personnel 3 stated all three (3) levels of QC for the Medonics must be within acceptable range. II. Based on observation, record review, and interview with personnel, the laboratory failed to perform corrective action when quality control was unacceptable for Chemistry testing. Findings: 1. Observation by surveyors during the laboratory tour on October 30, 2018 revealed the laboratory utilizes the following instruments for Chemistry

testing: a) AU 480: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase, Apolipoprotein A1 (APO A1), Apolipoprotein B (APO B), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, Gamma-Glutamyl Transferase (GGT), Iron. High Density Lipoprotein Cholesterol (HDL), Low Density Lipoprotein Cholesterol (LDL), Lipoprotein, Lipase, Magnesium, C Reactive Protein (CRP), Homocysteine,Glucose (Glu), Hemoglobin A1C (HgbA1C), Phosphorus, Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Triglyceride (Trig). b) Access 2: Progesterone, FSH, LH, Cortisol, Ferritin, Prolactin, Total T4, Folate, Total T3, Vitamin B12, Vitamin D, Testosterone, free T3, Growth Hormone, DHEA-S, Estradiol, hCG, and TSH. 2. In interview on October 31, 2018 at 1:07 pm, Personnel 2 stated the laboratory no longer performs Cortisol and Growth Hormone testing. Personnel 2 did not provide surveyors with the date testing was discontinued. 3. Review of "RB/CAL/QC Log" for the AU 480 for October 10, 2018 revealed the following analytes highlighted red: "QC No. 1" a) HDL: 0:1Q b) Glucose: 75.1:1Q c) LDL: 0:1Q d) C-Reactive Protein: 3.2:1Q "QC No.2" a) CO2: 32.3: 1Q b) BUN: 42:1Q c) HDL: 1:1Q d) LDL: 1:1Q e) Chloride: 110:1Q f) Hemoglobin A1C: %, ? g) C-Reactive Protein: 60.5:1Q 3. In interview on October 31, 2018 at 4:14 pm, Personnel 3 stated for the AU 480 the acceptable QC ranges are in the instrument. Personnel 3 further stated if "1 Q" is seen next to a QC value that indicates it is outside of 1 SD and nothing further is done. Personnel 3 stated she did not see that the identified Hemoglobin A1C control level 2 was repeated. 4. Review of the AU 480's user guide under "Summary of Error Flags" revealed the following: a)"1Q: QC data exceeds the ranged enterd in the Single Check Level field." b) "%: Clot detected." c) "?: Unable to calculate a result." 5. In further interview on November 1, 2018 at 3:30 pm, Personnel 3 stated the laboratory did not establish their own QC ranges for the AU 480. Personnel 3 stated the Pointe Scientific representative entered the parameters. Personnel 3 stated she did not know if the mean and Standard Deviation (SD) came from the package insert or the QC acceptability criteria. 6. Surveyors were not provided the laboratory's QC acceptable ranges in use September 2018 and October 2018 for the AU 480 or Access 2. 7. Review of the laboratory's QC records for the Access 2 from October 10, 2018 through October 25, 2018 revealed the following flags: October 10, 2018: BioRad 40961: Cortisol and Prolactin "QCF" flags (QCF= QC out) BioRad 40963: Cortisol, Total T4, and DHEA-S "QCF" flags October 12, 2018: BioRad 40961: Cortisol, Ferritin, Folate, and Total T3 "QCF" flags BioRad 40963: Cortisol, Prolactin, Total T3, DHEA-S, and hCG "QCF" flags October 15, 2018: BioRad 40961: Cortisol, Ferritin, Total T4, Total T3, and TSH "QCF" flags BioRad 40963: Total T3, DHEA-S, hCG, and TSH "QCF" flags October 16, 2018: BioRad 40961: LH, Cortisol, Ferritin, Total T4, Total T3, Testosterone, and TSH "QCF" flags BioRad 40963: LH, Total T3, Testosterone, DHEA-S, hCG, and TSH "QCF" flags October 17, 2018: BioRad 40961: Progesterone, FSH, LH, Cortisol, Total T4, Testosterone, DHEA-S, hCG, and TSH "QCF" flags BioRad 40963: Progesterone, LH, Cortisol, PSA, Testosterone, DHEA-S, Estradiol, and TSH "QCF" flags October 22, 2018: BioRad 40961: LH, Cortisol, Total T4, Insulin, Vitamin B12, and hCG "QCF" flags BioRad 60251: Vitamin A "QCF" flag BioRad 40963: LH, Cortisol, Insulin, Testosterone, DHEA-S and hCG "QCF" flags BioRad 60253: Vitamin A "QCF" flag October 23, 2018: BioRad 40961: Progesterone, Cortisol, Ferritin, Total T4, Testosterone, DHEA-S, and hCG "QCF" flags BioRad 40961: FSH, LH, Folate, Total T3, Insulin, Vitamin B12, and FT3 "SYS" flags (SYS=System Error) BioRad 60251: Vitamin A "QCF" flag BioRad 40963: Progesterone, Cortisol, Ferritin, Testosterone, DHEA-S, and hCG "QCF" flags BioRad 40963: FSH, LH, Folate, Total T3, Insulin, Vitamin B12, FT3, "SYS" flags October 24, 2018: BioRad 40963: Progesterone, LH, Cortisol, Total T3, Insulin,

	Vitamin B12, Testosterone, DHEA-S, and hCG "QCF" flags October 25, 2018: BioRad 40961: Progesterone, Cortisol, Total T3, Insulin, Vitamin B12, Testosterone, Growth Hormone, DHEA-S, hCG, and TSH "QCF" flags BioRad 60251: Vitamin A "QCF" flag BioRad 40963: Progesterone, FSH, Total T3, Insulin, Vitamin B12, Testosterone, DHEA-S, and hCG "QCF" flags BioRad 60253: Vitamin A "QCF" flag 8. Surveyors were not provided patients affected by identified flagged QC.
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 establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403. 3. The laboratory failed to address flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Refer to D5411 I. 4. The laboratory failed to address flags appearing on Chemistry results per manufacturer requirements. Refer to D5411 II. 5. The laboratory failed to address flags appearing on Endocrinology results per manufacturer requirements. Refer to D5411 III. 6. The laboratory failed to ensure patient samples for Chemistry were tested per manufacturer's requirements. Refer to D5411 IV. 7. The laboratory failed to ensure patient samples for Hematology were tested per manufacturer's requirements. Refer to D5411 V. 8. The laboratory failed to mix Hematology controls per manufacturer requirements. Refer to D5411 VI. 9. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 10. The laboratory failed to have complete performance verification studies for Chemistry testing. Refer to D5421 I. 11. The laboratory failed to have complete performance verification studies for Hematology testing. Refer to D5421 II. 12. The laboratory failed to establish calibration procedures for Hematology testing. Refer to D5425 I. 13. The laboratory failed to establish calibration procedures for Sodium, Potassium, and Chloride testing. Refer to D5425 II. 14. The laboratory failed to establish quality control procedures that monitor accuracy and precision for Chemistry testing to detect immediate errors. Refer to D5441. 15. The laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by manufacturer. Refer to D5469. 16. The laboratory failed to perform corrective action when quality control was unacceptable for Hematology testing. Refer to D5783 I. 17. The laboratory failed to perform corrective action when quality control was unacceptable for Chemistry testing. Refer to D5783 II.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the quality of testing within the postanalytic systems. Findings: 1. The laboratory failed to ensure the collection date and time and report date and time are accurately being transferred from the point of entry, through the testing process to final report destination. Refer to D5801 I. 2. The laboratory failed to ensure patient test results were reported in a timely manner. Refer to D5801 II. 3. The laboratory failed to ensure patient test results were reported. Refer to D5801 III. 4. The laboratory failed to ensure calculated Low Density Lipoprotein (LDL)results are reported accurately. Refer to D5801 IV. 5. The laboratory failed to notify providers of unacceptable samples. Refer to D5805. 6. The laboratory failed to provide reference intervals on final test reports for all Chemistry tests performed. Refer to D5807. 7. The laboratory failed to ensure providers are notified of critical values. Refer to D5813. 8. The laboratory failed to have a written policy for requests of patient laboratory reports. Refer to D5823. 9. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Refer to D5891.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure the collection date and time and report date and time are accurately being transferred from the point of entry, through the testing process to final report destination. Findings: 1. Review of random selection of patient requisitions and final reports from September 2018 and October 2018 revealed the collection date on patient requisitions differed from the collection date on final reports for the following of six patients reviewed: Patient 17: Test requisition collection date 9/ /18 (no day of collection provided on requisition). Final test report listed collection date as 09/15/18 Patient 18: Test requisition collection date: 9/17/18. Final test report listed collection date as 9/18/18 Patient 19: Test requisition collection date: 10/05/2018. Final test report listed collection date as 10/08/18 Patient 20: Test requisition collection date: 10 /25/18. Final test report listed collection date as 10/05/18 Patient 71: Test requisition collection date: 10/04/18. Final test report listed collection date as 10/05/18 2. In interview on October 30, 2018 at 3:06 pm, Personnel 2 stated the laboratory's LIS has not been validated. Personnel 2 stated the laboratory previously entered results manually and recently started using an electronic LIS. II. Based on record review and interview with personnel, the laboratory failed to ensure patient test results were

reported in a timely manner. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a turn around time policy for reporting of patient test results. 2. Review of random selection of patient requisitions, instrument printouts and final reports from September 2018 and October 2018 revealed the following turn around times: Patient 17: Test requisition collection date 9/ /18 (no day of collection provided on requisition). Instrument printout date 09/15 /18 for Chemistry analytes on the AU 480 and date reported: 09/27/18 Patient 18: Test requisition collection date: 9/17/18. Instrument printouts for Chemistry, Endocrinology and Complete Blood Counts were not provided to surveyors. Date reported: 10/30/18 Patient 19: Test requisition collection date: 10/05/2018. Instrument printout date 10/08/18 for Complete Blood Counts, 10/11/18 for Endocrinology analytes on the Access 2, and 10/12/18 for Chemistry analytes on the AU 480. Date reported 10/16/18. Patient 20: Test requisition collection date: 10/25/18. Instrument printout date 10/08/18 for Complete Blood Counts, 10/11/18 for Endocrinology analytes on the Access 2, and 10/12/18 for Chemistry analytes on the AU 480. Date reported 10/18/18. Patient 21: Test requisition collection date: 10/05/18. Instrument printout date 10/08/18 for Complete Blood Counts, 10/11/18 for Endocrinology analytes on the Access 2. Date reported 10/16/18. Patient 22: Test requisition collection date: 10/10/18. Instrument printout date 10/12/18 for Complete Blood Counts. Instrument printout for Endocrinology and Chemistry testing were not provided to surveyors. Date reported 10/25/18. Patient 37: Test requisition date of service: 09/13/18. Instrument printout was not provided to surveyors for Chemistry analytes. Date reported 09/26/18. Patient 117: Test requisition collection date: 10/10 /18. Instrument printout date 10/12/18 for the Access 2. Date reported 10/25/18. 3. In interview on October 30, 2018 at 3:06 pm, Personnel 2 stated the laboratory previously entered results manually and recently started using an electronic LIS. 4. In interview on October 31, 2018 at 11:47 am, Personnel 4 stated she was unable to locate the instrument printouts for the identified patients. III. Based on record review, the laboratory failed to ensure patient test results were reported. Findings: 1. Review of random selection of patient requisitions, instrument printouts and final reports on November 1, 2018 from September 2018 and October 2018 revealed the following two (2) patients had pending test results: A) Patient 114: Test requisition collection date: 09/17/18. Tests ordered: Complete Wellness Panel, which includes Complete Blood Counts (CBC). Instrument printouts showed CBC analysis date 09/19/18, Chemistry analysis on the AU 480 test date 09/21/18, and no instrument printout for analytes tested on Access 2. No report date was listed, only a time "16:13". The final report listed the following: "Report Status: Preliminary." "QNS" was listed for the following analytes: ALT, AST, BUN, Creatinine, DHEA-S, Ferritin, FSH, Free T3, Hemoglobin A1C, Homocysteine, Growth Hormone, Insulin, DL, Luteinizing Hormone, Lipoprotein (a), Prolactin, PSA, SHBG, Testosterone, TSH, Total T3, Total T4, Vitamin B12, and Vitamin D. Although the CBC analysis provided results, the final report had no CBC results included; "WBC" listed as "PENDING." Patient 124: Test requisition was not provided to surveyors. Instrument printouts were not provided to surveyors. Patient's final report listed the following: "Date of collection 09 /24/18, Accessioned: 09/25/18, and Reported: 10/17/18. Report status: PRELIMINARY." "PENDING" results were listed for the following Chemistry analytes: Albumin, ALP, ALT, Amylase, Apo A1, Apo B AST, BUN, Calcium, Total Cholesterol, Chloride, CO2, Cortisol, Creatinine, C-Reactive Protein, DHEA-S, Estradiol, Ferritin, FSH, Free T4, Glucose, Hemoglobin A1C, hCG, Homocysteine, HDL, Growth Hormone, Insulin, Potassium, LDL, Luetinizing Hormone, Lipoprotein (a), Magnesium, Sodium, Phosphorus, Prolactin, Progesterone, SHBG, Total Bilirubin, Testosterone, Thyroglobulin Ab, Total Protein, TPO Ab, Triglycerides, TSH, Total T3, Total T4, Vitamin B12, Vitamin D. "PENDING" results were listed

	for the following Hematology cells: Neutrophils, Lymphocytes, Monocytes, absolute neutrophils, absolute lymphocytes, and absoulte monocytes. IV. Based on record review and interview with personnel, the laboratory failed to ensure calculated Low Density Lipoprotein (LDL)results are reported accurately. Findings: 1. Review of random selection of patient test reports from September 2018 and October 2018 revealed LDL is a calculated value. 2. Further review of random selection of patient test reports revealed the laboratory reported the LDL value as "QNS", although results for Triglycerides, High Density Lipoproten (HDL) and Total Cholesterol were present for the following nine (9) patients: Patient 33 Patient 69 Patient 76 Patient 110 Patient 115-116 Patients 118-119 Patient 121 3. In interview on October 30, 2018 at 2:38 pm, Personnel 3 stated QNS is only used when quantity is insufficient.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to notify providers of unacceptable samples. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include specific actions to take for unacceptable samples. 2. Review of the random selection of patient final reports form September 2018 and October 2018 revealed the laboratory did not notify providers of the following thirteen (13) unacceptable samples: Patients 18-21, 35, 36, 38, 91, 109 reported Chemistry analytes as "QNS" (Quantity Insufficient) Patients 14-16, and 123. Samples were rejected due to stability. 3. In interview on October 30, 2018 at 12:00 pm, Personnel 3 stated patient samples may be rejected in accessioning for stability, mislabeling or QNS. Personnel 3 further stated she may also reject patient samples in the testing area if samples are hemolyzed or QNS. Personnel 3 stated rejected samples are listed in a patient log book. 4. Review of the "Specimen Problem Log" in the accessioning area and laboratory teasing area revealed the laboratory did not have documentation of providers being notified of insufficient quantity or stability for the identified patients.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide reference intervals on final test reports for all Chemistry tests performed. Findings: 1.

	Review of random selection of patient final test reports revealed reference ranges for the following analytes were not included: Lipase, LDL, DHEA-S , Ferritin, hCG, Transferrin, GGT, Iron, Progesterone, and Direct TIBC. 2. Review of random selection of patient final test reports from September 2018 and October 2018 revealed the following eleven (11) patients had analytes reported without reference ranges included: Patient 17: Lipase, Transferrin, GGT, Iron, TIBC, and Iron Patient 19: hCG Patient 37: Lipase, Transferrin, GGT, Iron, and TIBC Patient 38: Folate, DHEA-S, and hCG Patient 69: Folate, Progesterone, and hCG Patient 71: Progesterone and Folate Patient 76: hCG Patient 118: Folate and hCG Patient 119: Progesterone, Folate, Total T3, and hCG Patient 120: Folate, DHEA-S, and hCG Patient 121: Folate, DHEA-S, and hCG 3. In interview on October 31, 2018, Personnel 2 stated the reports need to be updated to include the identified analytes reference ranges. 4. Review of the laboratory's Task 1 and 3 forms revealed the laboratory did not include the annual volumes for each test.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure providers are notified of critical values. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory did not have a policy for reporting of critical values. 2. Surveyors were provided a "Critical Value" log; however, the laboratory did not have documentation of critical values for analytes. 3. In interview on October 31, 2018 at 1:00 pm, Personnel 3 stated she did not know where critical values came from. Personnel 3 further stated it was set up during the instruments install. 4. Further review of the laboratory's "Critical Value" log revealed the following: October 17, 2018: Patient 108: "Critical Value" log documented: 10/17/18 Critical Value: WBC 10.3 HCT 7.7 Time Recorded 12:05 pm, Time Reported: 12:10 pm" Medonic Instrument Printout: WBC 3.5 DE (DE=Small particle interference, re-analyze), HCT 12.5 L Date: 10/17/18 Time: 17:38 Final Test Report: WBC: 3.5 HCT= 12.5 L 5. Review of random selection of patient final test reports and instrument printouts for September 2018 and October 2018 revealed the following seven (7) patients had Potassium results that were flagged: AU Instrument Run Date: 09/21/18 Patient 2: Potassium reported 5.4 mEq/L (ph flag=Result is higher than the upper panic value) Patient 110: Potassium reported 8.1 mEq/L (ph flag) Patient 112: Potassium reported 7.3 mEq/L (ph flag) Patient 113: Potassium reported 5.4 mEq/L (ph flag) Patient 114: Potassium reported 6.9 mEq/L (ph flag) Patient 115: Potassium reported 5.2 mEq/L (ph flag) Patient 122: Potassium reported 9.6 mEq/L. Instrument printout was not provided to surveyors 6. Review of the laboratory's "Critical Values" log revealed the laboratory did not have documentation that providers for the identified patients were notified. 7. In further interview on October 31, 2018 at 2:32 pm, Personnel 3 stated the laboratory's critical policy was sent to the Laboratory Director to sign. Surveyors were not provided a copy of the critical policy.
D5823	TEST REPORTS CFR(s): 493.1291(l)

	Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a written policy for requests of patient laboratory reports. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy related to requests for patients laboratory reports. 2. In interview on October 31, 2018 at approximately 1:00 pm, Personnel 2 stated the laboratory's policies were being updated.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Findings: 1. The laboratory failed to ensure the collection date and time and report date and time are accurately being transferred from the point of entry, through the testing process to final report destination. Refer to D5801 I. 2. The laboratory failed to ensure patient test results were reported in a timely manner. Refer to D5801 II. 3. The laboratory failed to ensure patient test results were reported. Refer to D5801 III. 4. The laboratory failed to ensure calculated Low Density Lipoprotein (LDL)results are reported accurately. Refer to D5801 IV. 5. The laboratory failed to notify providers of unacceptable samples. Refer to D5805. 6. The laboratory failed to provide reference intervals on final test reports for all Chemistry tests performed. Refer to D5807. 7. The laboratory failed to ensure providers are notified of critical values. Refer to D5813. 8. The laboratory failed to have a written policy for requests of patient laboratory reports. Refer to D5823.
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 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 the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure that a

	quality control program was established and 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 patient test results were reported only when system functioning properly. Refer to D6025. 6. The Laboratory Director failed to ensure final test reports for Chemistry tests included pertinent information required for interpretation. Refer to D6026. 7. The Laboratory Director failed to ensure the laboratory employed a Technical Consultant for the technical and scientific oversight of the laboratory. Refer to D6028. 8. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6033. 9. 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. 10. The Laboratory Director failed to specify the duties of each Laboratory Personnel. Refer to D6032.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421 I and D5421 II.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to obtain a written request from the physician for Chemistry testing for one (1) of X patients reviewed. Refer to D5301. 2. The laboratory failed to ensure test requisitions included all tests performed at the laboratory. Refer to D5305 I. 3. The laboratory failed to ensure test requisitions included the collection date. Refer to D5305 II. 4. The

	laboratory failed to ensure patient blood samples for Chemistry and Hematology testing are stored and preserved per manufacturer requirements. Refer to D5311. 5. The laboratory failed to document the date and time specimens are received into the laboratory. Refer to 5313. 6. The laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory failed to address flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Refer to D5411 I. 4. The laboratory failed to address flags appearing on Chemistry results per manufacturer requirements. Refer to D5411 II. 5. The laboratory failed to address flags appearing on Endocrinology results per manufacturer requirements. Refer to D5411 III. 6. The laboratory failed to ensure patient samples for Chemistry were tested per manufacturer's requirements. Refer to D5411 IV. 7. The laboratory failed to ensure patient samples for Hematology were tested per manufacturer's requirements. Refer to D5411 V. 8. The laboratory failed to mix Hematology controls per manufacturer requirements. Refer to D5411 VI. 9. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to establish quality control procedures that monitor accuracy and precision for Chemistry and Hematology testing to detect immediate errors. Refer to D5441. 2. The laboratory failed to establish their own mean and ranges for Quality Control (QC) material utilized for Chemistry testing as required by manufacturer. Refer to D5469.
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.

	Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 3. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the postanalytic system. Refer to D5891.
D6025	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 patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient test results were reported only when system functioning properly. Findings: 1. The laboratory failed to ensure the collection date and time and report date and time are accurately being transferred from the point of entry, through the testing process to final report destination. Refer to D5801 I. 2. The laboratory failed to ensure patient test results were reported in a timely manner. Refer to D5801 II. 3. The laboratory failed to ensure patient test results were reported. Refer to D5801 III. 4. The laboratory failed to ensure calculated Low Density Lipoprotein (LDL)results are reported accurately. Refer to D5801 IV
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final test reports for Chemistry tests included pertinent information required for interpretation. Refer to D5807.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the

	appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory employed a Technical Consultant for the technical and scientific oversight of the laboratory. Refer to D6034.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to have documentation of training of all personnel performing testing. Refer to D6066. 2. Review of personnel records for Personnel 3 revealed competency assessments were not performed by the Laboratory Director. 3. In interview on November 1, 2018 at 10: 09 am, Personnel 2 confirmed he assessed Personnel 3 for her initial competency training.
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 observation, 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 and D5403.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to specify the duties of each Laboratory Personnel. Findings: 1. Review of personnel records revealed the laboratory did not specify the duties and responsibilities of each laboratory personnel. 2. In interview on November 1, 2018, Personnel 2 verified the laboratory staff sign all personnel job descriptions, not one specific to their actual role.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Refer to D6034.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to employ an individual who is qualified to provide technical consultation for each of the specialities the laboratory performs moderate complexity testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Record) submitted to surveyors on October 31, 2018 revealed the laboratory did not list a Technical Consultant. 2. In

	interview on October 31, 2018 at 2:32 pm, Personnel 4 stated she did not know who serves as the laboratory's Technical Consultant.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have documentation of training of all personnel performing testing. Findings: 1. Review of random selection of patient test reports, instrument printouts, and performance verification studies revealed Personnel 4 participated in validation of the Hematology analyzer and entering patient results. 2. Further review of the laboratory's Hematology method validation for the Medonic analyzer revealed Personnel 5 performed the laboratory's reference range study. 3. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed Personnel 5 was not included as Testing Personnel. 4. Review of personnel records for Personnel 5 revealed he did not possess a state of Louisiana license that included the specialty of Hematology. 5. Further review of personnel records for Personnel 5 revealed no documentation of training. 6. In interview on October 30, 2018 at approximately 1:15 pm, Personnel 2 stated Personnel 5 does not perform any patient testing. 7. In interview on October 30, 2018 at approximately 1:15 pm, Personnel 5 stated he entered patient results when the laboratory did not have a LIS system.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to meet CLIA requirements specified in 42 CFR 493.1775. Refer to D8103.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact

	duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to provide copies or exact duplicates of all records and data to ensure the laboratory is in compliance with CLIA Regulations Part 493. Findings: 1, Observation by surveyors during laboratory tour on October 30, 2018 revealed the laboratory performs Chemistry and Hematology testing. 2. On October 30, 2018 surveyors gave CMS 116, CMS 209 (Laboratory Personnel Report), Disclosure of Ownership and Task 1 and 3 forms to Personnel 4 for completion. Surveyors requested on two (2) occasions that laboratory personnel complete the Disclosure of Ownership and Task 1 and 3 forms, to include control material and annual volumes. The forms were not provided to surveyors by exit date, November 1, 2018. 3. The laboratory failed to maintain or provide copies of the following information: a) Package inserts for Sodium, Potassium, Chloride reagents b) Package inserts for QC material for the Access 2 and AU 480 c) Quality Control acceptable ranges for Access 2 and AU 480 d) Patients affected by unacceptable Quality Control (Refer to D5783 I and D5783 II) e) Instrument printouts for all requested patients 4. In interview on October 31, 2018 at 10:51 am, Personnel 3 stated the package inserts for the Access 2 were located online. Surveyors were not provided the inserts during the survey October 30, 2018 through November 1, 2018.