Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1018705	12/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Acadian Medical Center	3501 Highway 190 E, Eunice, 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 Validation Survey was performed at Acadian Medical Center a Campus of Mercy Regional Medical Center, CLIA ID # 19D1018705 on December 16, 2019 through December 20, 2019. Acadian Medical Center a Campus of Mercy Regional Medical Center 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
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: I. Based on record review and interview with personnel, the laboratory failed to establish written policy to assess competency for the Technical Consultant and General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Technical Consultant also serves as the General Supervisor. 2. Review of the laboratory's "Personnel Competency" policy revealed the laboratory did not include competency assessment for duties of Technical Consultant and General Supervisor including frequency. 3. Review of the Technical Consultant's personnel records revealed a "Laboratory Competency of Supervisory Personnel" form completed December 10, 2018; however, the Laboratory Director did not perform the assessment. 4. In interview on December 17, 2019 at 10:55 am, the Technical Consultant confirmed the Laboratory Director did not perform her competency assessment for supervisory duties. II. Based on record review and interview with personnel, the laboratory failed to follow written policy for

	competency assessments for testing personnel who perform Histopathology testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and two (2) Pathologists perform Histopathology testing. 2. Review of the laboratory's "Personnel Competency" policy revealed "Competency testing is carried out on all procedures starting at orientation, at 6 months, and each annual review." 3. Review of personnel records revealed the Laboratory Director and two (2) Pathologists did not have competency assessments performed. 4. In interview on December 19, 2019, the Technical Consultant confirmed the laboratory did not perform competency assessments for the two (2) Pathologists and Laboratory Director that perform Histopathology testing.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director or designee reviewed the proficiency testing performance evaluation results for the 3rd event for Microbiology and Chemistry. Findings: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2019 revealed the laboratory did not have documentation of review of the results by the Laboratory Director or designee for the following events: 2019 Microbiology 3rd Event: no signature by Laboratory Director or designee 2019 Chemistry Core 3rd Event: no signature by Laboratory Director or designee 2. In interview on December 16, 2019 the Technical Consultant confirmed the laboratory did not document review of the proficiency testing results for the identified events. II. Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed corrective actions for unsuccessful proficiency test results for the 3rd event for Microbiology and Chemistry. Findings: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2019 revealed the laboratory had the following unsuccessful results: 2019 Microbiology 3rd Event: 0% for sputum culture 2019 Chemistry Core 3rd Event: 0% for all analytes 2. Further review of the laboratory's proficiency testing records for 2019 revealed corrective action evaluations for the identified events; however, the Laboratory Director did not review. 3. In interview on December 16, 2019 at 4:05 pm, the Technical Consultant confirmed the Laboratory Director did not review the identified corrective actions.
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 detailed written instructions for providers to maintain the integrity of samples. Findings: 1. In interview on December 16, 2019 at 2:51 pm, the Technical Consultant stated the laboratory receives samples from local nursing homes and home

	health agencies. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed instructions for providers that include the following: (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 further interview on December 16, 2019 at 2:56 pm, the Technical Consultant confirmed the laboratory does not have written instructions related to sample collection, labeling, handling, and transport for providers.
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 complete policies and procedures. Refer to D5401 I. 2. The laboratory failed to follow their policy for monitoring the blood product storage equipment. Refer to D5401 II. 3. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer D5411 I. 5. The laboratory failed to use samples free of hemolysis as required by the manufacturer for RPR testing. Refer to D5411 II. 6. The laboratory failed to monitor the room temperature of the storage room where supplies are stored per manufacturer requirements. Refer to D5413. 7. The laboratory failed to document the lot numbers and expiration dates for the urinalysis microscopic quality controls (QC). Refer to D5415. 8. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417 I. 9. The laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Refer D5417 II. 10. The laboratory failed to have complete performance verification studies for Complete Blood Counts (CBC). Refer to D5421 I. 11. The laboratory failed to have complete performance verification studies for Coagulation testing. Refer to D5421 II. 12. The laboratory failed to ensure maintenance for the Siemens Dimension EXL with LM and Dimension EXL 200 analyzers were performed per manufacturer requirements. Refer to D5429 I. 13. The laboratory failed to ensure maintenance for the Sysmex CA-660 was performed per manufacturer requirements. Refer to D5429 II. 14. The laboratory failed to ensure maintenance for the Sorvall Cell Washer was performed per manufacturer requirements. Refer to D5429 III. 15. The laboratory failed to check the RPM of the automatic rotator used for RPR testing weekly. Refer to D5433. 16. The laboratory failed to perform two (2) levels of controls prior to patient testing for Chemistry. Refer to D5447 I. 17. The laboratory failed to perform two (2) levels of controls prior to patient testing for Hematology. Refer to D5447 II. 18. The laboratory failed to perform Rotavirus quality control each day of patient testing for nine (9) of seventeen

	(17) patients reviewed. Refer to D5447 III. 19. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for manual body fluids cell counts. Refer to D5469 I. 20. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469 II. 21. The laboratory failed to complete a crossmatch of emergency release blood for three (3) of ten (10) patients reviewed. Refer to D5553 I. 22. The laboratory failed to confirm ABO and Rh type of donor units before use. Refer to D5553 II. 23. The laboratory failed to perform a freezer alarm check for one (1) quarter out of four (4) in 2019. Refer to D5555. 24. The laboratory failed to follow corrective action policies for Chemistry testing. Refer to D5779. 25. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Refer to D5781 I. 26. the laboratory failed to document corrective actions performed when cuvette temperatures did not meet acceptable limits for the Siemens Dimension EXL with LM and Dimension EXL 200. Refer to D5781 II. 27. The laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783 I. 28. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783 II. 29. The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783 III. 30. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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: I. Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies and procedures that included: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria b) Corrective action to take if equipment temperatures are not within acceptable range c) Manual INR checks to include procedure and frequency d) Platelet poor plasma frequency of performance e) Current instrumentation for hematology differential policy f)Twice a year verification for accuracy of Histopathology testing (frozen sections) to include frequency, acceptability criteria, and corrective action plan g) Function check for automated rotator used for RPR testing to include frequency of performance and acceptable criteria. 2. In interview on December 20, 2019 the Technical Consultant confirmed the laboratory did not include the identified policies in their manual. II. Based on record review and interview with personnel, the laboratory failed to follow their policy for monitoring the blood product storage equipment. Findings: 1. Review of the laboratory's "Blood Bank Chart Recorder" policy revealed the following: a) "The temperature recorder chart is to be checked daily to assure it is functioning adequately" b) "Recorder charts are changed

	on Mondays" c) "Remove the existing chart and label the back of the chart with documentation of temperature fluctuations and technologists's initials" 2. Review of the laboratory's blood bank refrigerator and plasma freezer circular temperature charts for 2018 and 2019 revealed the temperature was not recorded and documentation by technologist was not included for the following dates: January 8, 2018 after 6:00 am April 30, 2018 after 6:00 am June 4, 2018 after 5:00 am September 9, 2019 after 6:00 am 3. Further review of the laboratory's blood bank refrigerator and plasma freezer circular temperature charts for 2018 and 2019 revealed the following date temperature fluctuations were indicated without documentation by technologist: Refrigerator: February 24, 2019 Freezer: August 19, 2019 Freezer: September 20-21, 2019 Freezer: September 25-26, 2019 Freezer: September 30-October 1, 2019 Freezer: November 6, 2019 4. In interview on December 19, 2019 at 10:20 am ,the Technical Consultant stated the technologists should document fluctuations and gaps on the circular temperature charts. The Technical Consultant confirmed the laboratory did not have documentation for the identified dates.
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 have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following procedures were not included: a) For Clinitek Advantus instrument and Histopathology (frozen sections): Detailed policies and procedures for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. b) Blood gas: policy to include manufacturer's specimen handling/processing requirements c) For Histopathology (frozen sections): Microscopic examination, including the detection of inadequately prepared slides d) For Clinitek Advantus instrument and Histopathology (frozen sections): Step-by-step performance of the procedure, including test calculations e) Quality Control: to include, but not limited to: what quality control is required for each instrument, establishment of ranges for which specific control material, acceptability criteria for each, corrective action for unacceptable results and flags. 2.

	In interview on December 19, 2019 at 3:46 pm, the Respiratory Personnel confirmed the blood gas policy and procedure did not include the manufacturer's sample processing requirements. 3. In interview on December 20, 2019, the Technical Consultant confirmed the identified policies were not included in the laboratory's policy and procedure manual.
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 use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes the Sysmex CA-660 for PT and International Normalized Ration (INR) testing. 2. Review of the "Siemens Healthcare Diagnostics Sysmex CA-600 Series Verification of Reference Interval" insert revealed the following donor requirements: a) " Donors must be from a healthy population (no known pathological condition; no pre-surgical or hospitalized patients) b) Donors should not take any medications, including aspirin c) Donors should span the adult age range. Note: A separate range should be established for pediatric populations) d) Testing should be performed over a period of several days and by different people if possible, to allow for day to day variation e) Samples should be drawn each testing day, following the established protocol for collection, storage and processing f) The test results from the donors should be analyzed statistically. Software that performs this calculation can be used." 3, Review of the laboratory's "Lot-to-lot Normal Range Study" policy revealed the following requirements: a) Collect specimens on at least 20 healthy individuals with a reasonably even distribution of males and females. Donors should span the adult age range of the population served. (See attached donor questionnaire). b) Testing should be performed over a period of several days and by different people, if possible, to minimize day to day variation. c) A minimum of 4-6 samples should be drawn each testing day, following established lab protocol for collection, storage and processing of patient plasma samples. d) Using the Excel Program express results using Mean, SD, and CV analysis. e) Interpret results using standard statistical analysis and record results on worksheet. f) Attach all instrument tapes and donor questionnaires to the excel worksheet. 4. Review of the laboratory's donor questionnaire form revealed the following "Yes/No" questions: a) "Are you feeling healthy and well today? b) Are you or have you ever been on hormone therapy? c) Are you on any 'blood thinner' medication such as Coumadin? d) Are you taking herbal supplements? e) Have you taken aspirin within the last 72 hrs? f) Have you taken any medication in the 24 hrs?" 5. Review of the laboratory's normal mean PT study for the instrument's initial stat-up/validation revealed the following one (1) of twenty (20) donors did not meet the "normal" criteria: Innovin Lot # 549724: February 14, 2019: Specimen Number 8: No answer indicated for "Are you on any blood thinner medication such as Coumadin" question 6. Review of the laboratory's lot- to-lot normal range study performed in August 2019 revealed the following five (5) of twenty (20) donors did not meet the "normal" criteria: August 20, 2019:

	Specimen Number 6: Responded "No" to "Are you feeling healthy and well today" question August 20, 2019: Specimen Number 8: Responded "No" to "Are you feeling healthy and well today" question August 23, 2019: Specimen Number 9: No answer indicated for "Are you taking herbal supplements" question August 20, 2019: Specimen Number 15: Responded "Yes" to "Have you taken any medication in the 24 hrs" question August 20, 2019: Specimen Number 20: Responded "Yes" to "Have you taken any medication in the 24 hrs" question 7. In interview on December 17, 2019 at 4:31 pm, the Technical Consultant stated the identified patients were not excluded as donors. 8. Review of the laboratory's test menu revealed the laboratory performs 3,575 PT/INR tests annually. 35369 II. Based on observation, record review and interview with personnel, the laboratory failed to use samples free of hemolysis as required by the manufacturer for RPR testing. Findings: 1. Observation during the laboratory tour on December 19, 2019 at 10:30am revealed patient separated serum samples stored in the refrigerator for later testing. Further observation revealed two (2) of the eight (8) patient samples were hemolyzed. 2. Review of the manufacturer instructions for the SureVue RPR test kit as well as the laboratory policy revealed "Samples should be free from bacterial contamination, hemolysis or lipemia". 3. Interview with Technical Consultant on December 19, 2019 at 10 am confirmed that patient specimens are batch tested on Monday, Wednesday and Friday and that hemolyzed samples should not be used for RPR testing. The Technical Consultant also confirmed the above hemolyzed samples were hemolyzed and stored for later testing.
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 observation, record review, and interview with personnel, the laboratory failed to monitor the room temperature of the storage room where supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2018 revealed the laboratory did not monitor the storage room where the following supplies were located: a) Stat Express Glucose Test Strips, Quantity: four (4) boxes b) BD Vacutainer Buffered Sodium Citrate blood collection tubes, Quantity: approximately 1600 tubes c) BD Vacutainer SST blood collection tubes, Lot # 9263408, Quantity: approximately 700 tubes d) BD Vacutainer PST Gel and Lithium Heparin blood collection tubes, Lot # 9260624,Quantity: approximately 700 tubes e) BD Vacutainer C and S Preservative Urine Tubes, Quantity: approximately 1300 tubes f) BD Vacutainer K2EDTA blood collection tubes, Lot #'s 8276808, 9260584,Quantity: approximately 700 tubes g) BD Vacutainer No additive plus tubes, Quantity: approximately 1100 tubes h) Sysmex DFL Cell pack, Quantity: three (3) boxes i) Cell Clean Auto, Quantity: four (4) boxes j) Sysmex Retic Fluorocell RET, Quantity: one (1) box k) Sysmex Fluorocell WDF, Quantity: five (5) boxes l) Flo Q Swabs, Lot # 1800477, Quantity: one (1) box m) BD Vacutainer Urine Complete Cups, Quantity: two (2) boxes n) BD Vacutainer

	Urinalysis tubes, Quantity: two (2) packs 2. Review of manufacturer storage requirements for the identified supplies revealed the following: a) BD Vacutainer collection tubes: storage requirement 4-25 degrees Celsius b) State Express Glucose test strips: storage requirement 1-30 degrees Celsius c) Sysmex DFL Cell pack: storage requirement 2-35 degrees Celsius d) Cell Clean Auto: storage requirement 1-30 degrees Celsius e) Sysmex Retic Fluorocell RET: storage requirement 2-30 degrees Celsius f) Sysmex Fluorocell WDF: storage requirement 2-35 degrees Celsius g) Flo Q swabs: storage requirement 2-30 degrees Celsius 3. In interview on December 16, 2019 at 2:08 pm, the Technical Consultant confirmed the temperature of the storage room is not monitored.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document the lot numbers and expiration dates for the urinalysis microscopic quality controls (QC). Findings: 1. Review of the laboratory's "General QC Policy" revealed "Quality control will be performed, at a minimum, with a frequency defined by the laboratory in accordance with manufacturer recommendations and/or state and federal guidelines, whichever is more stringent. Each specialty will have its own QC Frequency Statement under separate cover. A run is defined as follows: Urinalysis-24 Hours." 2. Review of the laboratory's test menu revealed "BioRad Urinalysis" controls are utilized for microscopic urinalysis. 3. Review of the laboratory's "Clinitek Quality Control Log" form revealed a section for documentation of the QC lot numbers and expiration dates for the "BioRad Urinalysis Microscopic controls." 4. Further review of the laboratory's "Clinitek Quality Control Log" for November 2019 revealed the laboratory did not document the lot numbers and expiration dates for urinalysis microscopic QC for the following fourteen (14) dates: November 7, 2019 November 8, 2019 November 9, 2019 November 10, 2019 November 11, 2019 November 12, 2019 November 13, 2019 November 21, 2019 November 23, 2019 November 24, 2019 November 25, 2019 November 27, 2019 November 29, 2019 November 30, 2019 5. In interview on December 19, 2019, the Technical Consultant confirmed the laboratory did not document the urinalysis microscopic control information for the identified dates.
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: I. Based on observation, record review, and interview with personnel, the laboratory

	failed to ensure supplies did not exceed their expiration date. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the following expired items: Located in Revco freezer: a) Access Total T4 Calibrators, Lot # 920984, Expiration date: 2019-11-30, Quantity: 1 box b) Access Folate Calibrators SO, Lot # 920944, Expiration date: 2019-11-30, Quantity: 2 boxes 2. In interview on December 16, 2019 at 2:36 pm, the Technical Consultant stated the identified calibrators were for the new equipment. The Technical Consultant confirmed the identified items were expired. 35369 II. Based on record review and interview with laboratory personnel, the laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Findings: 1. Review of laboratory body fluid cell count worksheets revealed the following quality control materials were used for patient testing beyond the manufacturer date of expiration: a) QC Lot - 8015 Expiration Date - 07/15/2018 b) QC Lot - 8183 Expiration Date - 01/02/2019 2. Review of patient final reports revealed the following three (3) of twenty-one (21) patients reviewed were performed on expired quality control material: a) Patient Number 5541482 performed on 07/16/2018 with QC Lot 8015 which expired 07/15 /2018 b) Patient Number 5542724 performed on 07/26/2018 with QC Lot 8015 which expired 07/15/2018 c) Patient Number 5567545 performed on 02/12/2019 with QC Lot 8183 which expired 01/02/2019 3. Interview with the Technical Consultant on December 19, 2019 confirmed the documentation reflects that the above patients were tested using expired quality control material.
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 Complete Blood Counts (CBC). Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes the Sysmex XN-550 and Sysmex XN-350 analyzers for CBC testing. 2. In interview on December 16, 2019 at 2:08 pm, the Technical Consultant stated the laboratory utilizes the Sysmex XN-550 as the primary analyzer an Sysmex-XN 350 as the back-up. The Technical Consultant stated the laboratory began patient testing on March 1, 2019. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a performance verification policy/procedure. 4. Review of the laboratory's validation records for the Sysmex XN-550 and Sysmex XN-350 analyzers revealed the following information was not included: a) Acceptability criteria b) Laboratory participation for reportable range study c) Normal patients for reference range study 5. In interview on December 17, 2019, the Technical Consultant stated the Sysmex field service representative performed the linearity (reportable range) studies. The Technical Supervisor further stated the laboratory used normal and abnormal patients for their reference range study. 6. In further interview on December 17, 2019, the Technical Consultant

	confirmed the laboratory did not include acceptability criteria for the Sysmex validation studies. 7. Review of the laboratory's test menu revealed the laboratory performs 112,025 CBC tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance verification studies for Coagulation testing. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory performs Prothrombin Time (PT), Partial Thromboplastin Time (PTT), and D-Dimer testing on the Sysmex CA-600 analyzer. 2. In interview on December 16, 2019 at 1:00 pm, the Technical Consultant stated the laboratory started patient testing on the Sysmex CA-600 analyzer on March 1, 2019. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a performance verification policy /procedure. 4. Review of the laboratory's validation studies for the Sysmex CA-600 revealed the following information was not included: a) PT and PTT: Acceptability criteria, raw data, reference range studies utilizing normal donors, and reportable range studies b) D-dimer: Acceptability criteria, raw data, precision to include day-to day, run-to-run, within-run, and operator variance, reportable and reference range studies. 3. In interview on December 18, 2019 at 2:21 pm, the Technical Consultant confirmed the laboratory did not include the identified information in their validation studies for Coagulation 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: I. Based on observation, record review, and interview with personnel, the laboratory failed to ensure maintenance for the Siemens Dimension EXL with LM and Dimension EXL 200 analyzers were performed per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM and Dimension EXL 200 analyzers for Chemistry testing. 2. Review of the "Dimension EXL with LM and Dimension EXL 200 Weekly/Monthly Maintenance" logs revealed the following weekly tasks: a) Clean Outside of R2 probe b) Clean Outside of HM Wash probes 3. Further review of the Dimension maintenance logs for July 2018, July 2019, and November 2019 revealed the laboratory did not perform weekly maintenance for the following weeks: Week of July 1, 2018 Week of July 15, 2018 Week of July 7, 2019 4. In interview on December 19, 2019 at 11:09 am, the Technical Consultant confirmed the identified weeks did not have documentation of weekly maintenance performance. II. Based on observation, record review, and interview with personnel, the laboratory failed to ensure maintenance for the Sysmex CA-660 was performed per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2019 revealed the laboratory utilizes the Sysmex CA-660 for Coagulation testing. 2. Review of the "Sysmex CA-600 series" maintenance logs revealed the following maintenance tasks: Weekly: a) Replace Trash Box Liner CA6 3. Further review of the Sysmex CA-600 series maintenance logs for July 2018, July 2019, and November 2019 revealed the laboratory did not document weekly maintenance for the following weeks: Week of July 7, 2019 Week of November 4, 2019 Week of November 17, 2019 4. Further review of the identified maintenance logs revealed the Technical Consultant signed

	the logs as reviewed. 5. In interview on December 18, 2019, the Technical Consultant confirmed the laboratory did not have documented weekly maintenance performance for the identified dates. III. Based on record review and interview with personnel, the laboratory failed to ensure maintenance for the Sorvall Cell Washer was performed per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes a Sorvall Cell Washer for Blood Bank testing. 2. Review of the laboratory's "Sorvall Cell Washer 2 Plus Maintenance Logs" revealed the following daily maintenance tasks: a) Inspect tubing and connections b) Inspect interior bowl c) Saline Volume Check (52-54 mL) 3. Review of the Sorvall Cell Washer maintenance logs for 2019 revealed the laboratory did not perform daily maintenance on the following two (2) days: June 22, 2019 June 23, 2019 4. In interview on December 19, 2019, the Technical Consultant confirmed the laboratory did not documented daily maintenance for the Sorvall Cell Washer on the identified dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to check the RPM of the automatic rotator used for RPR testing weekly. Findings: 1. Observation during the laboratory tour on December 19, 2019 revealed the laboratory utilized an automatic rotator for RPR testing using SureVue RPR kit. 2. Review of RPR Log Sheets revealed a weekly RPM Check of 100 +/- 1 for the automatic rotator used for RPR testing. Further review of the laboratory policy and procedure revealed the laboratory did not have a policy for this function check. 3. Further record review of RPR Log Sheets from November 2019 to July 2018 revealed the laboratory did not document the date of weekly RPM checks for the automatic rotator in serology. 3. Interview with Technical Consultant on December 19, 2019 confirmed the date of RPM checks was not documented to verify weekly performance.
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 (2) levels of controls prior to patient testing for Chemistry.

	Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM and Dimension EXL 200 for Chemistry testing. 2. Review of the laboratory's " Chemistry QC Frequency" policy revealed "Controls should be performed at least each 24 hours. Daily QC is usually performed following routine maintenance procedures in early AM (Shift 1). At a minimum, 2 levels of QC will performed." 3. Review of QC records from June 2019 through December 2019 revealed the laboratory did not perform two (2) levels of QC for the following dates: July 1, 2019: Digoxin: Multiqual Level 1 not performed September 9, 2019: Phenytoin Immunoassay Plus Level 1 and Level 3 not performed 4. Review of patient logs revealed the following patients were reported prior to performance of two (2) levels of QC: July 1, 2019: Digoxin: Patient 4200476 and Patient 4200481 September 9, 2019: Phenytoin: Patient 4209136 5. In interview on December 20, 2019 at 12:01 pm, the Technical Consultant confirmed the laboratory did not perform two (2) levels of QC prior to patient testing for the identified dates. 6. Review of the laboratory's test menu revealed the laboratory performs less than one hundred fifty (150) samples annually for Digoxin and Phenytoin. II. Based on record review and interview with personnel, the laboratory failed to perform two (2) levels of controls prior to patient testing for Hematology. Findings: 1. Review of QC records revealed the laboratory utilized a Sysmex XT-2000i for Complete Blood Count (CBC) testing in July 2018. 2. Review of the laboratory's "General QC policy" revealed "Quality control will be performed, at a minimum, with a frequency defined by the laboratory in accordance with manufacturer recommendations and/or state and federal guidelines, whichever is more stringent." Chemistry QC Frequency" policy revealed. Hematology-8 hours." 3. Review of CBC records for July 2018, July 2019, and November 2019 revealed the laboratory did not perform two (2) levels of QC prior to patient testing on the following date: July 2, 2018: no QC performed at 9:48 am and 17:39 ; "- - - -" reported 4. Review of patient logs from July 2018 revealed the following patients were reported prior to performance of two (2) levels of QC: Patient 5539691, Patient 5538056, and Patient 5539623; Total of fifty nine (59) patients reported. 5. In interview on December 18, 2019 at 9:18 am, the Technical Consultant confirmed the identified dates had QC and patients reported without corrective actions. 35369 III. Based on observation, record review and interview with laboratory personnel, the laboratory failed to perform Rotavirus quality control each day of patient testing for nine (9) of seventeen (17) patients reviewed. Findings: 1. Observation during the laboratory tour revealed the laboratory use Fisher Sure-Vue Rota Test for Rotavirus testing of patient samples. 2. Review of the laboratory policy revealed two levels of external quality control testing are to be performed each day of use. 3. Review of quality control and patient testing from July 2019 - December 10, 2019 revealed the following nine (9) of seventeen (17) patients had Rotavirus testing performed without two levels of external quality control (QC) testing: a) Patient ID 4200615 Rotavirus testing 07/02/19 at 1231. Previous QC performed 06/11/19. b) Patient ID 4201319 Rotavirus testing 07/11/19 at 1529. Previous QC performed 06/11/19. c) Patient ID 4201857 Rotavirus testing 07/11/19 at 1529. Previous QC performed 06/11/19. d) Patient ID 4210298 Rotavirus testing 09/17/19 at 1925. Previous QC performed 09/01 /19. e) Patient ID 4209581 Rotavirus testing 09/17/19 at 1927. Previous QC performed 09/01/19. f) Patient ID 4209584 Rotavirus testing 09/17/19 at 1929. Previous QC performed 09/01/19. g) Patient ID 4218249 Rotavirus testing 11/19/19 at 1422. Previous QC performed 11/08/19. h) Patient ID 4219854 Rotavirus testing 12/05 /19 at 1106. Previous QC performed 11/08/19. i) Patient ID 4218728 Rotavirus testing 12/06/19 at 0829. Previous QC performed 11/08/19. 4. Interview with the Technical Consultant on Decemeber 20, 2019 at 12 pm confirmed the Rota Tes quality control log did not have daily quality control documentation for each day of patient testing.

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: I. Based on observation, record review, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for manual body fluids cell counts. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes Streck Cell-Chex controls for manual cell counts. 2. Review of the Streck Cell-Chex package insert under "Expected Results" section revealed " Upon receipt of a new control lot, it is good laboratory practice that an individual laboratory establish its own mean and limits for each parameter. However, the control means established by the laboratory should fall within the expected range specified for the control." 3. In interview on December 20, 2019 at 12:11 pm, the Technical Consultant confirmed the laboratory does not establish QC parameters for Streck Cell-Chex controls. II. Based on observation, record review and interview, the laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Findings: 1. Observation during the tour of CATH Lab on December 19, 2019 revealed a Hemochron Jr. instrument utilized for ACT testing during CATH procedures. 2. Record review of Hemachron performance logs revealed the laboratory utilized Accriva external quality control material to maintain the ACT instrument. Further review of the package insert stated under the expected values of the quality control material "that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results." 3. Review of the QC records for testing revealed the laboratory determined QC acceptability based on the performance ranges and mean provided by the manufacturer. 4. Review of the test menu revealed the laboratory performs twenty one (21) ACT tests annually. 5. Review of the test log provided from July 2019 - December 14, 2019 revealed the laboratory performed thirty five (35) ACT tests in that period alone. 6. In interview on December 19, 2019, the Technical Consultant confirmed the laboratory uses the ranges provided by the manufacturer to determine acceptability of ACT quality control testing. The Technical Consultant stated the laboratory does not establish their own range or mean.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12);

	606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to complete a crossmatch of emergency release blood for three (3) of ten (10) patients reviewed. Findings: 1. Review of the laboratory's policy for Emergency Blood Transfusion Procedures revealed "the crossmatch must be completed in any event." This policy further stated "If any incompatibility is noted at any stage of the procedure, the patient's physician will be notified at once." 2. Review of the laboratory's emergency release and blood bank records revealed the following three (3) of ten (10) patients reviewed were issued blood products without completion of crossmatch or any compatibility testing: April 24, 2019 at 19:43: Patient 5572743 received 2 units of packed red blood cells upon emergency release November 15, 2019 at 15:24: Patient 4217862 received 1 unit of packed red blood cells upon emergency release November 15 24, 2019 at 13:50: Patient 4217862 received 1 unit of packed red blood cells upon emergency release 3. In interview on December 20, 2019, the Technical Consultant confirmed the above patients did not have a crossmatch completed as required by the laboratory policy for blood issued by emergency release. II. Based on record review and interview with personnel, the laboratory failed to confirm ABO and Rh type of donor units before use. Findings: 1. Review of the laboratory's policy for ABO Confirmation of Donor Blood stated "repeat testing is done on all RBC's received from the collection facility." 2. Interview with the Technical Consultant during the laboratory tour on December 19, 2019 of the blood bank revealed that the laboratory verifies the blood type of donor units at the time of a crossmatch. The Technical Consultant confirmed that units are not typed prior to being used as available inventory for patient testing. Further interview with the Technical Consultant confirmed the laboratory issues emergency release blood products from the available inventory. 3. Record review of emergency release records revealed the following ten (10) of ten (10) patients were issued emergency release blood units without confirmation of unit typing: Patient 5531477 received emergency release blood on May 7, 2018 Patient 4213563 received emergency release blood on October 13, 2019 Patient 4217862 received emergency release blood on December 20, 2019 Patient 5572743 received emergency release blood on March 24, 2019 Patient 4216301 received emergency release blood on November 4, 2019 Patient 4218237 received emergency release blood on November 7, 2019 Patient 5547372 received emergency release blood on August 31, 2018 Patient 5561910 received emergency release blood on December 27, 2018 Patient 5543878 received emergency release blood on August 3, 2018 Patient 5529692 received emergency release blood on April 12, 2018 4. Interview with Technical Consultant on December 20, 2019 confirmed the laboratory practice did not ensure that all units had repeat testing for blood type prior to issuance as emergency release for patient transfusion.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document

	all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform a freezer alarm check for one (1) quarter out of four (4) in 2019. Findings: 1. Review of the laboratory's "Freezer Alarm Test-High Activation" policy revealed "Performed quarterly to test the activation of the alarm at unsafe high temperatures." 2. Review of the laboratory's circular temperature charts for the plasma freezer revealed the laboratory did not perform an alarm check for the 3rd Quarter (due September 2019). 3. Further review of the laboratory's temperature charts and temperature logs revealed the plasma freezer was "not working" in September 25, 2019 through September 31, 2019; however, was back in use October 1, 2019. 4. In interview on December 19, 2019 at 10:55 am, the Technical Consultant stated the quarterly alarm check for the plasma freezer was not done in September because the freezer was not working. The Technical Consultant confirmed the laboratory did not perform the alarm check when the freezer was put back into use in October 2019.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to follow corrective action policies for Chemistry testing. Findings: 1. Review of the laboratory's "QC Remedial Action Policy" revealed the following: a) "Controls falling outside of acceptable limits will require troubleshooting and remedial action. Patient testing is to be suspended until QC failures have been investigated, resolved and are back within acceptable limit criteria." b) " Troubleshooting guidelines: Repeat the control 1 time, Rerun the control using a fresh aliquot or new bottle of QC material, investigate the assay history for the following: lot change, expiration date open stability, calibration issues; investigate the instrument for the following: preventative maintenance, system checks, instrument log; call Technical Support Hotline for assistance" c) "Accurately document all remedial/corrective actions taken on the appropriate log." d) "In the event remedial action involves anything other than changing quality control material, a patient impact study should be initiated and documented, along with the corrective action(s) taken, on a Quality Control Outlier Form (LB-QA-04) and forwarded to the laboratory manager for review." 2. Review of quality control records from July 2019 through December 2019 for Chemistry testing revealed the laboratory did not follow their corrective action policy for the following: a) July 9, 2019: Phenytoin: Immunoassay Plus Level 1; QC tested three (3) times; no documentation of corrective actions taken or patient impact study initiated b) July 23, 2019: CSF Total Protein: Spinal Fluid Level 2: no documentation of corrective actions taken c) July 23, 2019: CSF Glucose: Spinal Fluid Level 2: QC repeated twice; no patient impact study initiated d) August 7, 2019: CSF Total Protein: Spinal Fluid Level 1: QC repeated three (3) times; no patient impact study initiated e) August 30, 2019: CSF Total Protein: Spinal Fluid Level 1 and Level 2; "Reran QC on same cup"; fresh aliquot was not used f) September 10, 2019: Phenytoin: Immunoassay Plus Level 1 and Level 3: QC repeated twice; no patient impact study initiated g)

	December 11, 2019: Phenytoin: Immunoassay Plus Level 1: QC repeated twice; no patient impact study initiated 3. Review of patient records revealed the following patients were reported without corrective action: a) July 9, 2019: Phenytoin: Patient 4201223 and Patient 4201222 b) July 23, 2019: CSF Total Protein: Patient 4203097 c) July 23, 2019: CSF Glucose: Patient 4203097 d) August 7, 2019: CSF Total Protein: Patient 4204935 e) August 30, 2019: CSF Total Protein: Patient 4207961 f) September 10, 2019: Phenytoin: Patient 4209428 and Patient 4209298 g) December 11, 2019: Phenytoin: Patient 4220784 4. In interview on December 19, 2019, the Technical Consultant confirmed the laboratory did not follow the quality control corrective action policy for the identified dates.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Findings: 1. Review of the laboratory's temperature and humidity logs for 2018 and 2019 revealed the room's acceptable temperature as 18 degrees Celsius to 35 degrees Celsius. 2. Review of the temperature logs for the Cath laboratory revealed the room's acceptable temperature as 15 degrees Celsius to 30 degrees Celsius. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy related to corrective actions for temperature monitoring. 4. Review of the laboratory's temperature logs for 2018 and 2019 revealed the room temperature was documented as outside of the acceptable limits without documented corrective actions for the following thirteen (13) dates: a) Microbiology Daily Temperature Logs: January 20, 2018 documented temperature 25.2 degrees Celsius January 29, 2018 documented temperature 25.2 degrees Celsius March 20, 2018 documented temperature 25.2 degrees Celsius April 21, 2018 documented temperature 25.5 degrees Celsius June 24, 2018 documented temperature 25.2 degrees Celsius July 7, 2018 documented temperature 25.2 degrees Celsius July 16, 2018 documented temperature 25.9 degrees Celsius August 9, 2018 documented temperature 25.2 degrees Celsius August 26, 2018 documented temperature 26.4 degrees Celsius August 27, 2018 documented temperature 25.9 degrees Celsius b) Cath Lab Bench Temperature Logs: October 7, 2019 documented temperature 13.3 degrees Celsius October 9, 2019 documented temperature 13.3 degrees Celsius October 16, 2019 documented temperature 14.2 degrees Celsius 5. In interview on December 17, 2019, the Cath lab personnel confirmed the laboratory did not perform corrective actions for the identified dates. 6. In interview on December 20, 2019 at 8:35 am, the Technical Consultant stated the laboratory did not have a policy for corrective actions for temperature monitoring. The Technical Consultant confirmed the laboratory did not perform corrective actions

	for the identified dates. II. Based on observation, record review, and interview with personnel, the laboratory failed to document corrective actions performed when cuvette temperatures did not meet acceptable limits for the Siemens Dimension EXL with LM and Dimension EXL 200. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM and Dimension EXL 200 for Chemistry testing. 2. Review of the laboratory's maintenance logs for the Siemens Dimensions revealed the acceptable cuvette temperature range is 36.8 to 37.2 degrees Celsius. 3. Review of the laboratory's maintenance logs for the Siemens Dimension EXL 200 for July 2018, July 2019, and November 2019 revealed the following dates with unacceptable cuvette temperatures: Instrument Serial Number: 12252568 July 1, 2019: documented temperature 37.5 degrees Celsius July 2, 2019: documented temperature 37.6 degrees Celsius July 3, 2019: documented temperature 37.6 degrees Celsius July 4, 2019: documented temperature 37.4 degrees Celsius July 5, 2019: documented temperature 37.4 degrees Celsius July 6, 2019: documented temperature 37.4 degrees Celsius July 7, 2019: documented temperature 37.4 degrees Celsius July 8, 2019: documented temperature 37.5 degrees Celsius July 9, 2019: documented temperature 37.5 degrees Celsius July 10, 2019: documented temperature 37.3 degrees Celsius July 11, 2019: documented temperature 37.4 degrees Celsius July 12, 2019: documented temperature 37.4 degrees Celsius July 13, 2019: documented temperature 37.4 degrees Celsius July 14, 2019: documented temperature 37.5 degrees Celsius July 15, 2019: documented temperature 37.5 degrees Celsius July 16, 2019: documented temperature 37.5 degrees Celsius July 17, 2019: documented temperature 37.5 degrees Celsius November 8, 2019: documented temperature 37.3 degrees Celsius November 10, 2019: documented temperature 37.3 degrees Celsius November 13, 2019: documented temperature 37.3 degrees Celsius November 15, 2019: documented temperature 37.3 degrees Celsius November 17, 2019: documented temperature 37.3 degrees Celsius November 18, 2019: documented temperature 37.3 degrees Celsius November 19, 2019: documented temperature 37.3 degrees Celsius November 20, 2019: documented temperature 37.3 degrees Celsius November 22, 2019: documented temperature 37.3 degrees Celsius November 23, 2019: documented temperature 37.3 degrees Celsius November 24, 2019: documented temperature 37.3 degrees Celsius November 25, 2019: documented temperature 37.3 degrees Celsius November 27, 2019: documented temperature 37.3 degrees Celsius November 28, 2019: documented temperature 37.3 degrees Celsius 4. In interview on December 19, 2019 at 11:09 am, the Technical Consultant stated a temperature calibration should be done when the cuvette temperature is outside of acceptable limits. The Technical Consultant confirmed the laboratory did not perform corrective action for the identified dates,
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 take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2019 revealed the laboratory utilizes the Siemens Dimension EXL 200 for UDS testing of the following:Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid (THC),Cocaine, Methadone, Opiate, and Phencyclidine (PCP). 2. Review of the laboratory's "QC Remedial Action Policy" revealed "Controls falling outside of acceptable limits will require troubleshooting and remedial action. Patient testing is to be suspended until QC failures have been investigated, resolved and are back within acceptable limit criteria." 3. Review of QC records for July 2018, July 2019, and November 2019 revealed the laboratory reported unacceptable QC without corrective action for the following dates: Urine Drugs of Abuse Level 2: November 27, 2019 reported as "Negative" November 28, 2019 reported as "Negative" November 30, 2019 reported as "Negative" 4. Review of UDS patient reports for the identified dates revealed nineteen (19) patients were reported without corrective action. 5. In interview on December 19, 2019 at 9:53 am, the Technical Consultant stated she had not reviewed the QC for November 2019. The Technical Consultant confirmed the identified QC and patients were reported without corrective actions. II. Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Findings: 1. Observation by surveyor during the laboratory tour on December 16, 2019 revealed the laboratory utilizes the Siemens Dimension EXL with LM and Dimension EXL 200 for testing of the following: Albumin, Total Bilirubin, Direct Bilirubin, Calcium, Chloride, Total Cholesterol, CO2, Creatinine, Glucose, Phosphorus, Potassium, Total Protein, Sodium, Triglycerides, BUN, Uric Acid, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline Phosphatase (Alk Phos), Amylase, Creatine kinase (CPK), CKMB, HDL Cholesterol, Lactate Dehydrogenase (LDH), Magnesium, Prostate Specific Antigen (PSA), Urine Creatinine, Urine Protein, Lactic Acid, Lipase, Ferritin, Iron, Total Iron Binding Capacity (TIBC), BNP, CRP, Hemoglobin A1C, Urine Microalbumin, CSF Glucose, CSF Protein, Troponin, TSH, Total T4, T3 Uptake, Free T4, Serum Beta HCG, Acetaminophen, Blood Alcohol, Digoxin, Gentamycin, Phenobarbitol, Phenytoin, Salicylates. 2. Review of the laboratory's "QC Remedial Action Policy" revealed "Controls falling outside of acceptable limits will require troubleshooting and remedial action. Patient testing is to be suspended until QC failures have been investigated, resolved and are back within acceptable limit criteria." 3. Review of quality control (QC) records for July 2018, July 2019, and November 2019 revealed the following unacceptable QC reported: Dimension EXL with LM: July 21, 2018: Phenobarbitol: immunoassay Level 3: 49.8 Violation: F 1-2+ July 3, 2019: Digoxin: Multiqual Level 1 0.61 Violation: F 1-2S+ July 24, 2019: Iron: Multiqual Level 1: 77.0 Violation: F 1-2S+ July 28, 2019: Creatine kinase: Multiqual Level 1: 83 Violation: F 1-2S+; Multiqual Level 3: 620 Violation: F 1-2S+ November 2, 2019: Amylase: Multiqual Level 1: 46 Violation F 1-2S+ November 5, 2019: Total Bilirubin: Multiqual Level 3: 6.4 (reported at 4:49 am), Violation: F 1-2S+ November 7, 2019: Calcium: Multiqual Level 3: 12.4 Violation: F 1-2S+ November 12, 2019: TIBC: Multiqual Level 1: 190 Violation: F1-2S+ November 12, 2019: Acetaminophen: Immunoassay Plus Level 3: 133.4 Violation: F 1-2S November 15, 2019: Creatine kinase: Multiqual Level 1: 88.558 Violation: F 1-2S+ November 15, 2019: Creatine kinase: Multiqual Level 3: 623.16 Violation: F 1-2S November 16, 2019: Creatine kinase: Multiqual Level 1: 86 Violation: F 1-2S+ November 21, 2019: Calcium: Multiqual Level 3: 12.3 Violation: F 1-2S+ November 21, 2019: Beta HCG: Immunoassay Plus Level 3: 569 Violation: F 1-2S November 26, 2019: Creatine kinase: Multiqual Level 3: 639 Violation: F 1-2S+ November 28, 2019: Creatine kinase: Multiqual Level 3: 627.44 Violation: F 1-2S November 30, 2019: ALP:

	Multiqual Level 3: 274 Violation: F 1-2S November 30, 2019: Calcium: Multiqual Level 3: 11.6 Violation: F 1-2S+ November 30, 2019: Creatine kinase: Multiqual Level 1: 83 Violation: F 1-2S November 30, 2019: TIBC: Multiqual Level 1: 191 Violation: F 1-2S Dimension EXL 200: July 21, 2018: ALP: Multiqual Level 1: 313 Violation: F 1-2S+ July 21, 2018: Chloride: Multiqual Level 1: 124 Violation F 1-2S+ July 21, 2018: Potassium: Multiqual Level 1: 7.3 Violation: F 1-2S+ July 21, 2018: Sodium: Multiqual Level 1: 160 Violation: F 1-2S+ 4. Review of patient logs revealed the following patients were reported without corrective action: July 21, 2018: Phenobarbitol: Patient 9001173, patient July 21, 2018: ALP: Patient 0851992 , Patient 0851998, Patient 852105, and Patient 851941 July 21, 2018: Chloride: Patient 0851992 and Patient 0851998; Total of twenty-eight (28) patients reported July 21, 2018: Potassium: Patient 0851992 and Patient 0851998; Total of twenty-eight (28) patients reported July 21, 2018: Sodium: Patient 0851992 and Patient 0851998; Total of twenty-eight (28) patients reported July 3, 2019: Digoxin: Patient 4200862 and Patient 4200859 July 24, 2019: Iron: Patient 9200004 July 28, 2019: Creatine kinase: Patient 4203732 and Patient 4203763; Total of thirty-four (34) patients reported November 5, 2019: Total Bilirubin: Patient 4216418 November 7, 2019: Calcium: Patient 4216770, Patient 4216648, and Patient 4216539; Total of forty-three (43) patients reported November 21, 2019: Beta HCG: Patient 4218633 and Patient 4218713 November 26, 2019: Creatine kinase: Patient 4218017, Patient 4219218, Patient 4219291, and Patient 4219298 November 30, 2019: ALP: Patient 4219425, Patient 4219465, Patient 4219547, and Patient 4219461; Total of twenty-three (23) patients reported November 30, 2019: TIBC: Patient 4219549 5. In interview on December 19, 2019, the Technical Consultant confirmed the identified dates had QC and patients reported without corrective actions. The Technical Consultant stated at 9: 53 am, she had not reviewed the QC for November 2019. III. Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Findings: 1. Observation by surveyor during laboratory tour on December 16, 2019 revealed the laboratory utilizes the following instruments for Hematology testing: a) Sysmex CA-660: Prothrombin Time (PT), Partial thromboplastim time (PTT), and D-dimer testing b) Sysmex XNL-550 and Sysmex XNL-350: Complete Blood Counts (CBC) 2. Review of the laboratory's "QC Remedial Action Policy" revealed "Controls falling outside of acceptable limits will require troubleshooting and remedial action. Patient testing is to be suspended until QC failures have been investigated, resolved and are back within acceptable limit criteria." 3. Review of quality control (QC) records for July 2018, July 2019, and November 2019 revealed the following unacceptable QC reported: July 11, 2018: CBC: QC Level 1: MCH: 25.9 +, MPV: 10.3 + July 21, 2018: CBC: Diff-Y: 60.3-, MFR: 39.9 + July 14, 2019: PT Citrol Level 3: 38.4 Violation F 1-2S (reported at 1:53 am) 4. Further review of QC records revealed the laboratory utilized a Sysmex XT-2000i for CBC testing in July 2018. 5. Review of patient logs revealed the following patients were reported without corrective action: July 11, 2018: CBC: Patient 5541012, Patient 5541019, and Patient 5541020; Total of seven (7) patients reported July 21, 2018: CBC: Patient 5542156, Patient 5542161, and Patient 5542167 July 14, 2019: PT: Patient 000020935 (tested at 6:56 am) 6. In interview on December 18, 2019 at 9:18 am, the Technical Consultant confirmed the identified dates had QC and patients reported without corrective actions.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness

of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (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 assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401 I. 2. The laboratory failed to follow their policy for monitoring the blood product storage equipment. Refer to D5401 II. 3. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 4. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer D5411 I. 5. The laboratory failed to use samples free of hemolysis as required by the manufacturer for RPR testing. Refer to D5411 II. 6. The laboratory failed to monitor the room temperature of the storage room where supplies are stored per manufacturer requirements. Refer to D5413. 7. The laboratory failed to document the lot numbers and expiration dates for the urinalysis microscopic quality controls (QC). Refer to D5415. 8. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417 I. 9. The laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Refer D5417 II. 10. The laboratory failed to have complete performance verification studies for Complete Blood Counts (CBC). Refer to D5421 I. 11. The laboratory failed to have complete performance verification studies for Coagulation testing. Refer to D5421 II. 12. The laboratory failed to ensure maintenance for the Siemens Dimension EXL with LM and Dimension EXL 200 analyzers were performed per manufacturer requirements. Refer to D5429 I. 13. The laboratory failed to ensure maintenance for the Sysmex CA-660 was performed per manufacturer requirements. Refer to D5429 II. 14. The laboratory failed to ensure maintenance for the Sorvall Cell Washer was performed per manufacturer requirements. Refer to D5429 III. 15. The laboratory failed to check the RPM of the automatic rotator used for RPR testing weekly. Refer to D5433 16. The laboratory failed to perform two (2) levels of controls prior to patient testing for Chemistry. Refer to D5447 I. 17. The laboratory failed to perform two (2) levels of controls prior to patient testing for Hematology. Refer to D5447 II. 18. The laboratory failed to perform Rotavirus quality control each day of patient testing for nine (9) of seventeen (17) patients reviewed. Refer to D5447 III. 19. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for manual body fluids cell counts. Refer to D5469 I. 20. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469 II 21. The laboratory failed to complete a crossmatch of emergency release blood for three (3) of ten (10) patients reviewed. Refer to D5553 I. 22. The laboratory failed to confirm ABO and Rh type of donor units before use. Refer to D5553 II. 23. The laboratory failed to perform a freezer alarm check for one (1) quarter out of four (4) in 2019. Refer to D5555. 24. The laboratory failed to follow corrective action policies for Chemistry testing. Refer to D5779. 25. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Refer to D5781 I. 26. the laboratory failed to document corrective actions performed when cuvette temperatures did not meet acceptable limits for the Siemens Dimension EXL with LM and Dimension EXL 200. Refer to D5781 II. 27. The laboratory failed

	to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783 I. 28. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783 II. 29. The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783 III.
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: Based on record review and interview with personnel, the laboratory failed to ensure patient test results were reported for six (6) of twenty three (23) patient reviewed. Findings: 1. Review of patient test records from July 2019 to December 2019 revealed the following six (6) of twenty three (23)patients tested for Activated Clotting Time (ACT) were not reported: Patient # 4200981: tested in CATH Lab on July 17, 2019 at 12:10pm. Patient # 4200981: tested in CATH Lab on July 17, 2019 at 12:30pm. Patient # 006040013: tested in CATH Lab on July 23, 2019 at 11:35am. Patient # 006040013: tested in CATH Lab on July 23, 2019 at 11:49am. Patient # 006045471: tested in CATH Lab on July 30, 2019 at 11:58am. Patient # 006014923: tested in CATH Lab on July 30, 2019 (no time of test performance documented on log). Patient # 006500735: tested in CATH Lab on August 20, 2019 at 11:19am. Patient # 006500735: tested in CATH Lab on August 20, 2019 (no time of test performance documented on log). Patient # 006023664: tested in CATH Lab on July 1, 2019 at (no time of test performance documented on log). 2. In interview on December 19, 2019, the Technical Consultant confirmed the identified patients were not reported to the patients chart. The Technical Consultant further revealed the facility had moved to a new electronic record system and may not have had access to the correct systems for reporting. The Technical Consultant confirmed all ACT results should be reported.
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 report the correct patient test result for Cerebral Spinal Fluid cell counts for two (2) of twenty-one (21) patients reviewed. Findings: 1. Review of a body fluid cell count worksheets and final patient test reports revealed the final test result reported did not match the body fluid cell count worksheet result for the following three (3) of twenty-one (21) patients: a) Patient Number 5541482 on July 16, 2018: Worksheet WBC result - 72, Final report WBC result - 79.2 b) Patient Number 4204935 on August 07, 2018: Worksheet WBC result - 47.9, Final report WBC result - 87 2. Interview with the Technical Consultant on December 19, 2019, confirmed the patient test results reported did not match the results on the laboratory worksheets.
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 performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 4. 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. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 6. The Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D6023. 7. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 8. The Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Refer to D6029. 9.Tthe Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D6030. 10. 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.
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 performed test methods as required. Findings: 1. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 2. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer D5411 I. 3. The laboratory failed to use samples free of hemolysis as required by the manufacturer for RPR testing. Refer to D5411 II. 4. The laboratory failed to monitor the room temperature of the storage room where supplies are stored per manufacturer requirements. Refer to D5413. 5. The laboratory failed to document the lot numbers and expiration dates for the urinalysis microscopic quality controls (QC). Refer to D5415. 6. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417 I. 7. The laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Refer D5417 II. 8. The laboratory failed to check the RPM of the automatic rotator used for RPR testing weekly. Refer to D5433
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff

	to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5211 I and D5211 II.
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 perform two (2) levels of controls prior to patient testing for Chemistry. Refer to D5447 I. 2. The laboratory failed to perform two (2) levels of controls prior to patient testing for Hematology. Refer to D5447 II. 3. The laboratory failed to perform Rotavirus quality control each day of patient testing for nine (9) of seventeen (17) patients reviewed. Refer to D5447 III. 4. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for manual body fluids cell counts. Refer to D5469 I. 5. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469 II.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. 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 assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429 I and D5429 II.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to follow corrective action policies for Chemistry testing. Refer to D5779. 2. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Refer to D5781 I. 3. the laboratory failed to document corrective actions performed when cuvette temperatures did not meet acceptable limits for the Siemens Dimension EXL with LM and Dimension EXL 200. Refer to D5781 II. 4. The laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783 I. 5. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783 II. 6. The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783 III.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Findings: 1. The laboratory failed to ensure patient test results were reported for six (6) of twenty three (23) patient reviewed. Refer to D5801. 2. The laboratory failed to report the correct patient test result for

	Cerebral Spinal Fluid cell counts for two (2) of twenty-one (21) patients reviewed. Refer to D5805
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 record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records revealed the following personnel did not have documentation of an initial laboratory orientation or Laboratory Director's approval /signature for patient testing: Main Lab Testing Personnel 10: Hire Date: July 9, 2019 Main Lab Testing Personnel 11: Hire Date: October 18, 2019 Main Lab Testing Personnel 12: Hire Date: August 27, 2019: Laboratory Director did not approve/sign assessment 2. In interview on December 17, 2019, the Technical Consultant confirmed the laboratory did not have documentation of initial orientation/training for the identified personnel.
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 established for assessing personnel competency. Refer to D5209 I.
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 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. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401 I. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403 II.
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. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6043. 5. The Technical Consultant failed to evaluate the competency of main laboratory, nursing, and respiratory staff performing laboratory testing. Refer to D6046.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples. Refer to D5317. 2. The laboratory failed to use normal donors as required by manufacturer to verify reference intervals and establish their own normal Prothrombin (PT) mean with each new lot of thromboplastin. Refer D5411 I. 3. The laboratory failed to use samples free of hemolysis as required by the manufacturer for RPR testing. Refer to D5411 II. 4. The

	laboratory failed to monitor the room temperature of the storage room where supplies are stored per manufacturer requirements. Refer to D5413. 5. The laboratory failed to document the lot numbers and expiration dates for the urinalysis microscopic quality controls (QC). Refer to D5415. 6. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417 I. 7. The laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Refer D5417 II 8. The laboratory failed to check the RPM of the automatic rotator used for RPR testing weekly. Refer to D5433
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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421 I and D5421 II.
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 observation, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform two (2) levels of controls prior to patient testing for Chemistry. Refer to D5447 I. 2. The laboratory failed to perform two (2) levels of controls prior to patient testing for Hematology. Refer to D5447 II. 3. The laboratory failed to establish their own means and ranges for Quality Control (QC) material utilized for manual body fluids cell counts. Refer to D5469 I. 4. The laboratory failed to establish its own expected range of responses for Activated Clotting Time (ACT) quality control (QC) material. Refer to D5469 II. 5. The laboratory failed to perform Rotavirus quality control each day of patient testing for nine (9) of seventeen (17) patients reviewed. Refer to D5447 III.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range per laboratory policy. Refer to D5781 I. 2. the laboratory failed to document corrective actions performed when cuvette temperatures did not meet acceptable limits for the Siemens Dimension EXL with LM and Dimension EXL 200. Refer to D5781 II. 3. The laboratory failed to take corrective action when quality control samples were unacceptable for Urine Drug Screen (UDS) testing. Refer to D5783 I. 4. The laboratory failed to take corrective action when quality control samples were unacceptable for Chemistry testing. Refer to D5783 II. 5. The laboratory failed to take corrective action when quality control samples were unacceptable for Hematology testing. Refer to D5783 III.
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 record review and and interview with personnel, the Technical Consultant failed to evaluate the competency of main laboratory, nursing, and respiratory staff performing laboratory testing. Findings: 1. Review of the laboratory's "Personnel Competency" policy revealed "The Technical Supervisors are responsible for developing and maintaining current competency testing for each procedure in their sections. The competency evaluation is carried out by the technical supervisor or a designated employee who meets the CLIA requirements for a General Supervisor." 2. Review of the laboratory's "Staffing Responsibilities -CLIA Standards" policy under Technical Consultant Responsibilities" section revealed "The Technical Consultant is responsible for: 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." 3. Review of personnel records for nursing and respiratory staff who perform moderately complex testing revealed the Technical Consultant did not perform the competency assessments in 2018; the staff evaluated each other. 4. Review of personnel records for the main laboratory revealed the direct observation of test performance and maintenance for testing personnel were performed by other testing personnel, not the Technical Consultant. 5. In interview on December 17, 2019 at 10:09 am, the Technical Consultant confirmed she did not perform the competency evaluations for nursing and respiratory staff performing moderate complexity testing. The Technical Consultant stated she signs the competency forms to indicate the staff has been evaluated; she is not involved in the observations. The Technical Consultant confirmed she performs the document review for main laboratory staff, not the direct observations.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to follow their policy for monitoring the blood product storage equipment. Refer to D5401 II. 2. The laboratory failed to ensure body fluid cell count quality control material was not used for patient testing beyond its expiration date for three (3) of twenty-one (21) patients reviewed. Refer to D5417 II. 3. The laboratory failed to complete a crossmatch of emergency release blood for three (3) of ten (10) patients reviewed. Refer to D5553 I. 4. The laboratory failed to confirm ABO and Rh type of donor units before use. Refer to D553 II. 5. The laboratory failed to perform a freezer alarm check for one (1) quarter out of four (4) in 2019. Refer to D5555.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5469.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429 III.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must 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 reports included required pertinent information. Refer to D5805.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must 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 record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form and personnel records revealed the following personnel did not have documentation of an initial laboratory orientation or Laboratory Director's approval /signature for patient testing: Main Lab Testing Personnel 10: Hire Date: July 9, 2019 Main Lab Testing Personnel 11: Hire Date: October 18, 2019 Main Lab Testing Personnel 12: Hire Date: August 27, 2019: Laboratory Director did not approve/sign assessment 2. In interview on December 17, 2019, the Technical Consultant confirmed the laboratory did not have documentation of initial orientation/trainings for the identified personnel.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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. Refer to D5209 I and D5209 II.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to follow their policy for monitoring the blood product storage equipment. Refer to D5401 II. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403.