

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0460952	(X3) Date Survey Completed 04/13/2018
Name of Provider or Supplier Hamilton Medical Group - Main	Street Address, City, State 4809 Ambassador Caffery Parkway, Ste 200, Lafayette, 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 CERTIFICATION SURVEY was performed at Hamilton Medical Group - CLIA # 19D0460952 on April 13, 2018. Hamilton Medical Group was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing Moderate Complexity Testing, LABORATORY DIRECTOR 42 CFR 493.1409 CONDITION: Laboratories performing Moderate Complexity Testing, TECHNICAL CONSULTANT
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to maintain copies of the proficiency testing program attestation statements signed by the analyst and the laboratory director for two (2) of five (5) Proficiency Test (PT) events reviewed. Findings: 1. Review of American Proficiency Institute (API) PT records from January 1, 2017 through April 13, 2018 revealed the laboratory did not maintain copies of attestation statements signed by the analyst and the laboratory director for</p>

the following two (2) events: a) 2018 Chemistry Core Module 1st Event - attestation not signed by the laboratory director and testing personnel. d) 2018 Hematology /Coagulation Module 1st Event - the laboratory director did not sign the attestation. 2. Interview with personnel 4 on April 13, 2018 confirmed the laboratory did not maintain copies of the proficiency testing program attestation statements signed by the analyst and the laboratory director, for the two (2) PT events in 2018.

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 retain documentation of the calculations of the established means and ranges for quality control material utilized in Chemistry, Endocrinology and Hematology. Findings: 1. Observation by surveyor on April 13, 2018 revealed the laboratory maintained the following analyzers for patient testing for Chemistry, Endocrinology and Hematology: a) Alfa Wassermann Ace Alera Chemistry Analyzer for testing: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO₂), Creatinine (Creat), Cholesterol, High Density Lipoprotein Cholesterol (HDL), Cholesterol (Chol), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), and Triglyceride (Trig). b) Beckman Coulter Access 2 Immunoassay Analyzer for testing: Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT₄) and Prostate Specific Antigen (PSA). c) Horiba ABX Micros 60 Hematology Analyzer which tests for Complete Blood Cell (CBC) testing which includes: White Blood Cell counts (WBC), Red Blood Cell counts (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt) and Auto Differential. 2. Review of Quality Control package inserts revealed the following: a) Alfa Wassermann Ace Excel Chemistry Control package insert stated "Each laboratory establish its own mean and precision parameters." b) BIO-RAD Liquichek Immunoassay Plus Control package insert stated "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." c) Horiba Minotrol 16 Hematology Control package insert states it recommends the laboratory establish their own means and ranges. 3. Review of the laboratory policy and procedure manual revealed the laboratory had a procedure for establishing means and acceptable ranges for quality control material. 4. Review of Quality Control Records from April 7, 2017 through April 4, 2018 revealed the laboratory did not retain the documentation of establishing quality control ranges for Chemistry, Endocrinology and Hematology. Further review of the Quality Control records revealed the laboratory maintained copies of where they ran quality control 20 times; however the laboratory did not retain the documentation of the calculations for the mean and ranges. 5. Interview with Personnel 4 on April 13, 2018 revealed that the only testing person had quit. Personnel 4 did confirm that she was unable to locate documentation of the calculations of the means and ranges for the Chemistry, Endocrinology and Hematology quality control material.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with personnel 4 on April 13, 2018 revealed she was unaware of all the policies and procedures that were required. Personnel 4 confirmed the laboratory failed to have a complete policy and procedure manual.

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 ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Refer to D5417. 3. The laboratory failed to ensure that Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D5429. 4. The laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Refer to D5447 I. 5. The laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Refer to D5447 II. 6. The laboratory failed to perform two levels of control materials each day of

patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Refer to D5447 III. 7. The laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Refer to D5789. 8. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5791.

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:
Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Findings: 1. Observation by the surveyor on April 13, 2018 revealed the laboratory was performing NA, K, and CL testing on the Alfa Wassermann Ace Axcel Chemistry Analyzer. 2. Review of the Alfa Wassermann ACE ION Selective Electrode (ISE) Module for NA, K and CL package insert revealed under "Specimen Collection, Storage and Handling" to "Analyze serum/plasma specimens within 1 hour of collection." 3. Review of a random selection of patient records for NA, K and CL from August 10, 2017 through April 4, 2018 revealed the following five (5) patients failed to be analyzed within 1 hour of collection as required by the manufacturer: On April 4, 2018 Patient 1 was collected at 9:14 AM, and analyzed at 11:31 AM - exceeding the one (1) hour timeframe by 1 hour and 17 minutes. On March 12, 2018 Patient 4 was collected at 8:41 AM, and analyzed at 10:04 AM - exceeding the 1 hour timeframe by 23 minutes. On February 9, 2018 Patient 7 was collected at 7:55 AM, and analyzed at 9:27 AM - exceeding the 1 hour timeframe by 32 minutes. On December 15, 2017 Patient 15 was collected at 8:13 AM, and analyzed at 9:27 AM - exceeding the 1 hour timeframe by 14 minutes. On August 10, 2017 Patient 24 was collected at 7:55 AM, and analyzed at 10:26 AM - exceeding the 1 hour timeframe by by 1 hour and 31 minutes. 4. Interview with Personnel 4 on April 13, 2018 revealed that testing personnel recently quit. Personnel 4 confirmed the patient test results for NA, K and CL exceeded the 1 hour timeframe as required by the manufacturer.

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 laboratory personnel, the laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the

laboratory on April 13, 2018 revealed the following expired items in place for patient testing: Beckman Coulter Access Wash Buffer II: eight (8) 1950 ml bottles - lot number 331067F with an expiration date of 2017-06-30. Horiba Minotrol 16 Whole Blood Hematology Controls: lot MX406 - normal low and high with an expiration date of 2017-09-05. Becton Dickinson Vacutainer Lithium Heparin 95 USP Units 6.0 ml: three (3) tubes lot number 6279941 with an expiration date of 2018-03-31. Becton Dickinson Vacutainer Lithium Heparin 75 USP Units 4.0 ml: one (1) tube lot number 6253996 with an expiration date of 2018-01-31. Becton Dickinson Vacutainer Sodium Fluoride Potassium Oxylate 10mg/8mg - 4.0 ml: three (3) tubes lot number 6154520 with an expiration date of 2018-10, and one (1) tube lot number 6124903 with an expiration date of 2017-09. 2. Interview with personnel 4 and 5 on April 13, 2018 confirmed by observation the items cited were expired and in place for patient testing.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on observation, record review and interview with personnel, the laboratory failed to ensure that Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Findings: 1. Observation by the surveyor on April 13, 2018 revealed the laboratory maintained a Alfa Wassermann Ace Alera Chemistry Analyzer for testing: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Cholesterol, High Density Lipoprotein Cholesterol (HDL), Cholesterol (Chol), Glucose (Glu), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), and Triglyceride (Trig). 2. Review of Maintenance Logs for the Alfa Wassermann Ace Alera Chemistry Analyzer revealed the laboratory is to perform the following Maintenance: a) Daily Start Up: Remove Condensation from Reagent Compartment and Camera Lenses. Check Fluid Levels. Clean Touch Plate and Probe Pathway. Clean Exterior of Probe. Check Probe Alignment. Clean, Condition, Wash ISE. b) Daily Shutdown: Remove and Discard Used Sample Cups and Seglets. Empty the Cuvette Waste Box. Clean Exterior of Probe. Clean Touch Plate and Probe Pathway. Perform System Backup c) Weekly: Inspect Air Filters - Clean if required. Clean Exterior Surfaces of System and ISE Module. Clean ISE Sample Port. Perform Touch Plate Assembly Cleaning Procedure d) Monthly Rinse Probe and Fluid Lines with 10% Bleach. Clean Bottle Caps and Cap Connectors. Perform Sample Delay, Optical Calibration, and Table Offset. Clean Reference Housing. Further review of the maintenance logs from Log from January 1, 2017 through April 13, 2018 revealed the laboratory failed to maintain documentation of the Maintenance for the Alfa Wassermann Ace Alera Chemistry Analyzer for January 2018, February 2018 and March 2018. 3. Interview with personnel 4 on April 13, 2018 revealed that testing personnel had recently quit. Personnel 4 did confirm the laboratory failed to maintain maintenance records for January - March 2018.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Findings: 1. Observation by the surveyor on April 13, 2018 during the tour of the laboratory noted the laboratory maintained a Alfa Wassermann Ace Alera Chemistry Analyzer for the testing and reporting of PSA. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform two levels of quality control each day of patient testing for patient PSA testing. 3. Review of a random selection of Patient PSA testing and PSA Quality Control records from April 7, 2017 through April 4, 2018 revealed the following three (3) patients were tested and reported without having PSA Quality Control performed. On December 15, 2017 Patient 16 was tested and reported for PSA without having PSA Quality Control performed.. On November 6, 2017 Patient 21 was tested and reported for PSA without having PSA Quality Control performed. On August 9, 2017 Patient 25 was tested and reported for PSA without having PSA Quality Control performed.. 4. Interview with Personnel 4 on April 13, 20 18 revealed that testing personnel recently quit. Personnel 4 confirmed the laboratory failed to perform PSA Quality Control for the three (3) patients cited above. II. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Findings: 1. Observation by the surveyor on April 13, 2018 during the tour of the laboratory noted the laboratory maintained a Alfa Wassermann Ace Alera Chemistry Analyzer for the testing and reporting of FT4. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform two levels of quality control each day of patient testing for patient FT4 testing. 3. Review of a random selection of Patient FT4 testing and FT4 Quality Control records from April 7, 2017 through April 4, 2018 revealed the following three (3) patients were tested and reported without having FT4 Quality Control performed. On December 13, 2017 Patient 17 was tested and reported for FT4 without having FT4 Quality Control performed.. On November 3, 2017 Patient 22 was tested and reported for FT4 without having FT4 Quality Control performed. On August 14, 2017 Patient 26 was tested and reported for FT4 without having FT4 Quality Control performed.. 4. Interview with Personnel 4 on April 13, 20 18 revealed that testing personnel recently quit. Personnel 4 confirmed the laboratory failed to perform FT4 Quality Control for the three (3) patients cited above. III. Based on observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each day of patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Findings: 1. Observation by the surveyor on April 13, 2018 during the tour of the laboratory noted the laboratory maintained a Alfa Wassermann Ace Alera Chemistry Analyzer for the testing and reporting of TSH. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform two levels of quality control each day of

patient testing for patient TSH testing. 3. Review of a random selection of Patient TSH testing and TSH Quality Control records from April 7, 2017 through April 4, 2018 revealed the following patient was tested and reported without having TSH Quality Control performed. On April 7, 2017 Patient 27 was tested and reported for TSH without having TSH Quality Control performed.. 4. Interview with Personnel 4 on April 13, 20 18 revealed that testing personnel recently quit. Personnel 4 confirmed the laboratory failed to perform TSH Quality Control for patient 27.

D5789

TEST RECORDS
CFR(s): 493.1283(b)

Records of patient testing including, if applicable, instrument printouts, must be retained.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel the laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Findings: 1. Review of a random selection of Patient Test Records from April 7, 2017 through April 4, 2018 revealed the laboratory failed to retain the instrument printouts for the following nine (9) patients and tests. On December 15, 2017 Patient 16 had a Prostate Specific Antigen (PSA) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On December 13, 2017 Patient 17 had a Free Thyroxine (FT4) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On November 6, 2017 Patient 21 had a Prostate Specific Antigen (PSA) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On November 3, 2017 Patient 22 had a Free Thyroxine (FT4) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On August 9, 2017 Patient 25 had a Prostate Specific Antigen (PSA) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On August 14, 2017 Patient 26 had a Free Thyroxine (FT4) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On April 7, 2017 Patient 27 had a Thyroid Stimulating Hormone (TSH) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On April 7, 2017 Patient 28 had a Lipid Profile which includes: Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL) and Triglyceride (Trig) performed and reported; however the laboratory failed to retain the instrument printout for this patient. On April 7, 2017 Patient 29 had a Complete Metabolic Panel (CMP) which includes: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Total Bilirubin (TBil), Calcium (CA), Creatinine (Creat), Glucose (Glu), Sodium (NA), Potassium (K), Chloride (CL) Carbon Dioxide (CO2), Total Protein (TP), and Blood Urea Nitrogen (BUN), performed and reported; however the laboratory failed to retain the instrument printout for this patient. 2. Interview with Personnel 4 on April 13, 20 18 revealed that testing personnel recently quit. Personnel 4 confirmed the laboratory failed to retain the instrument printouts for the patients cited above.

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's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in Hematology as follows: a) The laboratory failed to ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Refer to D5411. b) The laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to ensure that Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D5429. d) The laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Refer to D5447 I. e) The laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Refer to D5447 II. f) The laboratory failed to perform two levels of control materials each day of patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Refer to D5447 III. g) The laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Refer to D5789. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with Personnel 4 on April 13, 2018 confirmed the laboratory was unaware of the issues cited above, and failed to monitor all phases of testing to assure that testing is being performed accurately and reliably.

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 laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 3. 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. 4. The Laboratory Director failed to ensure that the laboratory documented the Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D6023.

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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to retain documentation of the calculations of the established means and ranges for quality control material utilized in Chemistry, Endocrinology and Hematology. Refer to D3031. 2. The laboratory failed to ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Refer to D5411. 3. The laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Refer to D5417. 4. The laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Refer to D5789.

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 quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Refer to D5447 I. 2. The laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Refer to D5447 II. 3. The laboratory failed to perform two levels of control materials each day of patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Refer to D5447 III.

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. A review of patient test records and quality control records indicated problems found in Hematology as follows: a) The laboratory failed to ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Refer to D5411. b) The laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Refer to D5417. c) The laboratory failed to ensure that Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D5429. d) The laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Refer to D5447 I. e) The laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Refer to D5447 II. f) The laboratory failed to perform two levels of control materials each day of patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Refer to D5447 III. g) The laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Refer to D5789. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with Personnel 4 on April 13, 2018 confirmed the laboratory was unaware of the issues cited above, and failed to monitor all phases of testing to assure that testing is being performed accurately and reliably.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the

	<p>laboratory documented the Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D5429.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to meet the qualifications and provide technical oversight for a Technical Consultant of moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight for the laboratory. Refer to D6036. 2. The Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of one (1) personnel reviewed. Refer to D6054.</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure that patient samples for Sodium (NA), Potassium (K), and Chloride (CL) testing are analyzed within one (1) hour of collection according to the manufacturer for five (5) of seven (7) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure that buffers, controls and blood collection tubes are not used beyond their expiration dates. Refer to D5417. 3. The laboratory failed to ensure that Daily, Weekly and Monthly Maintenance on the Alfa Wassermann Ace Alera Chemistry Analyzer was performed as required by the manufacturer. Refer to D5429. 4. The laboratory failed to perform two levels of control materials each day of patient testing for Prostate Specific Antigen (PSA) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of seven (7) patients reviewed. Refer to D5447 I. 5. The laboratory failed to perform two levels of control materials each day of patient testing for Free Thyroxine (FT4) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for three (3) of six (6) patients reviewed. Refer to D5447 II. 6. The laboratory failed to perform two levels of control materials each day of patient testing for Thyroid Stimulating Hormone (TSH) performed on the Alfa Wassermann Ace Alera Chemistry Analyzer, for one (1) of eight (8) patients reviewed. Refer to D5447 III. 7. The laboratory failed to retain instrument printouts for nine (9) of thirty one (31) patients reviewed. Refer to D5789.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

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

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals annually, for one (1) of one (1) personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of the one testing personnel listed on the FORM 209 revealed the laboratory failed to include documentation of competency /evaluation of new personnel at least annually for Personnel 3. 3. Interview with the Office Manager (Personnel 4) on April 13, 2018 confirmed the laboratory failed to maintain documentation for an annual competency/evaluation for Personnel 3.