Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0484993	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Stephens Memorial Hospital	200 South Geneva St, Breckenridge, TX	

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	An entrance conference was held 10/14/2019 with the Testing Person. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 10/14/2019 through 10/17/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1240 Preanalytic Systems 493.1250 Anayltic Systems 493.1403 Laboratory Director Moderate Complexity 493.1409 Technical Consultant 493.1421 Testing Personnel 493.1441 Laboratory Director High Complexity 493.1447 Laboratory Technical Supervisor An exit conference was held on 10/17/2019 with the CEO and the CFO. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29 /2019). Findings included: 1. Review of the facility's policy (last effective date of 08 /31/2018) provided by the Chief Nursing Officer (CNO) on 10/24/2019 stated, "4.3 Acute Hemolytic Transfusion Reaction...Symptoms of acute hemolytic reactions include: Chills, Fever (change of 1 degree celcius [sic] with no known cause)

Increased pulse rate (tachycardia - heart rate >100, heart rate should decrease as transfusion progresses. If increases by >10 points, should report to MD) Decreased blood pressure (Decrease of 10 mm Hg since start of transfusion for either systolic or diastolic); chest tightness or pain; Shock; Dyspnea or tachypnea (Respirations should be 12-20 per minute unless patient has other known issues causing compromise [sic]); pulmonary rales; nausea and vomiting; flank or back pain; urticaria; hemoglobinuria... The transfusion must be stopped immediately and supportive measures instituted as ordered by physician." Review of the blood bank's policy (last effective date of 11/2 /2018) stated, "4.3 Acute Hemolytic Transfusion Reaction...Symptoms of acute hemolytic reactions include: Chills, Fever (change of 1 degree celcius [sic] with no known cause), Increased pulse rate (tachycardia), Decreased blood pressure (Acute Hypotension); Increased Blood Pressure (Acute Hypertension); chest tightness or pain; Shock; Dyspnea or tachypnea; pulmonary rales; nausea and vomiting; flank or back pain; urticaria; hemoglobinuria...The transfusion must be stopped immediately and supportive measures instituted as ordered by physician." The policies were not consistent with one another. During a telephone interview on 10/21/2019 at 10:00 am, the laboratory manager stated him, and a prior nurse worked on the blood bank policy (effective date 11/2/18) together and it was intended to also serve as the facility policy for consistency. 2. During an interview on 10/24/2019 at 2:24 pm, the CNO was asked about the inconsistencies in the facility and blood bank's transfusion policies, she stated the facility policy (last effective date of 08/31/2018) is the one she had worked on and was unaware of the blood bank's policy. 3. Review of patient transfusion records and patient charts from 04/2019 through 10//2019 revealed the following two patients who had acute hypertension/hypotension and were not promptly identified, investigated and reported to the laboratory: 04/18/2019 - Patient #43697 was transfused 1 unit of packed red blood cells beginning at 4:37 pm. Within 30 minutes of transfusion, the documented blood pressure was 169/72 mm Hg with a respiratory rate of 16 breaths per minute; within 1 hour of transfusion, the documented blood pressure was 140/83 mm Hg and a respiratory rate of 71 breaths per minute; and within 2 hours of transfusion the blood pressure was 113/73 mm Hg with a respiratory rate of 18 breaths per minute. A second unit was transfused beginning at 10:10 pm. Within 30 minutes of transfusion, the documented blood pressure was 152/74 mm Hg; within 1 hour of transfusion, the documented blood pressure was 128/74 mm Hg; and within 2 hours of transfusion the blood pressure was 116/67 mm Hg. The transfusion records included a checked off "NO" to the question "Was there a reaction to transfusion?" The patient chart did not include documentation of reporting to the blood bank of an acute drop of blood pressure or acute increase in breaths per minute. 07/29/2019 - Patient #389 was transfused 1 unit of packed red blood cells beginning at 5:50 pm. At 7:35 pm, the documented blood pressure was 137/56 mm Hg; and at 8:35 pm, the blood pressure was 163/62 mm Hg and a manual blood pressure was documented of 160/70 mm Hg. The transfusion records included a checked off "NO" to the question "Was there a reaction to transfusion?" The patient chart stated, "20:35, 07-29-2019. B/P 163/72. Manual B/P 160/70. No complaints. Color improved. Lips & skin tone pink. Called Dr [name] with update Advised him that she is on Metoprolol 25 mg BID with first dose to be given @ 9am. He ordered a dose to be given now" and "20:36, 07-29-2019. Dr [name] is aware that patient is asymptomatic with her elevated B/P." During an interview on 10/15/2019 at 2:24 pm, the CNO reviewed the above findings and confirmed the transfusions should have been reported to the blood bank. 4. Review of transfusion records from 10/2018 through 10/2019 included a total of 128 blood products transfused and no documented/investigated transfusion reactions. The laboratory had not had a transfusion reaction reported and investigated since 2010. The facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory.

D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, Sysmex CA-600 quality control records, Daily QC Error Log, and confirmed in interview, the laboratory failed to retain all quality control records for at least two years for 4 of 4 QC runs in 2019 (random review August-September). Findings: 1. Review of the laboratory's "Analytic Processes" policy revealed: "Quality Control ... Quality control logs will be maintained. The log will include the date tested, initials of the individual that performed, the result obtained, an indication of whether the result was acceptable or not, and if not acceptable-corrective actions taken ... All quality control records will be retained for two years." 2. Review of Sysmex CA-600 coagulation analyzer QC results and Daily QC Error Log revealed: 08/06/2019 D-Dimer QC level 1 lot #562234 expiration date 02/25/2020 07:28 hours result 0.30 (passed) 20:17 hours result 0.34 (passed) 20:39 hours result 0.32 (passed) D-Dimer QC level 2 lot #562134 expiration date 02/25/2020 07:32 hours result 2.40 (failed) 20:43 hours result 2.40 (failed) Review of corrective action for level 1 and level 2 was documented as "DDIMER RERUN 2X FAILED RERUN ON ALL FRESH ALIQOUT OF REAGENTS". Note: Level 1 QC result was documented as 0.20, however that value was not on the QC data from the analyzer. Level 2 QC was documented as 1.97 and that value was also not on the QC data from the analyzer. 9/12/2019 Prothrombin time (PT) QC level 3 lot #556501, expiration date 12/12/2020 06:32 hours result 47.3 (passed) Review of corrective action comment was documented "CONTROL LEVEL RERUN", however the failure was not part of the data. 9/23/2019 Prothrombin time (PT) QC level 3 lot #556501, expiration date 12/12/2020 06:34 hours result 46.7 (passed) Review of corrective action comment was documented three times "CONTROL LEVEL RERUN", however the failures were not part of the data. 09/24 /2019 Prothrombin time (PT) QC level 3 lot #556501, expiration date 12/12/2020 14: 30 hours result 48.4 (passed) Review of corrective action comment was documented "NEW BOTTLE (S) OF CONTROL RECONSTITUTED AND RERUN" and three times "CONTROL LEVEL RERUN" was documented, however the failures were not part of the data. 3. During an interview on 10/16/2019 at 2:06 pm, testing person-4 stated that QC values that are above 3 SD are deleted from the analyzer because they affect the monthly mean. The laboratory failed to retain all Sysmex CA-600 QC records for at least two years.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, client services manual, patient requisitions, patient test reports, instrument data, manifest logs, and laboratory's policy, the laboratory failed to meet requirements for the preanalytical systems, as evidenced by: 1. The laboratory failed to follow manufacturer's preanalytical requirements for testing erythrocyte sedimentation rate (ESR) to ensure accurate and reliable test results for 13 of 13 patients in 10/2019. Refer to D5311, I. 2. The laboratory failed to ensure Complete Blood Count (CBC) specimens were not analyzed beyond manufacturer's specimen stability for 2 of 3 patients on 10/10/2019 and 10/11/2019. Refer to D5311, II. 3. The laboratory failed to follow manufacturer's for establishing stability for patient complete blood count (CBC) specimens prior to testing 2 of 3 patients on the Sysmex XS 1000i hematology analyzer on 10/10/2019 and 10/11/2019. Refer to D5311, III. 4. The laboratory failed to enter an accurate received time for specimens received from outside clients in their LIS (Orchard) for 10 of 10 patients (random sampling from 10/14/19 and 10/15/19). Refer to D5313.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, client services manual, patient requisitions, patient test reports, instrument data, manifest logs, and in interview with staff, the laboratory failed to follow manufacturer's preanalytical requirements for testing erythrocyte sedimentation rate (ESR) to ensure accurate and reliable test results for 13 of 13 patients in 10/2019. Findings included: 1. Review of Sediplast Westergren ESR System instructions for use (manufacturer's instructions within the box) stated, "GENERAL GUIDELINES: Testing Timetable: Blood at room temperature (15-25)C: test should be set up within 4 hours. Refrigerated blood: must be brought to room temperature and thoroughly mixed before testing. Blood kept at 4C: test should be set up within 12 hours." Review of the laboratory's client services manual stated, "ROOM TEMP STABILITY HRS: ESR 24 WB EDTA." (Key: WB - whole blood; EDTA - Ethylenediaminetetraacetic acid [anticoagulant]) The laboratory's defined criteria for stability was not consistent with the Sediplast Westergren ESR System used for analysis. 2. During a tour of the laboratory on 10/16 /2019 at 2:40 pm, the following patient purple top EDTA tubes were observed in a rack collected 10/15/2019 and test requisitions, reports, ESR instrument data and manifest log were reviewed: Sample ID 192880074; collected 10/15/2019 at 5:00 am, received 10/15/2019 at 10:00 pm, analyzed 10/16/2019 at 12:06 am. Elapsed time of 19 hours and 6 minutes from time of collection to time of analysis (set up). Sample ID 192880063; collected 10/15/2019 at 6:00 am, received 10/15/2019 at 10:00 pm, analyzed 10/16/2019 at 12:06 am. Elapsed time of 18 hours and 6 minutes from time of collection to time of analysis (set up). Sample ID 192880053; collected 10/15/2019 at 7:15 am, received 10/15/2019 at 10:00 pm, analyzed 10/16/2019 at 12:06 am. Elapsed time of 16 hours and 51 minutes from time of collection to time of analysis (set up). Sample ID 192880070; collected 10/15/2019 at 7:30 am, received 10/15

/2019 at 10:00 pm, analyzed 10/16/2019 at 12:23 am. Elapsed time of 16 hours and 53 minutes from time of collection to time of analysis (set up). Sample ID 192880068; collected 10/15/2019 at 7:20 am, received 10/15/2019 at 10:00 pm, analyzed 10/16 /2019 at 12:06 am. Elapsed time of 16 hours and 46 minutes from time of collection to time of analysis (set up). Sample ID 192880109; collected 10/15/2019 at 6:37 am, received 10/15/2019 at 10:00 pm, analyzed 10/16/2019 at 12:06 am. Elapsed time of 17 hours and 29 minutes from time of collection to time of analysis (set up). The specimens were not analyzed within manufacturer's instructions (4C within 12 hours or 15-25C within 4 hours). Note: the analysis time was derived from the instrument data and "Sed Rate" log, which did not align with the final report "Approval Time." Review of the received log for 10/15/2019 included a written time stamp of "10:00" and temperatures "6.6; -27." The laboratory received specimens in the afternoon and documented a temperature for refrigerated and frozen transport conditions, it could not be determined which specimens came in at what temperature. There was another date/time stamp on the log but phlebotomists on 10/17/2019 at 1:30 pm, stated that was not their time stamp. 3. Further review of test requisitions, manifest logs, and test reports from 10/2019 revealed specimens for ESR were not analyzed within manufacturer's instructions (4C within 12 hours or 15-25C within 4 hours), as follows: Sample ID 192770116; collected 10/04/2019 at 4:50 am, received 10/04/2019 at 10:00 pm (written on log), analyzed 10/04/2019 at 11:47 pm. Elapsed time of 18 hours and 57 minutes from time of collection to time of analysis (set up). Sample ID 192810115; collected 10/08/2019 at 7:38 am, received 10/08/2019 at 9:34 pm (written on log), analyzed 10/09/2019 at 12:16 am. Elapsed time of 16 hours and 38 minutes from time of collection to time of analysis (set up). Sample ID 192810129; collected 10/08/2019 at 3:00 am, received 10/08/2019 at 9:34 pm (written on log), analyzed 10/09/2019 at 12:16 am. Elapsed time of 21 hours and 16 minutes from time of collection to time of analysis (set up). Sample ID 192870080; collected 10/14/2019 at 6:35 am, received 10 /14/2019 at 9:31 pm (written on log), analyzed 10/14/2019 at 11:18 pm. Elapsed time of 16 hours and 43 minutes from time of collection to time of analysis (set up). Sample ID 192870176; collected 10/14/2019 at 8:36 am, received 10/14/2019 at 9:31 pm (written on log), analyzed 10/15/2019 at 12:16 am. Elapsed time of 15 hours and 40 minutes from time of collection to time of analysis (set up). Sample ID 192870174; collected 10/14/2019 at 8:12 am, received 10/14/2019 at 9:31 pm (written on log), analyzed 10/15/2019 at 12:16 am. Elapsed time of 16 hours and 4 minutes from time of collection to time of analysis (set up). Sample ID 192870078; collected 10/14/2019 at 6:40 am, received 10/14/2019 at 9:31 pm (written on log), analyzed 10/14/2019 at 11:18 pm. Elapsed time of 16 hours and 38 minutes from time of collection to time of analysis (set up). Manifest log for 10/14/19 included documented temperatures of "6.0" and "-21." 4. The above specimens were collected in facilities throughout Texas and sent to a laboratory in Keller, TX. The Keller laboratory would then receive the specimens in the LIS (Orchard) and send them to Stephens Memorial Hospital for testing. The received time in the LIS was never changed to the accurate received time. The laboratory documented on the manifest log the received time. 5. During a telephone interview on 10/21/2019 at 10:00 am, the laboratory manager stated ESR specimens come in refrigerated and were stable for 24 hours. Documentation of this defined stability was not provided, nor did it align with manufacturer's instructions. 39812 II. Based on review of Sysmex XS 1000i hematology analyzer (Serial number 63777) manufacturer's instructions, laboratory's policy, laboratory specimen receipt logs, patient instrument test results, patient final test reports, and interview with staff, the laboratory failed to ensure Complete Blood Count (CBC) specimens were not analyzed beyond manufacturer's specimen stability for 2 of 3 patients on 10/10/2019 and 10/11/2019. Findings included: 1. Review of Sysmex XT-Series Implementation Manual (Document Number MKT-30-1009, October 2007) in the section 6 titled

"Sample collection conditions" stated the following: "After drawing the sample, analyze it within 4 hours, store it in a refrigerator at 2-8C until it can be analyzed." 2. Review of the laboratory policy titled "Pre-analytic procedures" (Signed by the laboratory director 09/2018) stated, "6. Follow all specimen requirements as described in each test procedure." 3. Review of the laboratory policy titled "Processing and Transportation of Blood Samples" (Effective date 04/01/2019) stated the following: "Temperature, shipping, and collection tube requirements for SMH (Stephens Memorial Hospital) lab: Room Temp Stability HRS; CBC; 24 WB EDTA." The laboratory requirements CBC were whole blood (WB) collection in an EDTA collection tube, room temperature storage and tested within 24 hours. This policy did NOT list any requirements for refrigerated (2-8C) stability for CBC specimens. This laboratory failed to follow manufacturer's instructions for sample conditions and stability. 4. Review of laboratory specimen receipt logs, patient instrument reports and patient final test reports from 10/10/2019 and 10/11/2019 revealed the following 2 of 3 Complete Blood Count (CBC) specimens analyzed beyond manufacturer's specimen stability: a. Patient 76419; Collected 10/09/2019 0733 hours; Received at the laboratory 10/10/2019 2020 hours at 2-8 C; Specimen analyzed 10/10/2019 2028 hours. The CBC specimen was NOT shipped at room temperature. The CBC specimen was analyzed 36 hours and 40 minutes after collection (32 hours and 40 minutes beyond the manufacturer's stability of 4 hours). b. Patient 74440; Collected 10 /10/2019 1600 hours; Received at the laboratory 10/11/2019 2050 hours at 2-8 C; Specimen analyzed 10/11/2019 2123 hours. The CBC specimen was NOT shipped at room temperature. The CBC specimen was analyzed 29 hours and 23 minutes after collection (25 hours and 23 minutes beyond the manufacturer's stability of 4 hours). 5. In an interview on 10/16/2019 at 1059 in the laboratory, testing person #1 was asked to provide stability studies performed by the laboratory to extend the manufacturer's specimen stability for CBC's at room temperature from 4 hours to 24 hours. She was also asked to provide stability and temperature studies for refrigerated CBC specimens. No documentation was provided. Word Key: EDTA - ethylenediaminetetraacetic acid III. Based on review of Sysmex XS 1000i hematology analyzer manufacturer's instructions, laboratory policy, patient test reports, and staff interview, the laboratory failed to follow manufacturer's for establishing stability for patient complete blood count (CBC) specimens prior to testing 2 of 3 patients on the Sysmex XS 1000i hematology analyzer on10/10/2019 and 10/11/2019. Findings included: 1. Review of Sysmex XS-Series Implementation Manual (Document Number MKT-30-1009, October 2007) stated, "Stability Study: Stability studies are performed to determine the readiness of a sample for CBC, differential and reticulocyte count analysis. Short term stability is performed with fresh samples drawn and analyzed at intervals at interval within one (1) hours. Long term stability is conducted under storage conditions and over a period of time defined by the laboratory as acceptable for specimen analysis. Typical long term studies include analysis of room temperature (18-26 degrees C) and refrigerated (4 degrees C) samples at intervals from zero to 48, 56 or 72 hours." The document included detailed instructions for conducting the stability studies (A. Samples for Stability Studies; B. Analysis Intervals; C. Data Analysis). 2. Review of Sysmex XS-Series Implementation Manual (Document Number MKT-30-1009, October 2007) in the section 6 titled "Sample collection conditions" stated the following: "After drawing the sample, analyze it within 4 hours, store it in a refrigerator at 2-8C until it can be analyzed." 3. Review of the laboratory policy titled "Processing and Transportation of Blood Samples" (Effective date 04/01/2019) stated the following: "Temperature, shipping, and collection tube requirements for SMH (Stephens Memorial Hospital) lab: Room Temp Stability HRS; CBC; 24 WB EDTA." The laboratory requirements CBC were whole blood (WB) collection in an EDTA collection tube, room

	temperature storage and tested within 24 hours. This policy did NOT list any requirements for refrigerated (2-8C) stability for CBC specimens. The laboratory was asked to provide CBC stability studies for defined stability, no documentation was provided. 4. Review of laboratory specimen receipt logs, patient instrument reports and patient final test reports from 10/10/2019 and 10/11/2019 revealed the following 2 of 3 Complete Blood Count (CBC) specimens analyzed beyond manufacturer's specimen stability: a. Patient 76419; Collected 10/09/2019 0733 hours; Received at the laboratory 10/10/2019 2020 hours at 2-8 C; Specimen analyzed 10/10/2019 2028 hours. The CBC specimen was NOT shipped at room temperature. The CBC specimen was analyzed 36 hours and 40 minutes after collection (32 hours and 40 minutes beyond the manufacturer's stability of 4 hours). b. Patient 74440; Collected 10 /10/2019 1600 hours; Received at the laboratory 10/11/2019 2050 hours at 2-8 C; Specimen analyzed 10/11/2019 2123 hours. The CBC specimen was NOT shipped at room temperature. The CBC specimen was analyzed 29 hours and 23 minutes after collection (25 hours and 23 minutes beyond the manufacturer's stability of 4 hours). 5. In an interview on 10/16/2019 at 1059 in the laboratory, testing person #1 was asked to provide stability studies performed by the laboratory to extend the manufacturer's specimen stability for CBC's at room temperature from 4 hours to 24 hours. She was also asked to provide stability and temperature studies for refrigerated CBC specimens. No documentation was provided. The laboratory failed to follow manufacturer's for establishing stability for patient complete blood count (CBC) specimens.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of manifest logs, patient reports, LIS documentation, and in interview with staff, the laboratory failed to enter an accurate received time for specimens received from outside clients in their LIS (Orchard) for 10 of 10 patients (random sampling from 10/14/19 and 10/15/19). Findings included: 1. Review of patient manifest log from 10/14/2019 included a documented "SMH 10-14-19" on top of log, "9:31" on the side, and a date/time stamp of "OCT 14 2019 PM4:48." Patient manifest log from 10/15/2019 included a documented "SMH 10-15-19" on top of log, "10:00" on the side, and a date/time stamp of "OCT 15 2019 PM6:14." The manifest logs accompanied all patient specimens via courier from a laboratory in Keller, TX for Stephens Memorial Hospital (SMH) laboratory to test. The laboratory in Keller, TX had been granted access to SMH LIS Orchard to be able to order tests and receive specimens. 2. During an interview on 10/17/2019 at 10:00 am, the phlebotomists explained that Pathos Clinical Solutions (laboratory in Keller, TX) received specimens in the Orchard system and that SMH did not enter a date/time of receipt in Orchard when specimens arrived in SMH for testing. They explained specimens arrive, SMH has labels, labels the specimens and analyzes the specimens on instrumentation. SMH only documents received date/time for outside specimens on the manifest logs. During an interview on 10/17/2019 at 10:27 am, TP-1 stated the processor (employee of SMH) for Pathos Clinical Solutions specimens checks orders in the system, labels, and hands specimens to the techs (testing persons) to load on the instrument for testing. Received date/time is never documented in the Orchard system by SMH staff. 3. Review of manifest logs and Orchard LIS documentation from 10/14 /2019 and 10/15/2019 revealed received times in the LIS were not the actual times

received into the SMH laboratory for specimens from Keller, TX, as follows: Sample ID 192870080; collected 10/14/2019 at 6:35 am and analyzed for ESR 10/14/2019 at 11:18 pm. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/14/2019 9:29 AM" and the manifest log included received date/time of 10/14/2019 at 9:31 pm (written on log). Sample ID 192870176; collected 10/14/2019 at 8:36 am and analyzed for ESR 10/15/2019 at 12: 16 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/14/2019 2:33 PM" and the manifest log included received date/time of 10/14/2019 at 9:31 pm (written on log). Sample ID 192870174; collected 10/14/2019 at 8:12 am and analyzed for ESR 10/15/2019 at 12: 16 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/14/2019 2:32 PM" and the manifest log included received date/time of 10/14/2019 at 9:31 pm (written on log). Sample ID 192870078; collected 10/14/2019 at 6:40 am and analyzed for ESR 10/14/2019 at 11: 18 pm. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/14/2019 9:28 AM" and the manifest log included received date/time of 10/14/2019 at 9:31 pm (written on log). Sample ID 192880074; collected 10/15/2019 at 5:00 am and analyzed for ESR, Vitamin D, and TSH 10/16/2019 at 12:06 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15/2019 12:19 PM" and the manifest log included received date/time of 10/15/2019 at 10:00 pm (written on log). Sample ID 192880063; collected 10/15/2019 at 6:00 am and analyzed for ESR 10/16/2019 at 12:06 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15/2019 12:08 PM" and the manifest log included received date/time of 10/15/2019 at 10:00 pm (written on log). Sample ID 192880053; collected 10/15/2019 at 7:15 am and analyzed for ESR 10/16/2019 at 12:06 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15/2019 12:01 PM" and the manifest log included received date/time of 10/15/2019 at 10:00 pm (written on log). Sample ID 192880070; collected 10/15/2019 at 7:30 am and analyzed for ESR 10/16/2019 at 12:23 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15/2019 12:14 PM" and the manifest log included received date/time of 10/15/2019 at 10:00 pm (written on log). Sample ID 192880068; collected 10/15/2019 at 7:20 am and analyzed for ESR, Vitamin B12, Folate, and TSH 10/16/2019 at 12:06 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15/2019 12:12 PM" and the manifest log included received date/time of 10/15 /2019 at 10:00 pm (written on log). Sample ID 192880109; collected 10/15/2019 at 6: 37 am and analyzed for 10/16/2019 at 12:06 am. Final test report did not include a received date/time into SMH laboratory. Orchard LIS included "Delivery Date 10/15 /2019 2:25 PM" and the manifest log included received date/time of 10/15/2019 at 10: 00 pm (written on log). Note: documentation revealed the individuals who received the above specimens into the Orchard system were employees of Pathos Clinical Solutions (laboratory in Keller, TX), not SMH staff. 4. During a telephone interview on 10/17/2019 at 1:50 pm, an employee from Pathos Clinical Solutions (laboratory in Keller, TX) stated SMH staff should be changing the received time in Orchard to the actual time SMH receives the specimens from Keller, TX. The employee was asked about the date/time stamp on the manifest logs received into SMH laboratory, she stated she was unsure of the stamp. She was asked if the specimens made a stop at a different laboratory before Keller, TX or SMH, she stated no. The manifest log from 10/14/2019 was faxed to that employee with the questionable date/time stamp circled, the employee never responded to explain. The patient manifest logs from 10/14/2019 with a date/time stamp of "OCT 14 2019 PM4:48" and from 10/15/2019 with a date

	/time stamp of "OCT 15 2019 PM6:14" were not consistent with times documented in the Orchard system. Phlebotomists on 10/17/2019 at 1:30 pm, stated that was not their date/time stamp. The SMH laboratory did not enter an accurate received time for specimens received from outside clients in their LIS (Orchard).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, client services manual, patient requisitions, patient test reports, instrument data, manifest logs, and laboratory's policy, the laboratory failed to establish and follow written policies for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytical systems, as evidenced by: 1. The laboratory failed to follow manufacturer's preanalytical requirements for testing erythrocyte sedimentation rate (ESR) to ensure accurate and reliable test results for 13 of 13 patients in 10/2019. Refer to D5311, I. 2. The laboratory failed to ensure Complete Blood Count (CBC) specimens were not analyzed beyond manufacturer's specimen stability for 2 of 3 patients on 10/10/2019 and 10/11/2019. Refer to D5311, II. 3. The laboratory failed to follow manufacturer's for establishing stability for patient complete blood count (CBC) specimens prior to testing 2 of 3 patients on the Sysmex XS 1000i hematology analyzer on 10/10/2019 and 10/11/2019. Refer to D5311, III. 4. The laboratory failed to enter an accurate received time for specimens received from outside clients in their LIS (Orchard) for 10 of 10 patients (random sampling from 10/14/19 and 10/15/19). Refer to D5313.
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 review of laboratory policy, patient wet prep records, manufacturer's instructions, UDS kit testing log, patient test reports, environmental logs, laboratory maintenance records, quality control (QC) records, expected value sheets, UDS Kit Testing Logs, facility's policies/procedures, blood bank's policies/procedures, transfusion records, patient charts, and corrective action logs, the laboratory failed to meet the requirments for analytic systems, as evidenced by: 1. The laboratory failed to follow its own policy for new lot control material receipt for 3 of 3 sets blood gas control material. Refer to D5401. 2. The laboratory failed to implement a written policy/procedure for wet prep test procedure. Refer to D5403. 3. The laboratory failed to follow the manufacturer's instructions for quality control preparation for the

Siemens Dimension EXL chemistry analyzer. Refer to D5411, I. 4. The laboratory failed to follow manufacturer's instructions for performing confirmatory testing on positive results for PROFILE-V MEDTOXScan Drugs of Abuse Test System for 7 of 25 patients in 2019 (random review 09/06/2019-10/16/2019). Refer to D5411, II. 5. The laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for the calibrators and controls for the Siemens Dimension EXL chemistry testing. Refer to D5413, I. 6. The laboratory failed to follow manufacturer's instructions for the storage of CA CLEAN II reagent. Refer to D5413, II. 7. The laboratory failed to label a secondary container of blood bank saline with the poured date, expiration date, and identification (lot number). Refer to D5415, I. 8. The laboratory failed to document the revised expiration dates for quality controls stored in the laboratory refrigerator. Refer to D5415, II. 9. The laboratory failed to ensure that in-use Hematology reagents and control material were labeled with new expiration dates according to the manufacturer. Refer to D5415, III. 10. The laboratory failed to document complete verification studies for the Siemens Dimension EXL-B chemistry analyzer. Refer to D5421. 11. The laboratory failed to have documentation of performing weekly maintenance for 36 of 36 weeks. Refer to D5429. 12. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of OPTI CCA-TS2 test performance with current and accurate statistical parameters. Refer to D5441, I. 13. The laboratory failed to ensure their control procedures detected immediate error and monitored over time the accuracy and precision of test performance for 1 of 1 sets of current lot numbers. Refer to D5441, II. 14. The laboratory failed to implement an IQCP to lessen the frequency of QC for PROFILE-V MEDTOXScan Drugs of Abuse Test System 2019. Refer to D5445. 15. The laboratory failed to document the verification of quality control acceptable ranges for quality control for the Siemens Dimension EXL chemistry analyzer. Refer to D5469, I. 16. The laboratory failed to document established and defined statistical parameters (standard deviation [SD]) for unassayed control material used on the Sysmex CA-600 analyzer for day-to-day acceptability since 08/2019. Refer to D5469 II. 17. The laboratory failed to ensure quality control results met the laboratory's criteria for acceptability prior to reporting patient results for the Siemens Dimension EXL chemistry testing. Refer to D5481, I. 18. The laboratory reported 4 of 4 patient test results when QC was NOT accessed for Total Hemoglobin (tHb) and Oxygen Saturation (SO2). Refer to D5481, II. 19. The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 2 of 2 patients in 2019 (random review July). Refer to D5481, III. 20. The laboratory failed to promptly investigate blood transfusion reactions for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D5559. 21. The laboratory failed to document the instrument to instrument verification records for its 2 of 2 Siemens EXL-A and EXL-B chemistry analyzers for the analytes: Glucose, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Alkaline Phosphatase, Alanine Aminotransferase, Total Bilirubin, Total Protein, Albumin, Urea nitrogen, Creatinine, CK, Lipase, and Troponin for 2018 and 2019. Refer to D5775. 22. The laboratory failed to document corrective action taken on coagulation analytes for 9 of 9 runs in 2019 (random review July-August). Refer to D5781. 23. The laboratory failed to document patient remediation of all patient test results obtained in the unacceptable test run and since the last acceptable test run for testing on the Siemens Dimension EXL chemistry analyzer. Refer to D5783, I. 24. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 4 of 4 patients in 2019 (random review July-September). Refer to D5783, II.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records for the OPTI CCA-TS2 blood gas analyzer (02/25/2019 through 10/14/2019) and staff interview, the laboratory failed to follow its own policy for new lot control material receipt for 3 of 3 sets blood gas control material. Findings included: 1. The laboratory policy titled "Analytic Processes" (Signed by the laboratory director 09/2015) stated the following: "When a new lot of control material is received, staff will run the new material several times over a couple of days to confirm that the expected values for the control material are obtained. Ideally, this should be performed at least 5 times and preferably over 5 days. During this period, the previous lot of control material will continue to be used to evaluate the performance of the test system. The new lot of control material should be run as a patient specimen." 2. Review of the laboratory QC records for the OPTI CCA-TS2 blood gas analyzer from 02/25/2019 through 10/14/2019 revealed the following sets of blood gas control material and the date each was put into use by the laboratory: a. Level 1, Lot Number 7119, Expiration date 08/2019; Level 2, Lot Number 7219, Expiration date 08/2019; Level 3, Lot Number 7319 Expiration date 08 /2019. Put into use by the laboratory 02/25/2019. b. Level 1, Lot Number 8129, Expiration date 05/2020; Level 2, Lot Number 8229, Expiration date 05/2020; Level 3, Lot Number 8339, Expiration date 05/2020. Put into use by the laboratory 04/11 /2019. c. Level 1, Lot Number 9139, Expiration date 01/2021; Level 2, Lot Number 9239, Expiration date 01/2021; Level 3, Lot Number 9349, Expiration date 01/2021. Put into use by the laboratory 08/01/2019. 3. In an interview on 10/16/2019 in the laboratory, testing person #6 was asked to provide documentation of running new lot blood gas control material several times to confirm expected values. She stated she was not aware of that policy and the laboratory started using the new lot of blood gas control material when the laboratory had used all the old lot of blood gas control material. This confirmed the above findings.
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 review of the laboratory's procedure manual, patient wet prep records and in interview with staff, the laboratory failed to implement a written policy/procedure for wet prep test procedure. Findings included: 1. Review of the laboratory's procedure manual did not include a written wet prep policy/procedure with the following: a) requirements for patient preparation; specimen collection, labeling, storage, preservation, stability; and criteria for specimen acceptability and rejection. b) microscopic examination c) step-by-step performance of the procedure, including interpretation of results. d) preparation of slides and solutions e) control procedures alternatives (pertinent literature references). f) limitations in the test methodology, including interfering substances. g) reference intervals (normal values). h) pertinent literature references (textbooks, pictographs). i) description of the course of action to take if a test system becomes inoperable. 2. Review of patient wet prep test reports from 06/2019 and 07/2019 included the following collection (draw) and approval date /time: Patient #38038 - Draw Date: 06/22/2019 5:01 pm; Approval date: 06/22/2019 6: 00 pm; results were negative for bacteria, clue cells, red blood cells, trichomonas, and yeast with a "TRACE" of white blood cells. Elapsed time of 59 minutes between time of collection and analysis. Patient #46152 - Draw Date: 06/23/2019 9:39 pm; Approval date: 06/27/2019 7:08 am; results were negative for clue cells, red blood cells, trichomonas, and yeast with a "TRACE" of bacteria and white blood cells. Elapsed time of 3 days, 9 hours, and 29 minutes between time of collection and analysis. Patient #48691 - Draw Date: 07/17/2019 8:50 am; Approval date: 07/19 /2019 9:58 am; results were negative for clue cells, trichomonas, and yeast with a "FEW" of bacteria, "MANY" red blood cells and "MODERATE" white blood cells. Elapsed time of 2 days, 1 hour, and 8 minutes between time of collection and analysis. The laboratory had not defined a stability for wet prep specimens to ensure integrity and accurate/reliable test results. The laboratory had not defined rejection criteria to ensure specimens were received and analyzed in the laboratory within an acceptable timeframe. 3. During an interview on 10/16/2019 at 4:20 pm, Testing Person - 2 (TP-2) was asked the stability of wet prep specimens and how soon should they be analyzed after collection, she stated within an hour. The surveyor provided Patient #46152 and 48691 reports with collection to analysis of greater than an hour, she stated they were having LIS (laboratory information system) issues at one point and had to enter results at a later time and ER (emergency room) was given verbal results. Documentation of this was not provided. During an interview on 10/17/2019 at 10:05 am, TP-1 stated providers in ER order chlamydia/gonorrhea with the wet prep test order and results for those send-outs (chlamydia/gonorrhea) take several days. Once those results are available from the reference laboratory, results are entered in their LIS which is the "Approval date." The date/time stamp of the wet prep test final analysis was not accurately documented in the system.
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 observations, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for quality control preparation for the Siemens Dimension EXL chemistry analyzer. Findings were: 1. Observations on 10/16/19 at 1305 hours revealed unopened bottles of Liquichek Unassayed Chemistry controls stored 2 - 8 C in the New laboratory refrigerator. Lot 56911, exp 11/30/20 Lot 56912, exp 11/30/20 2. An interview with testing person #2 on 10/16/19 at 1330 hours confirmed that the above bottles were in the refrigerator to thaw. She stated that "it's faster to thaw in the refrigerator the previous day prior to use." 3. Review of the Liquichek Unassayed Chemistry (2018-12; 4143) under reagent preparation revealed "To thaw the product, allow it to stand at room temperature (18 to 25C) until completely thawed but no longer than one (1) hour. For optimal analyte stability in the thawed state, promptly return to 2 to 8C storage after each use." 4. Review of the CMS116 revealed the laboratory performed approximately 186400 chemistry testing annually. 5. An interview with testing person #1 on 10/17/19 at 1005 hours in the laboratory confirmed the above findings. She was unaware lab personnel were thawing controls in the refrigerator. 40420 II. Based on review of manufacturer's instructions, UDS kit testing log, patient test reports, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing confirmatory testing on positive results for PROFILE-V MEDTOXScan Drugs of Abuse Test System for 7 of 25 patients in 2019 (random review 09/06/2019-10/16/2019). Findings: 1. Review of manufacturer's instructions for PROFILE-V MEDTOXScan Drugs of Abuse Test System revealed: "INTENDED USE ... THE PROFILE-V MEDTOXScan DRUGS OF ABUSE TEST SYSTEM PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY /MASS SPECTOMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY/TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED." 2. Review of laboratory records revealed the laboratory implemented PROFILE-V MEDTOXScan Drugs of Abuse Test System on 02/15/2019. 3. Random review of UDS Kit Testing Log and patient test records from 09/06/2019-10/16/2019 revealed the laboratory failed to follow manufacturer's instructions for performing confirmatory testing on the following 7 patients: 09/07 /2019 Patient ID 3057 at 9:32 pm positive for amphetamines and methamphetamines, a note on the UDS Kit testing log stated "called ER; provider not req. send-out for confirmation" 09/12/2019 Patient ID 43482 at 5:39 pm positive for opiates and oxycodone Patient ID 65630 at 8:20 am positive for benzodiazepines, opiates, and cannabinoids, a note on the UDS Kit testing log stated "Dr.X (name of provider) does not want send out!" 10/2/2019 Patient ID 53772 at 10:16 am positive for benzodiazepines and opiates, a confirmation was sent out for benzodiazepines but not opiates 10/3/2019 Patient ID 9219 at 1:38 am positive for cannabinoids 10/06/2019 Patient ID 35891 at 4:56 am positive for amphetamine, methamphetamine, opiates, cannabinoids, tricyclic antidepressants, and methadone 10/09/2019 Patient ID 65630 at 8:29 am positive for benzodiazepines and opiates, a note on the UDS Kit testing log stated "DR. said NO send out medication" 3. During an interview on 10/17/2019 at 1:

	30 pm, testing person-1 stated the positive urine drug screens were not always sent out for confirmation because the ordering provider did not want the confirmation. She also stated that some providers will only request certain drug analytes for confirmations and will not order a complete confirmation panel. This confirmed the above findings.
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: I. Based on a review of the manufacturer's instructions, laboratory's policy and environmental logs, and confirmed in interview, the laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for the calibrators and controls for the Siemens Dimension EXL chemistry testing. Findings were: 1. Review of the Siemens Dimension EXL LOCI Anemia CAL (PN 10865747-ES, 2015-03) under reagent preparation revealed "before use, thaw and equilibrate at room temperature (22 - 28 C) for at least 30 minutes. Mix the contents of the vial by inverting gently ten times. Store at -25 to -15 C." 2. Review of the Siemens Dimension EXL CKI/MBI CAL (PN 792032.002-US) under reagent preparation revealed "thaw at room temperature for 30 - 45 minutes before use. Do not thaw in a water bath or water above 25 C. Unopened vials must be stored frozen at -25 to -15 C." 3. Review of the instructions for use for the Liquichek Immunology Control (2018-02, 3200-00) revealed "if the product has been stored frozen, allow it to stand at room temperature 18-25 until it is completely thawed." 4. Review of the instructions for use for the Liquichek Immunoassay Control (2018-01, 4023-00) revealed "if the product has been stored frozen, allow it to stand at room temperature 18-25 until it is completely thawed." 5. Review of the laboratory policy Analytic Processes revealed "each day the laboratory is open, environmental conditions such as refrigerator, room temperature and humidity are monitored and recorded. If the reading is outside of the acceptable range as noted on the temperature log, corrective action is taken." 6. Review of the environmental logs used from May 2019 to October 2019 revealed an unacceptable temperature range of 18 - 30 C had been established. 7. An interview with the testing person # 1 on 10/17/19 at 1000 hours in the laboratory confirmed the above findings. She was unaware the acceptable room temperature range was 18-25 C. 40420 II. Based on direct observation, manufacturer's instructions and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the storage of CA CLEAN II reagent. Findings: 1. Review of manufacturer's package insert for CA CLEAN II reagent revealed: "Storage and shelf life of unopened product ... Store the product from 5 to 35C (Do not freeze)." 2. During a tour of the laboratory on 10/16/2019 at 1:55 pm, the surveyor observed in the hematology reagent refrigerator: 2 bottles of CA CLEAN II reagent, lot # A8038, expiration date: 01/10/2020, received date: 04/18/2018 Review of the laboratory's acceptable range for the refrigerator was 2-8C. The laboratory failed to follow manufacturer's instructions for the storage of CA CLEAN II reagent. 3. During

	an interview on 10/16/2019 at 2:06 pm, testing person-4 confirmed the above findings.
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: I. Based on direct observation, review of manufacturer's instructions, and in interview with staff, the laboratory failed to label a secondary container of blood bank saline with the poured date, expiration date, and identification (lot number). Findings included: 1. During a tour of the laboratory on 10/16/2019 at 1:25 pm, a clear plastic container (1000 mL) with a grey pump was observed to be stored on the counter in blood bank. A piece of tan-colored masking tape was seen covering the original label underneath with illegible writing. During an interview on 10/16/2019 at 1:30 pm, Testing Person - 2 (TP-2) pointed to a 4-liter box of SP Certified Blood Bank Saline stored on a shelf, stating that saline is poured from there (primary container) into the 1000 mL clear plastic container with a grey pump. She stated the saline is used to wash cells for blood bank procedures. She confirmed the secondary container was not labeled with the lot number, poured date or the opened expiration date. 3. Review of the SP Certified Blood Bank Saline 4-liter box (Lot #408674; expiration date 12/2019; received 9/19/19; opened 10/11/2019) manufacturer's instructions stated, "Store with spigot in down position. Use within one month of date opened." The laboratory did not label the secondary container of blood bank saline with the poured date, expiration date, and identification (lot number). 38387 II. Based on review of manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to document the revised expiration dates for quality controls stored in the laboratory refrigerator. Findings were: 1. Review of the instructions for use for the Liquichek Immunology Control (2018-02, 3200-00) revealed "when thawed and stored unopened at 2 - 8 C, this product will be stable as follows: all analytes 45 days." 2. Review of the instructions for use for the Liquichek Immunoassay Control (2018-01, 4023-00) revealed "when thawed and stored unopened at 2 - 8 C, this product will be stable as follows: all analytes 30 days except...Folate 4 days." 3. Review of the instructions for use for the Liquichek Ethanol/Ammonia Control (2019-08, 1496-00) revealed "once opened and stored unopened at 2 - 8 C, this product will be stable as follows: all analytes 20 days." 4. Random review of the quality control material stored in the EXL-B refrigerator on 10/16/19 at 1305 hours revealed the following quality control material with no documentation of the open expiration date: Liquichek Ethanol /Ammonia Control lot 54291, exp 2/28/21 lot 54293, exp 2/28/21 Liquichek Immunoassay Plus Control lot 40983, exp 9/30/20 Liquichek Immnology Control lot 66393, exp 10/31/19 5. Review of the CMS116 revealed the laboratory performed approximately 186400 chemistry testing annually. 6. An interview with testing person # 1 on 10/17/19 at 1000 hours in the laboratory confirmed the above findings. 39812 III. Based on direct observation, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that in-use Hematology reagents and control material were labeled with new expiration dates according to the manufacturer. Findings included: 1. During a tour of the laboratory on 10/17/2019 at

	0945 hours, revealed a Sysmex XS 1000i hematology analyzer (63777) with the following hematology reagents and control material open and in-use: a. Sysmex Stomatolyser; Lot Number Y9008; Expiration date 03/05/2020 b. Sysmex Sulfolyser; Lot Number Y9001; Expiration date 01/17/2020 c. Sysmex e-Check Hematology control material: Level 1, Lot Number 92110804; Expiration date 10/20/2019; Level 2, Lot Number 92110805; Expiration date 10/20/2019; Level 3, Lot Number 92110806; Expiration date 10/20/2019. The reagents and control material were NOT labeled with new expiration dates. 2. Review of manufacturer's instructions for in-use Hematology reagents and control material stated the following: a. Sysmex Stromatolyser: "Once opened and installed in the instrument, Stromatolyser is stable for 90 days." b. Sysmex Sulfolyser: "Once opened and installed in the instrument, product is stable for 60 days." c. Sysmex e-Check Hematology control material: "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C." The laboratory failed to ensure in-use Hematology reagents and control material were labeled with new expiration dates according to the manufacturer. 3. In an interview on 10/17/2019 at 0945 hours in the laboratory, testing person #1 confirmed the above findings.
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: Based on review of the laboratory policy, laboratory records and confirmed in interview, the laboratory failed to document complete verification studies for the Siemens Dimension EXL-B chemistry analyzer. Findings were: 1. Review of the laboratory policy Analytic Processes revealed "prior to using any nonwaived test system for patient testing, the laboratory will verify that the performance described in the manufacturer's package insert or operator's manual is capable of being reproduced in this facility using our own employees." 2. Review of the laboratory records for the Siemens Dimension EXL-B chemistry analyzer revealed the laboratory started patient testing on 09/2018 for the following analytes: Glucose Sodium Potassium Chloride Carbon Dioxide Calcium Alkaline Phosphatase Alanine Aminotransferase Total Bilirubin Total Protein Albumin Urea nitrogen Creatinine Uric Acid Creatine Kinase Vancomycin Gentamicin Digoxin Acetaminophen Ethanol Lipase Salicylate Troponin MMB HCg CRP Ammonia Hemoglobin A1c 2. Review of the laboratory records available revealed no documentation available for review of the verification studies (precision, accuracy, reportable range) for the above analytes on the EXL-B chemistry analyzer (DR271601). 3. An interview with testing person #1 on 10/16/19 at 1025 hours in the laboratory confirmed the above findings. She stated that the lab manager had them but was unable to provide them by the end of survey on 10/17/19.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, manufacturer's instructions for the OPTI CCA-TS2 blood gas analyzer, laboratory maintenance records (01/2019 through 09 /2019) and staff interview, the laboratory failed to have documentation of performing weekly maintenance for 36 of 36 weeks. Findings included: 1. The laboratory policy titled "Analytic Processes" (Signed by the laboratory director 09/2015) stated the following: "When applicable, all equipment maintenance and function checks are performed according to the manufacturer's instructions to ensure that the test system is ready for testing. Maintenance records, including any manufacturer performed service records, are retained for two years" 2. The manufacturer's instructions for the OPTI CCA-TS2 blood gas analyzer stated in the section titled "Weekly Maintenance": "Once a week, the Sample Measurement Chamber (SMC) must be cleaned. Open the top cover and clean the optics surface as well as the underside of the SMC cover with a lint-free cloth, dampened with a dilute alcohol or ammonia-based cleaner as needed. Be sure to remove all blood residue with a 10:1 diluted bleach solution. A cotton swab may be used for cleaning the smaller parts of the SMC." 3. Review of the laboratory maintenance records (01/2019 - 09/2019) revealed the laboratory failed to document weekly maintenance for 36 of 36 weeks. 4. In an interview on 10/16/2019 at 1020 hours in the laboratory, testing person #6 was asked to provide documentation of performance of weekly maintenance for the OPTI CCA-TS2 blood gas analyzer. No documentation was provided. She stated that the laboratory does NOT perform weekly maintenance. This confirmed the above finding.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, manufacturer's package inserts, OPTI CCA-TS2 blood gas analyzer (Serial Number 1288) quality controls (QC) records (02/25 /2019 through 10/14/2019), direct observation and staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of OPTI CCA-TS2 test performance with current and accurate statistical parameters. Findings included: 1. The laboratory policy titled "Analytic Processes" (Signed by the laboratory director 09/2015) stated the following: "In performing any testing, all procedural instructions must be followed exactly ..... Perform quality control per procedure and record the results. Confirm that quality

control results are acceptable prior to patient testing." The laboratory policy titled "Arterial Blood Gas Quality Control" stated, "External QC is to be run every thirty days and when there is a new lot for blood gas cartridges. Levels 1, 2, and 3 are to be run. And prior to running an ordered ABG (Arterial Blood Gas)." 2. Review of the laboratory QC records for the OPTI CCA-TS2 blood gas analyzer from 02/25/2019 through 10/14/2019 revealed the following sets of blood gas control material and the acceptable range limits for each analyte: a. Level 1, Lot Number 7119, Expiration date 08/2019 pH = 7.080-7.200 pCO2 = 65.0 - 81.0 PO2 = 58.0 - 88.0 tHb = 18.4 - 22.4 SO2 = 78.0 - 84.0 Level 2, Lot Number 7219, Expiration date 08/2019 pH = 7.340 -7.460 pCO2 = 38.0 - 48.0 PO2 = 82.0 - 112.0 tHb = 12.5 - 15.5 SO2 = 87.0 - 93.0 Level 3, Lot Number 7319 Expiration date 08/2019. pH = 7.570 - 7.670 pCO2 = 20.0 - 30.0 PO2 = 125.0 - 159.0 tHb = 7.4 - 10.4 SO2 = 93.0 - 99.0 b. Level 1, Lot Number 8129, Expiration date 05/2020 pH = 7.070-7.190 pCO2 = 66.0 - 82.0 PO2 = 56.0 - 86.0 tHb = 18.4 - 22.4 SO2 = 79.0 - 85.0 Level 2, Lot Number 8229, Expiration date 05/2020 pH = 7.350-7.470 pCO2 = 36.0 - 46.0 PO2 = 82.0 - 112.0 tHb = 12.5 - 15.5 SO2 = 86.0 - 92.0 Level 3, Lot Number 8339, Expiration date 05/2020 pH = 7.560 - 7.660 pCO2 = 20.0 - 30.0 PO2 = 121.0 - 155.0 tHb = 7.4 - 10.4 SO2 = 94.0 - 99.9 c. Level 1, Lot Number 9139, Expiration date 01/2021 pH = 7.080-7.200 pCO2 = 64.0 - 80.0 PO2 = 56.0 - 86.0 tHb = 18.4 - 22.4 SO2 = 79.0 - 85.0 Level 2, Lot Number 9239, Expiration date 01/2021 pH = 7.350 -7.470 pCO2 = 37.0 - 47.0 PO2 = 81.0 - 111.0 tHb = 12.5 - 15.5 SO2 = 86.0 - 92.0 Level 3, Lot Number 9349, Expiration date 01/2021. pH = 7.570 - 7.670 pCO2 = 19.0 - 29.0 PO2 = 126.0 - 160.0 tHb = 7.4 - 10.4 SO2 = 94.0 - 99.9 3. Further review of QC records for the OPTI CCA-TS2 blood gas analyzer revealed the following 11 of 16 dates with incorrect acceptable ranges for the control material lot numbers or with no acceptable control ranges. The QC data without acceptable control ranges represented quality control material tested on the instrument as a patient. a. 04/11/2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot number 7119 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 7219 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 7319 b. 05/19/2019 Level 1, 2 and 3 quality control material tested as a patient. No lot numbers documented. No acceptable ranges listed on instrument print outs. No control material values for tHb and SO2. c. 05/20/2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot number 7119 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 7219 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 7319 d. 06/10/2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot number 7119 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 7219 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 7319 e. 07 /16/2019 Level 1, 2 and 3 quality control material tested as a patient. No lot numbers documented. No acceptable ranges listed on instrument print outs. No control material values for tHb and SO2. f. 06/21/2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot number 7119 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 7219 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 7319 g. 09/01/2019 Level 1, 2 and 3 quality control material tested as a patient. No lot numbers documented. No acceptable ranges listed on instrument print outs. No control material values for tHb and SO2. h. 09/09/2019 Level 1, 2 and 3 quality control material tested as a patient. No lot numbers documented. No acceptable ranges listed on instrument print outs. No control material values for tHb and SO2. i. 09/10/2019 Level 1, 2 and 3 quality control material tested as a patient. No lot numbers documented. No acceptable ranges listed on instrument print outs. No control material values for tHb and SO2. j. 09/20 /2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot

number 9139 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 9239 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 9349 k. 10/14/2019 Level 1; Lot number 8129; Control values in instrument correspond to Lot number 9139 Level 2; Lot number 8229; Control values in instrument correspond to Lot number 9239 Level 3; Lot number 8339; Control values in instrument correspond to Lot number 9349 4. During a tour of the laboratory on 10/16/2019 at 1000 hours, the following lot numbers of OPTI CCA-TS2 blood gas analyzer control material was observed to be in use: OPTI Check Blood Gas Systems Level 1, Lot Number 8129, Expiration date 05/2020; Level 2, Lot Number 8229, Expiration date 05/2020; Level 3, Lot Number 8339, Expiration date 05/2020. 5. In an interview on 10/16/2019 at 1020 hours in the laboratory, testing person #6 was asked how she determined if blood control material is acceptable. She stated control material acceptable ranges were programmed in the instrument and if the values were within acceptable range the print out shows "OK". Testing person #6 was shown the current control material manufacturer's acceptable ranges and asked if those ranges corresponded to the ranges programmed in the instrument. She stated the ranges in the instrument did NOT correspond to the manufacturer's ranges. She stated that she did not realize the ranges did not correspond. The laboratory failed to have a system in place to detect immediate errors and the accuracy and precision of OPTI CCA-TS2 test performance with current and accurate statistical parameters. 6. Review of the QC records for the OPTI CCA-TS2 blood gas analyzer titled "PTS QC/ABG'S Levi-Jennings Graph" for 01/2019 through 06/2019 revealed the following: a. The QC data was plotted as bar graphs for pH, PO2, and PCO2 for Levels 1, 2, and 3 of control material. The laboratory did NOT utilize Levi-Jennings graphs as referenced in the title. b. QC result values for Lot numbers 7119 and 8129 were plotted on the same graph for each analyte (pH, PO2, and PCO2). The two lot numbers had different acceptable means and ranges. c. QC result values for Lot numbers 7219 and 8229 were plotted on the same graph for each analyte. The two lot numbers had different acceptable means and ranges. d. QC result values for Lot numbers 7319 and 8339 were plotted on the bar graph for each analyte. The two lot numbers had different acceptable means and ranges. e. There were NO defined means and NO 1SD or 2SD designated on each of the bar graphs. f. The date that the control material was tested was NOT indicated on each of the bar graphs. The laboratory failed to have a system in place to monitor errors over time for shifts and trends for the OPTI CCA-TS2 blood gas analyzer. Word Key: PCO2= Partial pressure of carbon dioxide PO2= Partial pressure of oxygen SO2 Sat=Oxygen saturation tHb=Total Hemoglobin SD=Standard Deviation 40420 II. Based on direct observation, review or laboratory policy, Sysmex CA-600 quality control (QC) records, and confirmed in interview the laboratory failed to ensure their control procedures detected immediate error and monitored over time the accuracy and precision of test performance for 1 of 1 sets of current lot numbers. Findings: 1. Review of the laboratory's quality assurance policy revealed: "IV. MONITORING THE LABORATORY ... 2. Quality Control Assessment (see CFR 493.1705) To ensure that quality control procedures are followed and that any out-of-control situations, not resolved by repeating the controls, will be documented. Trends and shifts in control data will be addressed and recorded in the daily quality control records. Effectiveness of the Laboratory's quality control actions will be evaluated." 2. Review of Sysmex CA-600 coagulation analyzer QC records revealed control procedures did not detect immediate error and did not monitor over time the accuracy and precision of test performance: Ci-Trol Control Level 1 lot #548071, expiration date 11/07/2020, date put in use 07/22/2019 Level 3 lot #556501, expiration date 12/12 /2020, date put in use 07/22/2019 Mean and ranges obtained from the lot to lot roll over were as follows: Prothrombin time (PT) Level 1: Mean 10.20, Range: 9.65-10.75 Level 3: Mean 47.2, Range: 44.6-49.8 Activated partial thromboplastin time (APTT)

	Level 1: Mean: 26.5, Range: 25-28 Level 3: Mean: 55.2, Range: 52.2-58.2 Review of means and ranges for everyday acceptability for the month of September 2019 were as follows: PT Level 1: Mean 10.2, Range: 9.4-11 Level 3: Mean 47.2, Range: 43.3-51.1 The laboratory's QC ranges were too wide to detect immediate error. Review of PT QC from September 2019 revealed 80 QC data points for level 1 with no QC failures and 79 QC points for level 3 with one QC failure. Corrective action comments were documented on 09/12/2019 level 3 stating QC had been rerun, however the failure was not part of the data. Corrective actions were documented on 09/23/2019 stating QC had been rerun 3 times, however the failures were not part of the data. Corrective actions were documented on 09/24/2019 stating QC had been rerun 4 times, however the failures were not part of the data. Quality control result failures were being deleted. The laboratory failed to monitor the accuracy and precision of the test system overtime. APTT Level 1: Mean: 26.5, Range: 24.2-28.8 Level 3: Mean: 55.2, Range: 50.7-59.7 The laboratory's QC ranges were too wide to detect immediate error. Review of APTT QC from September 2019 revealed 81 QC data points for level 1 with no QC failures and 80 QC points for level 3 with two QC failures. 3. During an interview on 10/16/2019 at 2:30 pm, testing person-2 and testing person-4 were asked how the means and ranges changed from the initial lot roll over on 7/22/2019 to September 2019 and they stated that the technical consultant would adjust the means and ranges on a monthly basis if they need to be adjusted. They stated that the data was kept in a binder "Record For ADJUSTED DATA." Review of the "Record For ADJUSTED DATA" binder for coagulation the section was blank. There was no data to review. During an interview on 10/17/2019 at 1:30 pm, testing person-1 stated that she deleted outliers in QC because it affects her monthly mean. She stated that once QC was deleted from the analyzer it was permanently gone, confirming the above findings. The laboratory failed to ensure their control procedures detected immediate error and monitored over time the accuracy and precision of test performance.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan), manufacturer's instructions, quality control (QC) logs, UDS Kit Testing Logs, patient records, and confirmed in interview the laboratory failed to implement an IQCP to lessen the frequency of QC for PROFILE-V MEDTOXScan Drugs of Abuse Test System 2019. Findings: 1. Review of the laboratory's IQCP Plan for PROFILE-V MEDTOXScan Drugs of Abuse Test System revealed no documentation of the quality control study that included at least two levels of external quality control material for a minimum of 7 days. 2. Review of manufacturer's instructions for PROFILE-V MEDTOXScan Drugs of Abuse Test System revealed: "Implementing Laboratory Quality Control Based on Risk Management ... Equivalent Quality Control (EQC) will be phased out by January 1, 2016. Once EQC is phased out, CLIA laboratories will

	have two options: to follow CLIA QC regulation requirements as written or implement an individualized Quality Control Plan (IQCP) ..." 3. The laboratory implemented PROFILE-V MEDTOXScan Drugs of Abuse Test System into use on 02 /15/2019. The laboratory did not perform external quality control at least once each day patient specimens were tested, as required per CFR 493.1256. 4. Review of PROFILE-V MEDTOXScan Drugs of Abuse Test System QC logs from 09/06/2019-10/19/2019 (random sampling) revealed external QC was performed on the following days: MEDTOX Negative Control Lot# N00104 MEDTOXScan Positive Control Lot# CC00710 PROFILE-V MEDTOXScan device Lot# TD189D21, expiration date 04/30/2021 09/06/2019 positive and negative control were tested 09/13/2019 positive and negative control were tested 09/20/2019 positive and negative control were tested 09/27/2019 positive and negative control were tested 10/04/2019 positive and negative control were tested 10/11/2019 positive and negative control were tested The laboratory did not implement an IQCP to lessen the frequency of required external QC. The laboratory did not analyze external QC for 7 consecutive days to ensure stability of material to lessen the frequency of QC. 5. Review of UDS Kit Testing Logs revealed 51 patients were tested. The following is a sampling of patients tested for urine drug screens: 09/07/2019: Patient ID 3057 09/12/2019: Patient IDs 43482, 65630 09/14/2019: Patient ID 37412 10/2/2019: Patient ID 53772 10/3/2019: Patient ID 9219 10/06/2019: Patient ID 35891 10/09/2019: Patient ID 65630 The laboratory did not perform external quality control at least once each day patient specimens were assayed, as required per CFR 493.1256. The laboratory did not analyze external QC for 7 consecutive days to ensure stability of material to lessen the frequency of QC. 6. Review of records revealed the laboratory had a test volume of 375 samples from 02 /15/2019 to 10/17/2019. 7. During an interview on 10/17/2019 at 9:45 am, testing person-1 (TP-1) stated that the only studies performed for the IQCP plan were comparison studies for the Alere test system and the PROFILE-V MEDTOXScan Drugs of Abuse Test System. She stated that laboratory did not analyze external QC for 7 consecutive days to lessen the frequency of QC and that they just began running QC weekly and for every new lot number, confirming the above findings.
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 review of the laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to document the verification of quality control acceptable ranges for quality control for the Siemens Dimension EXL chemistry analyzer. Findings were: 1. Review of the laboratory policy Analytic Processes

	revealed "when a new lot of control material is received, staff will run the new material several times over a couple of days to confirm that the expected values for the control material are obtained. Ideally this should be performed at least 5 times and preferably over 5 days. During this period the previous lot of control material will continue to be sued to evaluate the performance of the test system. The new lot of control material should be run as a patient specimen." 2. Random review of the quality control for the Siemens Dimension EXL chemistry analyzer revealed the laboratory used the following acceptable ranges for the following quality control. GGT (Gamma-glutamyl transferase) lot 56911, exp 11/30/20 acceptable range 49.23 - 54.95 CO2 (Carbon Dioxide) lot 56911, exp 11/30/20 acceptable range 17.67 - 19.87 TIBC (Total iron-binding capacity) lot 56912, exp 11/30/20 acceptable range 323.2 -(360 Vitamin B12 lot 40981, exp 9/30/20 acceptable range 245.5 - 274.1 TSH (thyroid stimulating hormone) lot 40981, exp 9/30/20 acceptable range 0.78 - 0.9 BNP (B-type natriuretic peptide) lot 23691, exp 11/30/20 acceptable range 56.8 - 62.8 3. Review of the laboratory records revealed no documentation of the 5 replicates of data over 5 days for the above quality control ranges established. 4. Review of the laboratory CMS116, the laboratory performed 186400 chemistry tests annually. 5. An interview with testing person #2 on 10/16/19 at 1400 hours in the laboratory confirmed the above findings. She stated that the lab manager had them but was unable to provide them by the end of survey on 10/17/19. 40420 II. Based on review of laboratory's policy, Seimens Innovance D-Dimer Controls manufacturer's instructions, expected value sheets, Sysmex CA-600 quality control (QC) data, and in interview with staff, the laboratory failed to document established and defined statistical parameters (standard deviation [SD]) for unassayed control material used on the Sysmex CA-600 analyzer for day-to-day acceptability since 08/2019. Findings: 1. Review of the laboratory's policy "Analytic Processes" revealed: "Quality Control ... When Opening a New Lot of Control Material: Quality control material has an expiration date, just like other reagents. Controls should not be used beyond their expiration date. It is important to ensure that control material is ordered and obtained on a regular schedule, to allow the laboratory sufficient time to verify the expected range of a new lot number of control material prior to the expiration of the previous lot number of control material. When a new lot of control material is received, staff will run the new material several times over a couple of days to confirm that the expected values for the control material are obtained. Ideally this should be performed at least 5 times and preferably over 5 days. During this period the previous lot of control material will continue to be used to evaluate the performance of the test system. The new lot of control material should be run as a patient specimen." 2. Review of Siemens Innovance D-Dimer Controls package insert revealed: "Assigned Constituent Values Refer to the enclosed Table of Assigned Values for acceptable reagent and instrument combinations and their assigned values and ranges ... If used as a precision control, the user should establish the target concentration and confidence limits during a preliminary phase. The ranges provided are intended only as guidelines. Each laboratory should determine its own individual ranges." 3. Review of D-Dimer control material level 1 (lot #562234, expiration date 02/25/2020) and level 2 (lot #562134, expiration date 02/25/2020) used on the Sysmex CA-600 analyzer revealed the lot numbers were put into use on 08/11/2019. The laboratory only provided the raw data. The statistical parameters could not be verified with what was on the analyzer to ensure that the parameters used for everyday acceptability were accurate. 4. During an interview on 10/16/2019 at 10:05 am, testing person-1 stated that she did not know where data for establishing the statistical parameters was located for D-Dimer, confirming the above findings.
D5481	CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's quality control policy, review of quality control results, and staff interview, the laboratory failed to ensure quality control results met the laboratory's criteria for acceptability prior to reporting patient results for the Siemens Dimension EXL chemistry testing. Findings were: 1. Random review of September and October 2019 quality control revealed the following days when quality control were outside of the acceptable range for the following analytes: GGT lot 56911, exp 11/30/20 acceptable range 49.23 - 54.95 9/5/19 41 9/7/19 57 CO2 lot 56911, exp 11/30/20 acceptable range 17.67 - 19.87 9/11/19 19.9 TIBC lot 56912, exp 11/30/20 acceptable range 323.2 - 360 9/19/19 362 Vitamin B12 lot 40981, exp 9/30 /20 acceptable range 245.5 - 274.1 9/3/19 276 9/4/19 319 9/5/19 290 9/7/19 279 TSH lot 40981, exp 9/30/20 acceptable range 0.78 - 0.9 9/11/19 0.93 9/18/19 0.94 9/15/19 0.92 9/21/19 0.91 BNP lot 23691, exp 11/30/20 acceptable range 56.8 - 62.8 9/6/19 75 9/7/19 74 9/8/19 75 2. Review of the patient test logs for the above dates revealed the laboratory analyzed patient testing for the above analytes: GGT Patient ID 9/5/19 76222, 76221 CO2 Patient ID 9/11/19 59897, 45925,41915, 65672 TIBC patient ID 9 /19/19 76300 TSH Patient ID 9/18/19 44714, 37839, 43246, 1500,41992 BNP Patient Id 9/6/19 4176, 41068,65401, 4749, 39973 3. Review of the laboratory records for the above dates revealed no documentation of performing corrective actions or reporting patient results after quality control results were acceptable. 4. An interview with testing person # 1 on 10/16/19 at 1130 hours in the laboratory confirmed the above findings. 39812 II. Based on review of laboratory policy, quality control (QC) records for the OPTI CCA-TS2 blood gas analyzer (02/25/2019 through 10/14/2019), patient arterial blood gas reports, and staff interview, the laboratory reported 4 of 4 patient test results when QC was NOT accessed for Total Hemoglobin (tHb) and Oxygen Saturation (SO2). Findings included: 1. The laboratory policy titled "Analytic Processes" (Signed by the laboratory director 09/2015) stated the following: "In performing any testing, all procedural instructions must be followed exactly ..... Perform quality control per procedure and record the results. Confirm that quality control results are acceptable prior to patient testing." The laboratory policy titled "Arterial Blood Gas Quality Control" stated, "External QC is to be run every thirty days and when there is a new lot for blood gas cartridges. Levels 1, 2, and 3 are to be run. And prior to running an ordered ABG (Arterial Blood Gas)." 2. Review of QC records for the OPTI CCA-TS2 blood gas analyzer revealed blood gas control material (Levels 1, 2, and 3) was tested on the analyzer as a patient, not as quality control material on 07/16/2019, 09/01/2019, 09/09/2019, and 09/10/2019. The Hemoglobin/Oxygen Status reported "----g/dL" for tHb and "----%" for SO2 for each of the 3 levels of control for each day. Running the control material as a patient failed to provide any result values for the tHb and SO2 analyte. 3. Review of patient arterial blood gas reports for 07/16/2019, 09/01/2019, 09/09/2019, and 09/10/2019 revealed the following patients tested and the tHb and SO2 analytes reported when QC was not accessed for those analytes: a. 07/16/2019; Patient 1073; tHB=11.7 g/dL; SO2=99.4% b. 09/01/2019; Patient 76202; tHB=12.5 g/dL; SO2=70.8% c. 09/09/2019; Patient 45894; tHB=9.5 g/dL; SO2=97.0% d. 09/10/2019; Patient 49609; tHB=8.1 g/dL; SO2=96.2% 4. In an interview on 10/16/2019 at 1020 hours in the laboratory, testing person #6 confirmed that the tHb and SO2 blood gas analytes for the patients listed

	above were reported without quality control assessment for those analytes. 40420 III. Based on direct observation, review of laboratory policy, Sysmex CA-600 quality control records, patient test records, and confirmed in interview, the laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 2 of 2 patients in 2019 (random review July). Findings: 1. Review of the laboratory's Quality Control Review Policy revealed: "IV. RESPONSIBILITY: Each individual analyst is responsible for performing the required quality control tests and for documenting the results. The analysts is responsible for insuring that patient results are not reported unless quality control material results are within the acceptable ranges. The Laboratory Manager or Designee will be responsible for obtaining the QC data for review, performing the reviews and documenting the reviews ..." 2. Review of Sysmex CA-600 QC records revealed the following QC results for D-Dimer on 07/26/2019: QC level 1 lot #562245 expiration date 11/06/2020 The laboratory's acceptability range was 0.32-0.44 mg/L. 11:08 hours result: 0.30 mg/L 11:30 hours result: 0.29 mg/L 11:45 hours result: 0.29 mg/L 12:08 hours result: 0.30 mg/L 12:49 hours result: 0.30 mg/L 14:35 hours result: 0.31 mg/L 15:48 hours result: 0.40 mg/L 3. Review of patient test records revealed two patients were tested and reported on 7/26/2019 when QC was not within acceptable limits for D-Dimer: Patient ID: 15, sample was collected at 10: 38 am and reported at 11:19 am Patient ID: 2024, sample was collected at 11:41 am and reported at 12:54 pm 4. During an interview on 10/17/2019 at 10:55 am, testing person-4 (TP-4) stated the above patients were from the emergency room and their results needed to be released "to meet the one hour turn-around time." TP-4 stated that it was okay to test and release the results because QC was out of 2 SD (standard deviation) but within 3SD. The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the laboratory failed to promptly investigate blood transfusion reactions for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Findings included: 1. Review of the facility's policy (last effective date of 08/31/2018) provided by the Chief Nursing Officer (CNO) on 10/24/2019 stated, "4.3 Acute Hemolytic Transfusion Reaction...Symptoms of acute hemolytic reactions include: Chills, Fever (change of 1 degree celcius [sic] with no known cause) Increased pulse rate (tachycardia - heart rate >100, heart rate should decrease as transfusion progresses. If

increases by >10 points, should report to MD) Decreased blood pressure (Decrease of 10 mm Hg since start of transfusion for either systolic or diastolic); chest tightness or pain; Shock; Dyspnea or tachypnea (Respirations should be 12-20 per minute unless patient has other known issues causing compromise [sic]); pulmonary rales; nausea and vomiting; flank or back pain; urticaria; hemoglobinuria...The transfusion must be stopped immediately and supportive measures instituted as ordered by physician." Review of the blood bank's policy (last effective date of 11/2/2018) stated, "4.3 Acute Hemolytic Transfusion Reaction...Symptoms of acute hemolytic reactions include: Chills, Fever (change of 1 degree celcius [sic] with no known cause), Increased pulse rate (tachycardia), Decreased blood pressure (Acute Hypotension); Increased Blood Pressure (Acute Hypertension); chest tightness or pain; Shock; Dyspnea or tachypnea; pulmonary rales; nausea and vomiting; flank or back pain; urticaria; hemoglobinuria... The transfusion must be stopped immediately and supportive measures instituted as ordered by physician." The policies were not consistent with one another. During a telephone interview on 10/21/2019 at 10:00 am, the laboratory manager stated him, and a prior nurse worked on the blood bank policy (effective date 11/2/18) together and it was intended to also serve as the facility policy for consistency. 2. Review of "Previous Record Review" (Effective Date: 07/08) policy stated, "Previous record checks are performed to verify patient history and specific needs. Examples are ABO /RH, Antibody screen and ID testing, Type/Hold protocol, Compatibility Testing, blood component work ups, irradiation, CMV, washed products. The patient's blood bank records must be reviewed by searching for a patient problem work up file system ...PROCEDURE: 1. Review the blood bank records to: a. Compare and confirm ABO group and Rh type results b. Identify, compare and/or confirm the presence of clinically significant unexpected antibodies*** c. Identify, compare and/or confirm difficulties encountered in blood typing d. Identify and review previous adverse transfusion reactions ... 3. The blood bank technologist will check in the blood bank log noting that records were reviewed. 4. Any discrepancies found during the record review MUST BE RESEOLVED before any blood bank result is released or blood products issued for administration. COMMENTS: Discrepancies must be reported to the Director to ensure proper follow-up and documentation Of [sic] the resolution." The only review that was performed by a blood bank technologist was gathering data of number and type of transfused products quarterly. A review of "previous adverse transfusion reactions" was not documented in any of the blood bank records. 3. Review of patient transfusion records and patient charts from 04/2019 through 10 //2019 revealed the following two patients who had acute hypertension/hypotension and were not promptly investigated: 04/18/2019 - Patient #43697 was transfused 1 unit of packed red blood cells beginning at 4:37 pm. Within 30 minutes of transfusion, the documented blood pressure was 169/72 mm Hg with a respiratory rate of 16 breaths per minute; within 1 hour of transfusion, the documented blood pressure was 140/83 mm Hg and a respiratory rate of 71 breaths per minute; and within 2 hours of transfusion the blood pressure was 113/73 mm Hg with a respiratory rate of 18 breaths per minute. A second unit was transfused beginning at 10:10 pm. Within 30 minutes of transfusion, the documented blood pressure was 152/74 mm Hg; within 1 hour of transfusion, the documented blood pressure was 128/74 mm Hg; and within 2 hours of transfusion the blood pressure was 116/67 mm Hg. The transfusion records included a checked off "NO" to the question "Was there a reaction to transfusion?" The patient chart did not include documentation of reporting to the blood bank of an acute drop of blood pressure or acute increase in breaths per minute. 07/29/2019 - Patient #389 was transfused 1 unit of packed red blood cells beginning at 5:50 pm. At 7:35 pm, the documented blood pressure was 137/56 mm Hg; and at 8:35 pm, the blood pressure was 163/62 mm Hg and a manual blood pressure was documented of 160/70 mm Hg. The transfusion records included a checked off "NO" to the question "Was there a

	reaction to transfusion?" The patient chart stated, "20:35, 07-29-2019. B/P 163/72. Manual B/P 160/70. No complaints. Color improved. Lips & skin tone pink. Called Dr [name] with update Advised him that she is on Metoprolol 25 mg BID with first dose to be given @ 9am. He ordered a dose to be given now" and "20:36, 07-29-2019. Dr [name] is aware that patient is asymptomatic with her elevated B/P." During an interview on 10/15/2019 at 2:24 pm, the CNO reviewed the above findings and confirmed the transfusions should have been reported to the blood bank. 4. Review of transfusion records from 10/2018 through 10/2019 included a total of 128 blood products transfused and no documented/investigated transfusion reactions. The laboratory had not had a transfusion reaction reported and investigated since 2010. 5. During a telephone interview on 10/21/2019 at 10:00 am, the laboratory manager confirmed a blood bank technologist gathered data of number and type of transfused products quarterly. The laboratory failed to promptly investigate blood transfusion reactions and make recommendations to the medical staff regarding improvements in transfusion procedures. The laboratory did not ensure transfusion reaction policies aligned with the facilities. The laboratory did not ensure all necessary remedial actions were taken and documented to prevent recurrences of transfusions reactions; and all policies were reviewed to assure they were adequate to ensure safety of individuals being transfused.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and records and confirmed in interview, the laboratory failed to document the instrument to instrument verification records for its 2 of 2 Siemens EXL-A and EXL-B chemistry analyzers for the analytes: Glucose, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Alkaline Phosphatase, Alanine Aminotransferase, Total Bilirubin, Total Protein, Albumin, Urea nitrogen, Creatinine, CK, Lipase, and Troponin for 2018 and 2019. Findings were: 1. Review of the laboratory policy EXL agreeance study revealed "in order to verify patient results on certain tests that are now being tested on two analyzers, the lab staff will process 1 patient every 6 months on both analyzers. The results must agree within 95% and will be filed in general lab office for review." 2. Random review of the laboratory records from chemistry revealed the laboratory performed the following analytes for both Siemens EXL-A and EXL-B chemistry analyzers. Glucose Sodium Potassium Chloride Carbon Dioxide Calcium Alkaline Phosphatase Alanine Aminotransferase Total Bilirubin Total Protein Albumin Urea nitrogen Creatinine CK Lipase Troponin 3. Review of the laboratory records from 2018 and 2019 revealed no documentation of the comparison of the above analytes for both Siemens EXL-A and EXL-B chemistry analyzers. 4. An interview with the testing person #1 on 10/16/19 at 1110 hours in the laboratory confirmed the above findings.
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:
Based on review of laboratory policy, quality control records, corrective action logs, patient records, and confirmed in interview, the laboratory failed to document corrective action taken on coagulation analytes for 9 of 9 runs in 2019 (random review July-August). Findings: 1. Review of "STANDARD OPERATING PROCEDURE-QC-CORRECTIVE ACTIONS" laboratory policy revealed: "PURPOSE: WHEN QC FAILS TO FALL WITHIN THE DEFINED LIMITS OF ACCEPTABILITY, THE LABORATORY MIST IDENTIFY THE REASON FOR THE FAILURE AND CORRECT THE PROBLEM BEFORE RESUMING TESTING. THE LABORATORY MUST EVALUATE ALL PATIENT TEST RESULTS SINCE THE LAST ACCEPTABLE CONTROL RUN ... CLASS I: FAILURE OF QC MATERIAL WHEN A QC VALUE DOES NOT MEET ACCEPTABLE CRITERIA, PERFORM THE FOLLOWING STEPS: CHECK ALL PRE-ANALYTICAL STEPS, LOT#, EXPIRATION DATES, STORAGE TEMPERATURE, CORRECT QC, RECONSTITUTED FILL VOLUME, CORRECT DILUENT USED ETC. ONCE THE ABOVE ITEMS HAVE BEEN ADDRESSED REPEAT THE QC. IF QC PASSES CONTINUE WITH PATIENT TESTING. IF QC FAILS AGAIN, USE FRESHLY OPENED OR RECONSTITUTED QC AND REPEAT TESTING. IF QC FAILS AGAIN FOLLOE [sic] TROUBLE SHOOTING GUIDE TO ASSESS CLASS II FAILURE CLASS II: FAILURE OF ANALYTICAL SYSTEM WHEN REMEDIAL ACTION OF FAILED QC DOES NOT YEILD ACCEPTABLE RESULTS, PROCEED WITH VERIFICATION OF REAGENTS AND INSTRUMENT. CHECK REAGENT STABILITY, LOT #, EXPIRATION, CALIBRATION, INSTRUMENT MAINTENANCE AND OPERATING CONDITIONS ETC. ONCE THE ABOVE TESTING ITEMS HAVE BEEN ADDRESSED REPEAT QC. IF QC PASSES CONTINUE WITH PATIENT TESTING. IF QC FAILS AGAIN, CONTACT TECHNICAL SUPPORT. DOCUMENT ALL CORRECTIVE ACTIONS TAKEN!!!" FOR ANLY CORRECTIVE ACTION FALLING IN CLASS I ONLY REALTED TO QC MATERIAL ITSELF, AFTER ACHIEVING ACCEPTABLE QC RESULTS PROCEED WITH PATIENT TESTING. FOR ALL CORRECTIVE ACTIONS FALLING IN CLASS II WHERE ACTIONS ARE REQUIRING MANIPULATION OF THE ANANLYTIC SYSTEM PATIENT REMEDIATION IS REQUIRED." 2. Review of coagulation QC records and "Daily QC Error Log" revealed the laboratory failed to document all corrective actions taken. The following dates and times are a sampling from July-August 2019: 07/01/2019 QC level 1: lot #548071, expiration date 11/07/2020 15:02 hours QC passed for PTT, but was documented as a failure and that it was repeated 15:17 hours QC failed 16:08 hours QC failed 16:59 hours QC passed The only corrective action documented was a check mark under the column "Repeat." The laboratory failed to document all corrective actions taken for QC failures. QC level 3: lot #556501, expiration date 12/12/2020 16:06 hours QC failure for PT 16:57 hours QC failed 17:12 hours QC failed 17:43 hours QC failed 18:20

	hours QC passed The only corrective action documented was a check mark under the column "Repeat." The laboratory failed to document all corrective actions taken for QC failures. 07/03/2019 QC level 3: lot #556501, expiration date 12/12/2020 14:59 hours QC failure for PT 15:28 hours QC failed 15:37 hours QC failed 15:59 hours QC failed 16:26 hours QC failed 21:51 hours QC failed The only corrective action documented was a check mark under the column "Repeat" and under the "Corrective Action" column "PT rerun" was written. The laboratory failed to document all corrective actions taken for QC failures. 07/05/2019 QC level 3: lot #556501, expiration date 12/12/2020 14:55 hours QC failure for PT 21:08 hours QC failed 21: 18 hours QC failed 21:42 hours QC failed The only corrective action documented was a check mark under the column "Repeat" and under the "Corrective Action" column "PT rerun" was written. The laboratory failed to document all corrective actions taken for QC failures. QC level 1: lot #548071, expiration date 11/07/2020 21:06 hours QC failed for PTT 21:20 hours QC failed 21:44 hours QC passed The only corrective action documented was a check mark under the column "Repeat" and under the "Corrective Action" column "PTT rerun" was written. The laboratory failed to document all corrective actions taken for QC failures. 07/17/2019 QC level 2 lot # 562145 expiration date 11/06/2020 19:51 hours D-Dimer QC failed 20:22 hours QC failed 20:33 hours QC failed 20:45 hours QC failed 21:30 hours QC passed The laboratory failed to document all corrective actions taken for QC failures. 07/21/2019 QC level 2 lot # 562145 expiration date 11/06/2020 02:15 hours D-Dimer QC failed 02:35 hours QC failed The only corrective action documented was a check mark under the column "Repeat" and under the "Corrective Action" column "DDimer" was written. The laboratory failed to document all corrective actions taken for QC failures. 07/26/2019 QC level 1 lot #562245 expiration date 11/06/2020 11:08 hours D-Dimer QC failed 11:30 hours QC failed 11:45 hours QC failed 12:08 hours QC failed 12:49 hours QC failed 14:35 hours QC failed 15:48 hours QC passed The laboratory failed to document all corrective actions taken for QC failures. 08/23/2019 QC level 2 lot # 562134 expiration date 02/25/2020 10:08 hours D-Dimer QC failed 10:25 hours QC failed 10:48 hours QC failed 12:07 hours QC failed 13:29 hours QC passed The laboratory failed to document all corrective actions taken for QC failures. 3. During an interview on 10/16/19 at 11:20 am, testing person-4 confirmed the laboratory failed to document all corrective actions taken for QC failures.
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 review of the laboratory policy, laboratory quality control records, and confirmed interview, the laboratory failed to document patient remediation of all patient test results obtained in the unacceptable test run and since the last acceptable test run for testing on the Siemens Dimension EXL chemistry analyzer. Findings were: 1. Review of the laboratory policy Analytic Processes under Standard Operating Procedures QC Corrective Actions revealed "when QC fails to fall within the defined

limits of acceptability, the laboratory must identify the reason for the failure and correct the problem before resuming testing. The laboratory must evaluate all patient test results since the last acceptable control run." 2. Random review of quality control records from September 2019 revealed QC corrective actions that included recalibration for the following analytes on the following days: Folate - 9/11/19 Vitamin B12 - 9/4/19 3. Review of the laboratory records revealed the laboratory analyzed Folate on 9/10/19 and Vitamin B12 on 9/3/19, the dates of the last acceptable QC run. 9/10/19 Folate: Patient ID 9166, 9184, 1911243, 36083, 1920105 9 /3/19 Vitamin B12: Patient ID 46651, 76194, 76195, 66090, 20066, 81645, 8997 4. Review of the laboratory records from 09/2019 revealed no documentation of the patient evaluation for the above patients. 5. An interview with the testing person #2 on 10/16/19 at 1405 hours in the laboratory confirmed the above findings. 40420 II. Based on review of laboratory policy, coagulation quality control (QC) records, corrective action documentation, patient test reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 4 of 4 patients in 2019 (random review July-September). Findings: 1. Review of "STANDARD OPERATING PROCEDURE-QC-CORRECTIVE ACTIONS" laboratory policy revealed: "PURPOSE: WHEN QC FAILS TO FALL WITHIN THE DEFINED LIMITS OF ACCEPTABILITY, THE LABORATORY MIST IDENTIFY THE REASON FOR THE FAILURE AND CORRECT THE PROBLEM BEFORE RESUMING TESTING. THE LABORATORY MUST EVALUATE ALL PATIENT TEST RESULTS SINCE THE LAST ACCEPTABLE CONTROL RUN ... CLASS I: FAILURE OF QC MATERIAL WHEN A QC VALUE DOES NOT MEET ACCEPTABLE CRITERIA, PERFORM THE FOLLOWING STEPS: CHECK ALL PRE-ANALYTICAL STEPS, LOT#, EXPIRATION DATES, STORAGE TEMPERATURE, CORRECT QC, RECONSTITUTED FILL VOLUME, CORRECT DILUENT USED ETC. ONCE THE ABOVE ITEMS HAVE BEEN ADDRESSED REPEAT THE QC. IF QC PASSES CONTINUE WITH PATIENT TESTING. IF QC FAILS AGAIN, USE FRESHLY OPENED OR RECONSTITUTED QC AND REPEAT TESTING. IF QC FAILS AGAIN FOLLOE [sic] TROUBLE SHOOTING GUIDE TO ASSESS CLASS II FAILURE. CLASS II: FAILURE OF ANALYTICAL SYSTEM WHEN REMEDIAL ACTION OF FAILED QC DOES NOT YEILD ACCEPTABLE RESULTS, PROCEED WITH VERIFICATION OF REAGENTS AND INSTRUMENT. CHECK REAGENT STABILITY, LOT #, EXPIRATION, CALIBRATION, INSTRUMENT MAINTENANCE AND OPERATING CONDITIONS ETC. ONCE THE ABOVE TESTING ITEMS HAVE BEEN ADDRESSED REPEAT QC. IF QC PASSES CONTINUE WITH PATIENT TESTING. IF QC FAILS AGAIN, CONTACT TECHNICAL SUPPORT. DOCUMENT ALL CORRECTIVE ACTIONS TAKEN!!!" FOR ANLY CORRECTIVE ACTION FALLING IN CLASS I ONLY REALTED TO QC MATERIAL ITSELF, AFTER ACHIEVING ACCEPTABLE QC RESULTS PROCEED WITH PATIENT TESTING. FOR ALL CORRECTIVE ACTIONS FALLING IN CLASS II WHERE ACTIONS ARE REQUIRING MANIPULATION OF THE ANANLYTIC SYSTEM PATIENT REMEDIATION IS REQUIRED. PROCEDURE FOR PATIENT REMEDIATION ESTABLISH A LIST OF ALL PATIENTS THAT HAVE BEEN COMPLETED SINCE THE LAST ACCEPTABLE RUN OF QC PRIOR TO THE CURRENT RUN, RETREIVE SAMPLES AND REPEAT TESTING. IF THERE IS INSUFFICIENT SAMPLE OF RETEST, INFORM TECHNICAL CONSULTANT SO EVALUATION OF REMAINING PATIENTS CAN BE USED IN JUDGEMENT IF AMEDED REPORT IS NECESSARY. THE LABORATORY HAS AN ESTABLISHED POLICY THAT

	REPEAT PATIENT RESULTS FROM A CLASS II FAILURE MUST AGREE WITHIN 5% OF THE ORIGINAL VALUE. IF REPEAT TESTING YIELDS A RESULT OUTSIDE THIS RANGE AN AMENED REPORT MUST BE GENERATED WITH A COMMENT ATTACHED TO THE RESULT. IF NEEDED, CONTACT THE PHYSICAN TO HAVE PATIENT REDRAWN FOR VERIFICATION. DOCUMENT ALL CORRECTIVE ACTIONS TAKEN!!!" 2. Review of Sysmex CA-600 coagulation analyzer QC data and Daily QC Error Log revealed the troubleshooting the laboratory performed for the following sampling of QC test events in 2019: 08/2/2019 D-Dimer QC level 2 lot #562134 expiration date 02 /25/2020 09:58 hours QC failed 10:11 hours QC failed 10:44 hours QC failed 11:04 hours QC passed Review of corrective action for level 2 QC was documented as "DDIMER RERUN FRESH QC FAILED RERUN FRESH ALIQOUT RGT". The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (08/01/2019): Patient IDs: 45384, 63581, 67479 08/06/2019 D-Dimer QC level 2 lot #562134 expiration date 02/25/2020 07:32 hours QC failed 20:43 hours QC failed Review of corrective action for level 1 (lot #562234 expiration date 02/25/2020) and level 2 was documented as "DDIMER RERUN 2X FAILED RERUN ON ALL FRESH ALIQOUT OF REAGENTS". Note: Level 1 QC result was documented as 0.20, however that value was not on the QC data from the analyzer. Level 2 QC was documented as 1.97 and that value was also not on the QC data from the analyzer. During an interview on 10/16/2019 at 2:06 pm, testing person-4 stated that QC values that are above 3 SD are deleted from the analyzer because they affect the monthly mean. The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (08/05 /2019): Patient ID: 44822 3. During an interview on 10/16/19 at 11:20 am, testing person-4 stated she did not recall remediating patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results, confirming the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient wet prep records, manufacturer's instructions, UDS kit testing log, patient test reports, environmental logs, laboratory maintenance records, quality control (QC) records, expected value sheets, UDS Kit Testing Logs, facility's policies/procedures, blood bank's policies/procedures, transfusion records, patient charts, and corrective action logs, the laboratory failed to establish and follow written policies for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems, as evidenced by: 1. The laboratory failed to follow its own policy for new lot control material receipt for 3 of 3 sets blood gas control material. Refer to D5401. 2. The laboratory failed to implement a written policy/procedure for wet prep test procedure. Refer to D5403. 3. The laboratory failed to follow the manufacturer's instructions for quality control preparation for the Siemens Dimension EXL chemistry analyzer. Refer to D5411, I. 4. The laboratory failed to follow manufacturer's instructions for performing

	confirmatory testing on positive results for PROFILE-V MEDTOXScan Drugs of Abuse Test System for 7 of 25 patients in 2019 (random review 09/06/2019-10/16 /2019). Refer to D5411, II. 5. The laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for the calibrators and controls for the Siemens Dimension EXL chemistry testing. Refer to D5413, I. 6. The laboratory failed to follow manufacturer's instructions for the storage of CA CLEAN II reagent. Refer to D5413, II. 7. The laboratory failed to label a secondary container of blood bank saline with the poured date, expiration date, and identification (lot number). Refer to D5415, I. 8. The laboratory failed to document the revised expiration dates for quality controls stored in the laboratory refrigerator. Refer to D5415, II. 9. The laboratory failed to ensure that in-use Hematology reagents and control material were labeled with new expiration dates according to the manufacturer. Refer to D5415, III. 10. The laboratory failed to document complete verification studies for the Siemens Dimension EXL-B chemistry analyzer. Refer to D5421. 11. The laboratory failed to have documentation of performing weekly maintenance for 36 of 36 weeks. Refer to D5429. 12. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of OPTI CCA-TS2 test performance with current and accurate statistical parameters. Refer to D5441, I. 13. The laboratory failed to ensure their control procedures detected immediate error and monitored over time the accuracy and precision of test performance for 1 of 1 sets of current lot numbers. Refer to D5441, II. 14. The laboratory failed to implement an IQCP to lessen the frequency of QC for PROFILE-V MEDTOXScan Drugs of Abuse Test System 2019. Refer to D5445. 15. The laboratory failed to document the verification of quality control acceptable ranges for quality control for the Siemens Dimension EXL chemistry analyzer. Refer to D5469, I. 16. The laboratory failed to document established and defined statistical parameters (standard deviation [SD]) for unassayed control material used on the Sysmex CA-600 analyzer for day-to-day acceptability since 08/2019. Refer to D5469 II. 17. The laboratory failed to ensure quality control results met the laboratory's criteria for acceptability prior to reporting patient results for the Siemens Dimension EXL chemistry testing. Refer to D5481, I. 18. The laboratory reported 4 of 4 patient test results when QC was NOT accessed for Total Hemoglobin (tHb) and Oxygen Saturation (SO2). Refer to D5481, II. 19. The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 2 of 2 patients in 2019 (random review July). Refer to D5481, III. 20. The laboratory failed to promptly investigate blood transfusion reactions for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D5559. 21. The laboratory failed to document the instrument to instrument verification records for its 2 of 2 Siemens EXL-A and EXL-B chemistry analyzers for the analytes: Glucose, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Alkaline Phosphatase, Alanine Aminotransferase, Total Bilirubin, Total Protein, Albumin, Urea nitrogen, Creatinine, CK, Lipase, and Troponin for 2018 and 2019. Refer to D5775. 22. The laboratory failed to document corrective action taken on coagulation analytes for 9 of 9 runs in 2019 (random review July-August). Refer to D5781. 23. The laboratory failed to document patient remediation of all patient test results obtained in the unacceptable test run and since the last acceptable test run for testing on the Siemens Dimension EXL chemistry analyzer. Refer to D5783, I. 24. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 4 of 4 patients in 2019 (random review July-September). Refer to D5783, II.
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 direct observation and staff interview, the laboratory failed to have documentation of verifying result data and calculated result data sent to the Laboratory Information System (LIS) from the Sysmex XS 1000i hematology analyzer, the Siemens Advia Centaur chemistry analyzer, and the Dimension EXL chemistry analyzers to ensure the accuracy and reliability of patient results. Findings included: 1. During a tour of the laboratory on 10/17/2019 at 1004 hours, the Orchard Laboratory Information System was observed to be in use by the laboratory. 2. In an interview on 10/17/2019 at 1059 hours in the laboratory, Testing person #1 was asked when the Orchard Laboratory Information System was implemented by the laboratory. She stated the laboratory started using the system in January 2019. Testing person #1 was asked to provide documentation of verifying result data and calculated result data sent to the Laboratory Information System (LIS) from the Sysmex XS 1000i hematology analyzer, the Siemens Advia Centaur chemistry analyzer, and the Dimension EXL chemistry analyzers. No documentation was provided. The laboratory failed ensure the accuracy and reliability of result data and calculated result data sent to the Laboratory Information System from laboratory hematology and chemistry instrumentation.
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 review of manufacturer's instructions, client services manual, patient requisitions, patient test reports, instrument data, manifest logs, CMS-209 form, testing personnel records, and laboratory's policy, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure all requirements were met for testing in prenanalytic systems. Refer to D6007. 2. The laboratory director failed to ensure 1 of 9 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6029.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, client services manual, patient requisitions, patient test reports, instrument data, manifest logs, and laboratory's policy, the laboratory director failed to ensure all requirements were met for testing in prenanalytic systems, as evidenced by: 1. The laboratory failed to follow manufacturer's preanalytical requirements for testing erythrocyte sedimentation rate (ESR) to ensure accurate and reliable test results for 13 of 13 patients in 10/2019. Refer to D5311, I. 2. The laboratory failed to ensure Complete Blood Count (CBC) specimens were not analyzed beyond manufacturer's specimen stability for 2 of 3 patients on 10/10/2019 and 10/11/2019. Refer to D5311, II. 3. The laboratory failed to follow manufacturer's for establishing stability for patient complete blood count (CBC) specimens prior to testing 2 of 3 patients on the Sysmex XS 1000i hematology analyzer on 10/10/2019 and 10/11/2019. Refer to D5311, III.
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 review CMS-209 form, testing personnel records and staff interview, the laboratory director failed to ensure 1 of 9 testing personnel had qualifying education documentation prior to performing patient testing. Refer to D6065
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 review of laboratory policy, manufacturer's instructions, UDS kit testing log, patient test reports, environmental logs, laboratory maintenance records, verification studies, UDS Kit Testing Logs, quality control records, and expected value sheets, and

	corrective action logs, the technical consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant failed to provide technical and scientific oversight for analytic systems. Refer to D6036. 2. The technical consultant failed to ensure verification of the test procedures performed and establishment of the laboratory's test performance characteristics. Refer to D6040. 3. The technical consultant failed to establish a quality control program and establish parameters for acceptable levels of analytic performance and ensure levels were maintained throughout the entire process. Refer to D6042. 4. The technical consultant failed to resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's performance specifications. Refer to D6043. 5. The technical consultant failed to ensure patient test results were not reported until all corrective actions have been taken and the test system in functioning properly. Refer to D6044. 6. The technical consultant failed to include the review of quality control (QC) results as part of the competency assessment for 5 of 9 testing persons. Refer to D6049.
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 review of laboratory policy, manufacturer's instructions, UDS kit testing log, patient test reports, environmental logs, laboratory maintenance records, and UDS Kit Testing Logs, the technical consultant failed to provide technical and scientific oversight for analytic systems, as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for quality control preparation for the Siemens Dimension EXL chemistry analyzer. Refer to D5411, I. 2. The laboratory failed to follow manufacturer's instructions for performing confirmatory testing on positive results for PROFILE-V MEDTOXScan Drugs of Abuse Test System for 7 of 25 patients in 2019 (random review 09/06/2019-10/16/2019). Refer to D5411, II. 3. The laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for the calibrators and controls for the Siemens Dimension EXL chemistry testing. Refer to D5413, I. 4. The laboratory failed to follow manufacturer's instructions for the storage of CA CLEAN II reagent. Refer to D5413, II. 5. The laboratory failed to document the revised expiration dates for quality controls stored in the laboratory refrigerator. Refer to D5415, II. 6. The laboratory failed to ensure that in-use Hematology reagents and control material were labeled with new expiration dates according to the manufacturer. Refer to D5415, III. 7. The laboratory failed to have documentation of performing weekly maintenance for 36 of 36 weeks. Refer to D5429. 8. The laboratory failed to document the instrument to instrument verification records for its 2 of 2 Siemens EXL-A and EXL-B chemistry analyzers for the analytes: Glucose, Sodium, Potassium, Chloride, Carbon Dioxide, Calcium, Alkaline Phosphatase, Alanine Aminotransferase, Total Bilirubin, Total Protein, Albumin, Urea nitrogen, Creatinine, CK, Lipase, and Troponin for 2018 and 2019. Refer to D5775.
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 review of laboratory's policy and verification studies, the technical consultant failed to ensure verification of the test procedures performed and establishment of the laboratory's test performance characteristics. The laboratory failed to document complete verification studies for the Siemens Dimension EXL-B chemistry analyzer. Refer to D5421.
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 review of laboratory's policy, quality control records, and expected value sheets, the technical consultant failed to establish a quality control program and establish parameters for acceptable levels of analytic performance and ensure levels were maintained throughout the entire process, as evidenced by: 1. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of OPTI CCA-TS2 test performance with current and accurate statistical parameters. Refer to D5441, I. 2. The laboratory failed to ensure their control procedures detected immediate error and monitored over time the accuracy and precision of test performance for 1 of 1 sets of current lot numbers. Refer to D5441, II. 3. The laboratory failed to implement an IQCP to lessen the frequency of QC for PROFILE-V MEDTOXScan Drugs of Abuse Test System 2019. Refer to D5445. 4. The laboratory failed to document the verification of quality control acceptable ranges for quality control for the Siemens Dimension EXL chemistry analyzer. Refer to D5469, I. 5. The laboratory failed to document established and defined statistical parameters (standard deviation [SD]) for unassayed control material used on the Sysmex CA-600 analyzer for day-to-day acceptability since 08/2019. Refer to D5469 II.
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 review of laboratory policy, quality control records, corrective action logs, and patient records, the technical consultant failed to resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's performance specifications, as evidenced by: 1. The laboratory failed to

	document corrective action taken on coagulation analytes for 9 of 9 runs in 2019 (random review July-August). Refer to D5781. 2. The laboratory failed to document patient remediation of all patient test results obtained in the unacceptable test run and since the last acceptable test run for testing on the Siemens Dimension EXL chemistry analyzer. Refer to D5783, I. 3. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 4 of 4 patients in 2019 (random review July-September). Refer to D5783, II.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control policy, review of quality control results, and patient test records, the technical consultant failed to ensure patient test results were not reported until all corrective actions have been taken and the test system in functioning properly, as evidenced by: 1. The laboratory failed to ensure quality control results met the laboratory's criteria for acceptability prior to reporting patient results for the Siemens Dimension EXL chemistry testing. Refer to D5481, I. 2. The laboratory reported 4 of 4 patient test results when QC was NOT accessed for Total Hemoglobin (tHb) and Oxygen Saturation (SO2). Refer to D5481, II. 3. The laboratory failed to ensure results of control materials met the laboratory's test system criteria for acceptability before reporting patient test results for 2 of 2 patients in 2019 (random review July). Refer to D5481, III.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to include the review of quality control (QC) results as part of the competency assessment for 5 of 9 testing persons. Findings included: 1. A review of the laboratory's personnel records revealed the laboratory 2019 competency document for the OPTI CCA-TS2 blood gas analyzer listed the following: "a. Familiarity with Blood Gas Procedure Manual; i. Maintenance; ii. Testing; iii. Troubleshooting." The technical consultant failed to ensure that the review of quality control results was part of the competency assessment for 5 of 9 testing persons. The laboratory was asked to provide documentation that QC review was part of competency assessment. No documentation was provided. 2. An interview with testing person #6 on 10/16/2019 at 1020 hours in the laboratory revealed this element was NOT part of the laboratory's competency assessment for testing personnel. This confirmed the findings.

D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 1 of 9 testing persons met the qualifications required to perform moderate complexity testing. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 1 of 9 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #9 listed to perform moderate complexity testing. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: a. Testing person #9; No education documents provided 3. In an interview on 10/16/2019 at 1020 hours in the laboratory, testing person #6 was asked to provide educational documentation for testing person #9. No documentation was provided. This confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the laboratory director failed to provide overall management and direction in accordance

	with 493.1445 of this subpart. The laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology. Refer to D6082.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology, as evidenced by: 1. The facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D3025. 2. The laboratory failed to promptly investigate blood transfusion reactions for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D5559.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the technical supervisor failed to provide technical supervision in accordance with 493. 1451 of this subpart. The technical supervisor failed to provide technical and scientific oversight of immunohematology. Refer to D6112.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of the facility's policies/procedures, blood bank's policies /procedures, transfusion records, patient charts and in interview with staff, the technical supervisor failed to provide technical and scientific oversight of immunohematology, as evidenced by: 1. The facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D3025. 2.

	The laboratory failed to promptly investigate blood transfusion reactions for 2 of 67 transfused blood products in 2019 (04/18/2019 and 07/29/2019). Refer to D5559.