Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2062571	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Valley Regional Laboratory	7349 Middlebrook Pike, Knoxville, TN	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: ========== Based on an on-site observation 10/22/19 and 10/23/19 and upon review of the Laboratory's Tennessee State License required and issued by the State of Tennessee, Department of Health, for operation of a reference laboratory, observation and review of laboratory testing to include Chemistry, Endocrinology, Toxicology, Hematology, Coagulation, Clostridium Difficile, Urinalysis, Strep A and Influenza A & B and upon interview with the Office Manager, it was determined the Laboratory's Tennessee State License had expired January 31, 2019 with the laboratory still in operation. The findings include: 1. A review of the Laboratory's Tennessee State License (facility license number 4260) issued by the State of Tennessee, Department of Health, revealed an expiration date of January 31, 2019. 2. Upon observation and review of the laboratory on 10/22/19 and 10/23/19 it was revealed that testing of moderately complex testing and reporting to include Chemistry, Endocrinology, Toxicology, Hematology, Coagulation, Clostridium Difficile, Urinalysis, Strep A and Influenza A & B was still in operation. ==========
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 review of Quality Control results, lack of manufacturer's Quality Control (QC) assay sheets for Chemistry, Endocrinology, Toxicology, Hematology and Coag Testing and upon interview with the Medical Laboratory Technician (MLT), it was determined the laboratory failed to save QC assay sheets for 2018 and 2019. The findings include: 1. A review of Quality Control results for 2018 and 2019 for Chemistry, Endocrinology, Toxicology, Hematology and Coag Testing revealed no QC assay sheets had been saved for the two year period to determine the accuracy of the control materials. 2. Upon an interview at approximately 3:00 p.m. on October 23, 2019 with the MLT, it was confirmed that no manufacturer's QC assay sheets had been saved for 2018 and 2019. ==========
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 two patient tracers for the test Ammonia on 1/28/19 and 2/4/19, time of specimen collection and receipt documentation, test instructions from the reference laboratory where specimen was sent for testing and interview with the Office Manager, it was determined that proper specimen handling was not followed. The findings include: 1. Patient tracer (#3478) for Ammonia on 1/28/19 showed collection time at 6:40 a.m. and received in lab at 11: 34 a.m. with no documentation of specimen being placed on ice or separated from red cells within 20 minutes and frozen per test collection instructions. 2. Patient tracer (#4686) for Ammonia on 2/4/19 showed collection time on patient test order as 7:30 a. m. but no received time documented and no documentation of specimen being placed on ice or separated from red cells within 20 minutes and frozen per test collection instructions. 3. Test instructions for Ammonia from the reference lab states to "Place specimen on ice immediately after collection. Plasma should be separated within 20 minutes from cells and frozen". 4. An interview at approximately 3:00 p.m. on 10/23 /19 with the Office Manager confirmed the specimens had no way of being separated within 20 minutes of collection and frozen. ==========
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 and review of the analytic systems throughout the laboratory, determined the laboratory failed to establish and follow protocols to: Provide procedure manuals for all tests performed (Refer to D5401); Ensure laboratory complies with manufacturer's instructions for each test system (Refer to D5411); Ensure proper storage temperatures for specimen integrity and reagents (Refer to D5413); Ensure reagents and control materials are not used when they have exceeded their expiration date (Refer to D5417); Ensure linearities are performed for Chemistry analytes (Refer to D5437); Ensure Calibration Verifications are performed for CBC analyzer (Refer to D5439). ==========
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 lack of procedure manuals for moderately complex texting performed to include Chemistry, Endocrinology, Toxicology, Hematology, Coagulation and Clostridium Difficile (C. Diff) and upon interview with the MLT and Office Manager, it was determined the laboratory failed to present procedure manuals on 10/22/19 for all tests, assays and examinations performed. The findings include: 1. The laboratory did not have any procedure manuals for review on 10/22/19 for the moderately complex testing performed to include Chemistry, Endocrinology, Toxicology, Hematology, Coagulation and Clostridium Difficile (C. Diff). 2. Upon an interview at approximately 3:00 p.m. on 10 /22/19 with the MLT and Office Manager, it was confirmed there were no procedure manuals available for review for all tests, assays and examinations performed. ==========
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 lack of documentation for verification of the normal patient Prothrombin (PT) mean study and lack of accuracy verification of the INR calculation (manual, instrument or LIS) and upon interview with the MLT, it was determined the laboratory failed to ensure that verification studies had been performed for the PT/INR for 2018 and 2019. The findings include: 1. There was no documentation to ensure verification of the normal patient

	Prothrombin mean study for 2018 or 2019. 2. There was no documenation to ensure accuracy verification for the INR calculations by manual, instrument or LIS methods. 3. An interview at approximately 3:00 p.m. on October 23, 2019 with the MLT confirmed that verification studies had not been performed for the normal patient Prothrombin (PT) mean study and for the INR calculations for the two year period. ==========
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: ========== Based on review of the 2019 Refrigerator, Freezer and Room Temperature Computer Temperature Log Summary and upon an interview with the Office Manager and MLT, it was determined the laboratory failed to define normal temperature ranges and humidity levels. The findings include: 1. A review of the Refrigerator, Freezer and Room Temperature Computer Temperature Log Summary dated 2/9/19 to 10/23/19 failed to have defined criteria for temperature ranges and humidity levels to ensure proper storage of reagents and specimens. 2. An interview at approximately 3:00 p.m. on 10/23/19 with the Office Manager and MLT confirmed the Computer Temperature Log Summary for 2019 failed to have defined criteria for temperature ranges and humidity levels to ensure proper storage of reagents and specimens. ==========
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 of reagents in use during laboratory tour at approximately 8:30 a.m. 10/22/19 and review of patient tracer results for 2018 and 2019 and upon interview with the MLT, it was determined the laboratory had used reagents and Quality Control materials beyond their expiration date for patient testing. The findings include: 1. During laboratory tour on 10/22/19 and upon review of 2 patient tracers for Prothrombin Time (PT) and INR results performed on 8/1/19 and 8/30/19, it was observed that expired Hemosil Diluent-Lot #: N0277007, Expiration date of July 2019 was in use for the ACL Elite Coagulation Instrument along with 2 more expired bottles, Lot #: N0863975, Expiration date of January 2019 and Lot #: N1065107, Expiration date of April 2019 sitting used by the instrument. 2. During laboratory tour on 10/22/19 and upon review

	of 1 patient tracer for Vitamin B-12, Vitamin D and TSH (Thyroid Stimulating Hormone) performed on 10/22/19, it was observed that expired Wash Buffer-Lot #: 331651F, Expiration date of 10/15/19 was in use on the Access 2 and 16 bottles of the same were observed stored on shelf beside the instrument. 3. During laboratory tour on 10/22/19 and upon review of 3 patient tracers performed on 2/4/19, 8/1/19 and 10 /22/19, it was observed that expired ISE Reference Solution-Lot #: M707082, Expiration date of 12/31/2018 was in use on the AU-480 Chemistry Analyzer. 4. A review of 2 patient CBC (Complete Blood Count) tracers performed on 8/1/19 and 8 /30/19 revealed expired CBC Quality Control materials used (QC-Lot #'s: 91130710, 91130711 and 91130712, Expiration date of 7/31/19). (Assay Sheets for Controls printed from Web-site) 5. A review of 16 patients tested for Clostridium Difficile from 12/18/18 to 2/05/19 revealed expired test kit used, Lot #: 1017084, Expiration date of 12/01/2018. 6. A review of 1 patient tracer for TSH, Free T4, Folate, Ferritin and Vitamin B-12 performed on 4/05/18 and 1 patient tracer for TSH and Free T4 performed on 9/28/18 revealed expired QC materials used (QC lot #'s: 40911 and 40912, Expiration date of 2/28/18). 7. A review of 1 patient tracer for CBC performed on 9/28/18 revealed expired QC materials used (QC lot #: 81420710-Expiration date of 8/29/18, QC lot #: 80580710-Expiration date of 6/6/18 and QC lot #: 80580712-Expiration date of 6/6/18). 8. Upon interview at approximately 3:00 p.m. October 23, 2019 with the MLT, it was confirmed that reagents and control materials were used for patient testing beyond their expiration dates. ==========
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: ========== Based on review of maintenance records for 2018 and 2019 for the Chemistry analyzer AU-480 and upon interview with the MLT, it was determined that Linearities had not been performed for the two year period. The findings include: 1. A review of maintenance records for the Chemistry analyzer AU-480 revealed no linearities documented for 2018 or 2019. 2. An interview at approximately 3:00 p.m. on October 23, 2019 with the MLT confirmed there were no linearities performed for the two year period for the Chemistry analyzer AU-480. ==========
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: ========== Based on review of maintenance records for 2018 and 2019 for the CBC analyzer Sysmex XP-300 and upon interview with the MLT, it was determined that Calibration Verifications had not been performed for the two year period. The findings include: 1. A review of maintenance records for the CBC analyzer Sysmex XP-300 revealed no Calibration Verifications documented for 2018 or 2019. 2. An interview at approximately 3:00 p.m. on October 23, 2019 with the MLT confirmed there were no Calibration Verifications performed for the CBC Sysmex XP-300 for two year period. ==========
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 documentation of laboratory deficiencies, the laboratory director failed to fulfill his duty to provide overall management and direction for the laboratory in accordance with $493.1407; failed to hire staff with competent experience (Refer to D6004); failed to ensure a safe environment to protect employees from physical, chemical and biological hazards (Refer to D6011); failed to ensure verification procedures were adequate to determine accuracy and precision of method (Refer to D6013); failed to ensure enrollment in a Proficiency Testing Program (Refer to D6015); failed to ensure a quality assessment program was established to assure quality of lab services provided (Refer to D6021); failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system (Refer to D6023); failed to ensure personnel training and competency prior to patient testing (Refer to D6029) and failure to ensure procedure manuals were available for testing processes (Refer to D6031). ==========

D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: ========== Based on lack of training and competency documentation for the Medical Laboratory Technician (MLT) performing and reporting all lab testing, review of work performance since hire date of 1/26/18 and upon interview with the MLT, determined the laboratory director failed to ensure MLT had appropriate experience, training and competency to operate equipment and perform testing to include CBC's (Complete Blood Counts), Prothrombin Times and INR's (International Normalized Ratio), Chemistry and Endocrinology testing and Urine Sediment Analysis since hire date. The findings include: 1. There was no training and competency documentation for MLT for operation of equipment, performance of testing and reporting results to include CBC's performed on the Sysmex, Prothrombin Times and INR's performed on the ACL Elite, Chemistry testing performed on the Beckman Coulter AU-480, Endocrinology testing performed on the Beckman Coulter Access 2 and Urine Sediment Analysis, since hire date of 1 /26/18. 2. A review of MLT's work performance since hire date revealed expired reagents in use on the Beckman Coulter AU-480, the Access 2, the ACL Elite, no Quality Control (QC) assay sheets were available for CBC's, Prothrombin Times, Chemistry, Endocrinology and Urinalysis, no Calibration Verification performed for the CBC instrument, no Linearities performed for the Chemistry instrument, no validation of new reagent lot performed for Prothrombin Times and INR's, unacceptable urine centrifuge and unserviced microscope for use with urine sediment analysis since hire date of 1/26/18. 3. An interview with the MLT at approximately 3: 00 p.m. October 23, 2019 confirmed she had never managed a laboratory before and did not have the experience or training upon hire date of 1/26/18 to ensure proper operation of equipment and test performance for all she was responsible for . ==========
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by:

	========== Based on observation on 10/22/19 at approximately 8:30 a.m. of food and drink stored in the laboratory and of chemicals and acids stored in the laboratory (not in a protective biological safety cabinet) and upon interview with the MLT, it was determined the laboratory director failed to ensure a safe laboratory environment which employees are protected from physical, chemical and biological hazards. The findings include: 1. Observation on 10/22/19 at approximately 8:30 a.m. of food and drink stored in the laboratory area on a shelf with test kits in use. 2. Observation on 10/22/19 at approximately 8:30 a.m. of Citranox, Sodium Hypochlorite, Isopropol Alcohol, Sodium Hydroxide and Hydochloric Acid stored together on an open shelf underneath the Distilled Water Device. 3. An interview on 10/23/19 at approximately 3:00 p.m. with the MLT confirmed there was food and drink stored in the laboratory and also chemicals and acids were stored in the laboratory not in a safety cabinet. ==========
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 lack of instrument linearities for the Chemistry AU-480 analyzer; lack of Calibration Verification for the CBC Sysmex XP-300 analyzer, lack of Normal Patient Prothrombin study verification and accuracy verification for INR calculations for the ACL Elite analyzer and upon interview with the MLT, it was determined the laboratory director failed to ensure verification procedures were performed to determine accuracy, precision and other pertinent performance characteristics of the method were met for patient testing. The findings include: 1. Lack of instrument linearities for the Chemistry AU-480 for tests performed: Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, Carbon Dioxide, Total Protein, Albumin, Calcium, Alkaline Phosphatase, ALT, AST, Total Bilirubin, Cholesterol, HDL andTriglycerides for 2018 and 2019. 2. Lack of Calibration Verification for the CBC Sysmex XP-300 analyzer for 2018 and 2019. 3. Lack of normal patient Prothrombin study verification and lack of accuracy verification of INR calculations by manual, instrument and LIS methods for 2018 and 2019. 4. Interview on 10/23/19 at approximately 3:00 p.m. with the MLT confirmed that Chemistry Linearities, CBC Calibration Verifications, Normal Patient Prothrombin study verifications and accuracy verifications for INR calculations had not been performed for 2018 and 2019. ==========
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: ========== Based on review of Proficiency Testing (PT) enrollment and interview with the Office Manager, it was determined the laboratory failed to enroll in Proficiency Testing until the third event testing of 2019 while patient testing was being performed in 2018 and 2019 for Chemistry, Hematology, Coagulation, Endocrinology, Toxicology, Bacteriology and Urinalyis. The findings include: 1. A review of the Proficiency Testing enrollment revealed the laboratory failed to enroll in Proficiency Testing until the 3rd event testing of 2019 while patient testing had been performed for 2018 and 2019. 2. An interview on 10/23 /19 at approximately 3:00 p.m. with the Office Manager confirmed the laboratory failed to enroll in proficiency testing until the 3rd event of 2019 and patient testing had been performed for 2018 and 2019. ==========
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 the lack of a laboratory quality assessment program or documentation of quality assessment reviews and upon interview with the MLT and Office Manager, it was determined the Laboratory Director failed to ensure a quality assessment program was established for 2018 and 2019. The findings include: 1. There was no laboratory quality assessment program established for 2018 or 2019. 2. There was no documentation of quality assessment reviews for 2018 or 2019. 3. An interview on 10/23/19 at approximately 3:00 p.m. with the MLT and Office Manager confirmed the laboratory did not have a quality assessment program established to ensure the quality of laboratory services provided for 2018 or 2019. ==========
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 lack of Quality Control Assay Sheets for Chemistry, Hematology, Endocrinology, Toxicology, Coagulation and Urinalysis tests and upon interview with the MLT, it was determined the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system for 2018 and 2019. The findings include: 1. There were no Quality Control Assay Sheets available for review for Chemistry, Hematology, Endocrinology, Toxicology, Coagulation and Urinalysis tests for 2018 and 2019 to ensure acceptable levels of analytical performance had been established and maintained for the two year period. 2. An interview on 10/23/19 at 3: 00 p.m. with the MLT confirmed that Quality Control assay sheets had not been saved for any test systems for 2018 or 2019. ==========
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: ========== Based on the lack of documentation of work experience, training or competency for the MLT hired 1/26/2018 and upon interview with the office manager and MLT, it was determined the laboratory director failed to ensure MLT had the appropriate experience, receive the appropriate training and have demonstrated performance competency for the type and complexity of the services offered to provide and report accurate test results. The findings include: 1. There was no documentation available for review for the MLT, hire date of 1/26/18, to ensure MLT had the appropriate experience, received the appropriate training and have demonstrated performance competency for the type and complexity of the services offered to provide and report accurate test results. 2. An interview on 10/23 /19 at approximately 3:00 p.m. with the office manager and MLT confirmed the laboratory director failed to ensure MLT had the appropriate experience, receive the appropriate training and have demonstrated performance competency for the type and complexity of the services offered to provide and report accurate patient test results since hire date 1/26/2018. ==========
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 lack of procedure manuals for review on 10/22/19 and upon interview with MLT and office manager, the laboratory director failed to ensure there were approved procedure manuals available for all aspects of testing. The findings include: 1. There were no procedure manuals for review during survey on 10/22/19 for all aspects of testing which includes: Chemistry, Hematology, Endocrinology, Coagulation, Urinalysis and Clostridium Difficile testing. 2. An interview at approximately 10:00 a.m. on 10/22/19 with the MLT and office manager confirmed there were no procedure manuals available for review. ==========
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: ========== The Technical Consultant (TC) failed to fulfill the technical consultant's responsibilities since hire date in July of 2018. The TC failed to ensure verification of test procedures performed (Reference D6040); failed to ensure a Quality Control program was established for testing performed (Refer to D6042) and failed to ensure competency of MLT performing moderately complex testing (Refer to D6046). ==========
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: ========== Based on lack of Quality Control (QC) verification studies for establishing reference ranges, precision and accuracy for Chemistry, Endocrinology, Toxicology, Hematology and Coagulation tests, lack of assay sheets to ensure correct QC data, lack of linearity studies for the Chemistry analyzer, lack of Calibration Verification for the Hematology analyzer, lack of normal patient Prothrombin mean study to establish INR calculations and upon interview with the MLT and office manager, it was determined the Technical Consultant failed to ensure verification of the laboratory's QC performance, precision and accuracy of each test system for 2018 and 2019. The findings include: 1. There was no evidence of QC verification for establishing reference ranges, precision and accuracy for Moderately Complex testing performed to include Chemistry, Endocrinology, Toxicology, Hematology and Coagulation tests for 2018 and 2019. 2. There were no QC assay sheets available for review to ensure correct QC data was established for Moderately Complex testing performed for 2018 and 2019. 3. There was no

	documentation of normal patient Prothrombin mean study for establishing INR calculations for 2018 and 2019. 4. An interview at 3:00 p.m. on 10/23/19 with the MLT and office manager confirmed the Technical Consultant had not been on-site to ensure verification of Quality Control reference ranges, establishment of precision and accuracy of tests performed and establishemnt of INR calculations for 2018 and 2019. ==========
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: ========== Based on lack of a documented Quality Control (QC) Program, lack of established normal patient ranges, critical values, specimen collection, handling and processing protocol and an interview with the MLT and office manager, it was determined the Technical Consultant failed to establish a QC program appropriate for the testing performed for 2018 and 2019. The findings include: 1. There was no Established Quality Control Program available for testing performed to include: Chemistry, Endocrinology, Toxicology, Hematology Coagulation, Urinalysis and C. Diff testing. 2. There was no documentation for establishing patient ranges for each test system. 3. There were no critical values defined for each test system. 4. There were no guidelines available for receipt, analysis and reporting of patient results. 5. An interview at approximately 3:00 p.m. on 10/23/19 with the MLT and office manager confirmed there was no QC program available for review for testing performed for the two year period. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: ========== Based on lack of documented competency assessment for the one Medical Laboratory Technician (MLT) hired 1/26 /18 for performing moderately complex testing and upon interview with the MLT, determined the Technical Consultant failed to assess the competency of the MLT since hire date. The findings include: 1. There was no competency assessment for the one MLT performing moderately complex testing available for review. 2. An interview at approximately 3:00 p.m. on October 23, 2019 with the MLT confirmed she had never been evaluated for competency assessment for the moderately complex testing performed to include Chemistry, Endocrinology, Toxicology, Hematology, Coagulation, Urinalysis and C. Diff testing since hire date of 1/26/19. ==========