Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0506298	08/27/2021

Name of Provider or Supplier	Street Address, City, State
Dimmit Regional Hospital	704 Hospital Drive, Carrizo Springs, 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	A recertification survey was conducted August 23-27, 2021. An exit conference was held on August 27, 2021. In attendance was the Laboratory Director, Chief Executive Officer, the Technical Consultant (Laboratory Manager), and the Executive Director of Outpatient Operations. The facility was informed that an unannounced revisit will be conducted. The following condition level deficiencies were found out of compliance: D5300 - 42 C.F.R 493.1240 Condition: Pre-Analytic Systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records, review of the laboratory's College of American

	Pathologist's (CAP) proficiency testing records, and staff interview it was revealed the laboratory failed to have documentation of the laboratory director signing 63 of 116 attestation statements. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2020 and 2021 revealed the facility failed to have documentation of the laboratory director signing 62 of 112 attestation statements: a) Q1 Chemistry and Non Chemistry 2020 3 of 21 attestation statements not signed b) Q3 Chemistry and Non Chemistry 2020 29 of 30 attestation statements not signed c) Q1 Chemistry and Non Chemistry 2021 10 of 30 attestation statements not signed d) Q2 Chemistry and Non Chemistry 2021 20 of 30 attestations statements not signed 2. A review of the laboratory's College of American Pathologist's (CAP) proficiency testing records from 2020 and 2021 revealed the facility failed to have documentation of the laboratory director signing 1 of 4 attestation statements: a) AQ- A 2021 3. The laboratory was asked to provide documentation of the laboratory director signing the identified attestation statements. No documentation was provided. 4. An interview with the general supervisor on 08/24 /2021 at 1045 hours in his office - after his review of the records- confirmed the findings.
D2076	GENERAL IMMUNOLOGY CFR(s): 493.837(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency results from 2020 and 2021, and staff interview it was revealed the laboratory failed to attain a score of 80% for the analyte of Creatinine Kinase - muscle /brain for 1 of 4 events. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021 revealed the laboratory received a score of 60% for the analyte Creatinine Kinase - muscle/brain for Q3 Chemistry of 2020. The results incorrect results were: Specimen 12 reported value: 20 expected range: 7 - 9 Specimen 14 reported value: 107 expected range: 53 - 64 2. Corrective actions were not performed by the facility by the time of the survey. 3. An interview with the general supervisor on 08/24/2021 at 1600 hours in the break room - after his review of the records- confirmed the findings.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021, and staff interview, it was revealed the laboratory failed to obtain a score of 80% for the analyte human chorionic gonadotropin for 1 of 4 events reviewed. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021 revealed the laboratory received a score of 60% for the analyte

	human chorionic gonadotropin for Q3 Chemistry of 2020. The results incorrect results were: Specimen 12 reported value: 327 expected range: 423 - 535 Specimen 13 reported value: 247 expected range: 269 - 327 2. Corrective actions were not performed by the facility by the time of the survey. 3. An interview with the general supervisor on 08/24/2021 at 1600 hours in the break room - after his review of the records- confirmed the findings.
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021, and staff interview, it was revealed the laboratory failed to obtain a score of 100% for compatibility testing for 1 of 4 events reviewed. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021 revealed the laboratory received a score of 80% for compatibility testing for Q2 Non Chemistry of 2020. The incorrect result was: Specimen 9 reported: compatible expected result: Not compatible 2. Corrective actions were not performed by the facility by the time of the survey. 3. An interview with the general supervisor on 08/24 /2021 at 1600 hours in the break room - after his review of the records- confirmed the findings.
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: I. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to retain records. The findings include: 1. A review of the laboratory's records revealed the facility was inable to locate the following records for review during the survey: a) instrument printouts for instrument comparison studies in hematology for 1 of 2 events in 2020 and 1 of 1 events so far in 2021. b) instrument maintenance records for Access 2 (serial number 572386) for May 2021 and July 2021 c) instrument maintenance records for Access 2 (serial number 572387) for April 2021, May 2021 and June 2021 2. The laboratory was asked to provide documentation of the missing documents. No documentation was provided. 3. An interview with the general supervisor on 08/27/2021 at 0945 hours in the laboratory revealed he was unable to locate the missing records. This confirmed the findings. 36914 II. Based on review of the laboratory's quality control records for the Sensititre analyzer, Sysmex CA-600 and Triage D-Dimer, instrument printouts for the Sysmex CA-600, and confirmed in interview of facility personnel, it was revealed the laboratory failed to retain quality control records and instrument printouts. The findings included: 1. A review of the laboratory's quality control records for the Sensititre from April 2021 to July 2021 found the facility failed to retain Gram

	negative quality control records 3 of 18 weekly QC runs: 2021 missing weekly QC records from Sensititre (Gram negative) April 16, 2021 April 23, 2021 April 30, 2021 2. A review of the laboratory's quality control records for PT & PTT from January 2020 to August 2021 found the facility failed to retain quality control records for the Sysmex CA-600 for the following 5 of 12 months in 2020 and the following 1 of 7 months in 2021: 2020 missing QC records from Sysmex CA-600 January 2020 February 2020 March 2020 May 2020 June 2020 2021 missing QC records from Sysmex CA-600 January 2021 3. A review of the laboratory's quality control records for the Triage D-Dimer from January 2020 to July 2021 found the facility failed to retain quality control records 12 of 12 months in 2020: 2020 missing QC records from Triage D-Dimer January 2020 February 2020 March 2020 April 2020 May 2020 June 2020 July 2020 August 2020 September 2020 October 2020 November 2020 December 2020 4. A review of the laboratory's coagulation records from October, November, and December 2020 and January, February, and March 2021 found that instrument print outs for patient testing and quality control were not retained. 5. The laboratory was asked to provide documentation of the missing quality control records and instrument print outs. No documentation was provided. 6. An interview with the CEO and Technical Consultant on August 27, 2021 at 11:00 hours in the conference room confirmed the findings. They revealed that the hospital is trying to go paperless and many of these records are probably in transition. Key: QC - quality control PT - Prothrombin Time PTT - Partial Thromboplastin Time CEO - Chief Executive Officer
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's policies, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of policy to perform competency assessments on the technical consultant and general supervisor. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical consultant, 1 technical supervisor and 1 general supervisor. 2. A review of the laboratory's policies revealed the facility failed to have documentation of a policy addressing performing competency assessments on consultants and supervisors. 3. A review of the laboratory's personnel files revealed competency assessments had not been performed on the technical consultant, technical supervisor and general supervisor. 4. An interview with the general supervisor on 08/26/2021 at 8:30 am in his office - confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB)

	proficiency testing results from 2020 and 2021, review of the laboratory's College of American Pathologists' (CAP) proficiency testing results from 2020 and 2021, and staff interview, it was revealed the laboratory failed to have documentation of the review of results for 8 of 14 events. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021 revealed the laboratory failed to have documentation of the review of results for 7 of 10 events. They were: Q3 Chemistry 2020 Q1 Non Chemistry 2020 Q2 Non Chemistry 2020 Q3 Non Chemistry 2020 Q1 Chemistry 2021 Q1 Non Chemistry 2021 Q2 Non Chemistry 2021 2. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing results from 2020 and 2021 revealed the laboratory failed to have documentation of the review of results for 1 of 4 events. The event was: AQ-A 2021 Critical Care Blood Gas w/chemistry 3. The laboratory was asked to provide documentation of reviewing the results of the identified proficiency testing results. No documentation was provided. 4. An interview with the general supervisor on 08/24/2021 at 1600 hours in the break room - after his review of the records- confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing results from 2020 and 2021, and staff interview it was revealed the laboratory failed to have documentation of evaluating proficiency results which were not graded by the proficiency testing agency. The findings include: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2020 and 2021 revealed the proficiency testing agency utilized the following message flags for results: a) ? "This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus." b) # "This method was not graded due to an insufficiency number of peer respondents. No appropriate default grouping was available. This listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 2. Further review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2020 and 2021 revealed the laboratory failed to have documentation of evaluating the following results which were not graded by the proficiency testing agency: a) Q3 Non Chemistry 2020 Cell Identification Sample 11 Flag: ? Gram Stain Morphology Sample 13 Flag: ? b) Q3 Chemistry 2020 Uric Acid Sample 14 Flag: # Urine Sediment Sample 12 Flag: ? Urine Sediment Educational Sample 11 Flag: ? c) Q1 Chemistry 2021 Alanine Aminotransferase Sample 5 Flag: # Chloride Sample 5 Flag: # Uric Acid Sample 4 Flag: # Salicylates Sample 2 Flag: # d) Q2 Chemistry 2021 Alcohol, Serum Sample 6 Flag: # Alcohol, Serum Sample 7 Flag: # Alcohol, Serum Sample 8 Flag: # Alcohol, Serum Sample 9 Flag: # Alcohol, Serum Sample 10 Flag: # Nasal Eosinophils Sample 6 Flag: ? Gamma-Glutamyltransferase Sample 9 Flag: # Urinalysis - Red Blood Cells Sample 6 Flag: ? Gram Stain Morphology Sample 6 Flag: ? Gram Stain Morphology Sample 10 Flag: ? 3. The laboratory was asked to provide documentation of evaluating the results

	not graded by the proficiency testing agency. No documentation was provided. 4. An interview with the general supervisor on 08/24/2021 at 1600 hours in the break room - after is review of the records- confirmed the findings.
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 surveyor observations, review of laboratory policies, manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of monitoring and evaluating overall quality of its preanalytic systems as evidenced by: 1. The laboratory failed to have documentation of following manufacturer's instructions for: A) removal of plasma from cells for Lactate samples, B) Ammonia samples centrifuged in a cold centrifuge, and, C) Ammonia samples tested within 3 hours of collection (refer to D5311). 2. The laboratory failed to provide its clients written instructions for patient preparation, specimen collection, labeling, storage and preservation, transportation, processing, acceptability and rejection, and referral if appropriate (refer to D5317).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test records and staff interviews, it was revealed the laboratory failed to have documentation of following manufacturer's instructions for: A) removal of plasma from cells for Lactate samples B) Ammonia samples centrifuged in a cold centrifuge, and C) Ammonia samples tested within 3 hours of collection. The findings include: A) Lactate samples 1. A review of the manufacturer's instructions for the Beckman Coulter Lactate assay (OSR6193) under the section titled "Specimen Collection and Preparation" revealed: "Keep the sample on ice and separate plasma from cells within 15 minutes of collection." 2. A random sampling of patient test records from 2020 and 2021 identified 12 of 45 samples (26.7%) where the time from collection to receipt in the laboratory exceeded 15 minutes, and thus, the plasma was not removed from the cells within the time required. They were: a) 2020 Patient: 10194660 collected: 09/30/2020 15:56 received: 09/30/2020 17:15 elapsed time: 79 minutes Patient: 10195362

	collected: 10/12/2020 08:45 received: 10/12/2020 09:59 elapsed time: 74 minutes Patient: 10198916 collected: 12/08/2020 16:45 received: 12/08/2020 17:40 elapsed time: 55 minutes Patient: 10199934 collected: 12/29/2020 01:08 received: 12/29/2020 01:35 elapsed time: 27 minutes b) 2021 Patient: 10200267 collected: 01/02/2021 15:15 received: 01/02/2021 16:45 elapsed time: 90 minutes Patient: 10202675 collected: 02/08/2021 00:25 received: 02/08/2021 00:47 elapsed time: 22 minutes Patient: 10202976 collected: 02/11/2021 21:50 received: 02/11/2021 22:41 elapsed time: 51 minutes Patient: 10204205 collected: 03/05/2021 20:05 received: 03/05/2021 20:41 elapsed time: 36 minutes Patient: 10206546 collected: 04/11/2021 15:15 received: 04/11/2021 15:46 elapsed time: 31 minutes Patient: 10207182 collected: 04/21/2021 09:02 received: 04/21/2021 09:30 elapsed time: 28 minutes Patient: 10209611 collected: 05/29/2021 16:31 received: 05/29/2021 17:00 elapsed time: 29 minutes Patient: 10209630 collected: 05/30/2021 13:12 received: 05/30/2021 14:03 elapsed time: 51 minutes 3. The laboratory performed 336 lactate tests in 2020 and 519 lactate tests thus far in 2021. 4. An interview with the general supervisor on 08/25/2021 at 1030 hours in his office revealed the laboratory was unaware of the time requirements to remove lactate plasma sample from cells within 15 minutes of collection. This confirmed the findings. B) Ammonia samples spun in a cold centrifuge 1. A review of the manufacturer's instructions for the Beckman Coulter Ammonia assay (OSR61154) under the section titled "Specimen Collection and Preparation" revealed: "Centrifuge (cold) the sample as soon as possible and separate plasma and store at 2 - 4 C until analysis." 2. A review of the laboratory's centrifuge revealed the facility did not have one which could spin samples at a cold temperature. The laboratory utilized a STAT Express Spin 3 centrifuge for ammonia samples which kept samples at room temperature. 3. The laboratory perform 63 ammonia tests in 2020 and 139 ammonia test thus far in 2021. 4. An interview with the general supervisor on 08/25/2021 at 0910 hours in the laboratory revealed the facility did not spin ammonia samples in a cold centrifuge. This confirmed the findings. C) Ammonia samples not tested within 3 hours of collection 1. A review of the manufacturer's instructions for the Beckman Coulter Ammonia assay (OSR61154) under the section titled "Sample Storage and Stability" revealed: "Ammonia samples are stable for 3 hours at 2 - 4C or 24 hours at -20C." 2. A review of patient test records from 2020 and 2021 identified the following samples where the time from collection to testing was more than 3 hours. They were: Patient: 101996812 collected: 11/04/2020 09:19 tested: 11/04/2020 12:46 elapsed time: 3 hours 27 minutes Patient: 10209639 collected: 05/30/2021 17:04 tested: 05/30/2021 20:26 elapsed time: 3 hours 22 minutes 3. The laboratory perform 63 ammonia tests in 2020 and 139 ammonia test thus far in 2021. 4. An interview with the general supervisor on 08/25/2021 at 0910 hours in the laboratory revealed the facility only received ammonia samples on ice and did not receive them on dry ice to maintain -20 C. Thus, they needed to be tested within 3 hours of collection. This confirmed the findings.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, and confirmed in interview with facility personnel, the laboratory failed to provide written instructions to its clients. The findings

	included: 1. Surveyor observation on August 26, 2021 revealed a home health nurse deliver a patient sample in a cooler with 1 ice pack containing two green tops, one on ice and one not. There was no documentation available to determine if temperature is monitored during transit and no documentation of monitoring the temperature of the specimens upon arrival was observed. 2. The laboratory was asked to provide documentation of providing written instructions to clients that included instructions for patient preparation, specimen collection, labeling, storage and preservation, transportation, processing, acceptability/rejection criteria, and referral. No documentation was provided. 3. The surveyor asked three lab assistants on August, 26, 2021 in the laboratory how the home health nurses knew what to draw, they explained that they either knew or they would call. When asked if the laboratory provided written instructions to its outside clients, they answered, "No."
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 surveyor observations, review of laboratory policies, review of manufacturer's instructions, review of laboratory verification records, review of quality control records, environmental records, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to provide documentation of following its own policies and procedures (refer to D5401). 2. The laboratory failed to provide documentation of following manufacturer's instructions when setting up quality control microorganisms using Microbiologic ATCC culture swabs (refer to 5411-I). 3. The laboratory failed to provide documentation of following manufacturer's instructions for storage of STRECK ESR-Check Plus once it is brought to room temperature (refer to D5411-II). 4. The laboratory failed to provide documentation of establishing and monitoring an acceptable room humidity range in the room where epoc blood gas analyzers were in use (refer to D5413). 5. The laboratory failed to provide documentation of following the manufacturer's open vial stability for control materials (refer to D5415-I and D5415-II). 6. The laboratory failed to ensure expired Microbiologics quality control organisms were not used to perform weekly quality control testing (refer to D5417). 7. The laboratory failed to have documentation of complete studies for A) Beckman Coulter DxC 700 AU (serial number 2020051466), B) Beckman Coulter DxC 700 AU (serial number 2020021341), C) Beckman Coulter Access 2 (serial number 572386), D) Beckman Coulter Access 2 (serial number 572387), E) Desse Mini-Cube (serial number 1308) (refer to D5421). 8. The laboratory failed to have documentation of performing required instrumentation maintenance (refer to D5429). 9. The laboratory failed to have documentation of performing calibration verification every six months for analytes requiring it on the Beckman Coulter DxC 700 AU analyzers (refer to D5439). 10. The laboratory failed to have documentation of monitoring controls to detect errors over time (refer to D5441 I and D5441 II). 11. The laboratory failed to have documentation of performing RPR (Rapid Plasma Reagin) quality control each

	day of patient testing (refer to D5451). 12. The laboratory failed to provide documentation of verifying new lot numbers of epoc quality control prior to putting them into use (refer to D5469). 13. The laboratory failed to provide documentation of performing media quality control for each batch/shipment when it did not develop an IQCP (refer to D5477). 14. The laboratory failed to ensure quality control values were acceptable prior to reporting patient results (refer to D5481). 15. The laboratory failed to perform complete quality control testing to determine Clindamycin inducibility (D Test) (refer to D5507). 16. The laboratory failed to have a policy for investigation of potential transfusion reactions (D5559). 17. The laboratory failed to have documentation of performing twice annual instrument comparisons in 2019 and 2020 (refer to D5775). 18. The laboratory failed to have documentation of performing corrective action when blood bank temperature wheels were incomplete (refer to D5781). 19. The laboratory failed to have documentation of performing corrective actions when recorded refrigeration temperatures were outside of the laboratory's established acceptable range (refer to D5785). 20. The laboratory failed to provide documentation of a written policy and procedure for an ongoing mechanism to monitor, assess, and correct when the blood bank refrigerator alarm was activated and hospital staff did not know procedures to follow (refer to D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of laboratory policy, review of laboratory analytic records, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy when performing annual platelet poor studies from January 2020 to December 2020. The findings included: 1. Review of the laboratory's policy titled, "General: Laboratory Quality Control Policy, Plan and Guidelines (not approved by the current laboratory director), stated, "I. Annually, a minimum of 20 coagulation specimens will be analyzed for platelet count to ensure that there is adequate centrifugation to yield an adequate "platelet poor plasma" sample for coagulation testing." 2. Review of laboratory analytic records found the laboratory performed a platelet poor study for the current lot of Innovin (Lot 549755, expiration 06-06-2022 put into use February 2020. The study was done using 5 samples. 3. The laboratory was asked to provide documentation of following its own policy to use a minimum of 20 coagulation specimens to perform platelet poor studies. No documentation was provided. 4. An interview with the Technical Consultant on August 26, 2021 at 17:30 hours in his office confirmed the findings. He revealed that he was not aware that the policy said to utilize 20 samples. B. Based on review of the laboratory's policies and procedures, random review of the Monthly Blood Volume Monitoring log and interview with the staff it was determined the laboratory failed to follow its own procedure for performing monthly blood volume monitoring from June of 2019 to July of 2021. The findings were: 1. Review of the laboratory's policy Microbiology-Monitoring of Blood Volume for Blood Culture revealed "Volume of blood collected for blood culture will be monitored a minimum of one day per month with feedback provided to the collector. The assigned day would be the 15th of every month regardless of the number of orders." 2. Review of the laboratory's Monthly Blood Volume Monitoring

	log revealed there was no documentation of blood volume monitoring after May 15th, 2019. 3. In an interview on 08/24/2021 at 1300 hours in the laboratory the Testing Person #1 (as documented on CMS Form 209, signed by the laboratory director on 08 /23/2021) stated that the laboratory does not perform blood volume monitoring. This confirmed the findings.
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 surveyor observation, review of laboratory policy, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions when preparing Microbiologics KWIK-STIK microorganisms for random review of 5 of 5 lot numbers of quality control. The findings included: 1. Surveyor observation on August 24, 2021 at 13:20 hours in the Microbiology Department found the following random quality control Microbiologics KWIK-STIK microorganisms: Escherichia coli ATCC 35128 Lot 495-98-2 Expiration date: 06-30-2019 Escherichia coli ATCC 25922 Lot 335-494-1 Expiration date: 09-30-2020 Klebsiella pneumoniae ATCC 33495 Lot 957-51-5 Expiration date: 01-30-2020 Enterococcus faecalis ATCC 29212 Lot 366-330-4 Expiration date: 10-31-2020 Staphylococcus aureus ATCC 43300 Lot 852-66-1 Expiration date: 12-31-2019 Note: Each of the 5 of 5 lot numbers of quality control microorganisms were expired (refer to D5417). 2. Review of laboratory policies found no policy on how to prepare quality control stock cultures from the lyophilized Microbiologics KWIK STIKs pellets. 3. Review of the manufacturer's instructions for Microbiologics KWIK STIKs (PI.194.ENG Rev D, 2018.July 30) stated, "PRODUCT DESCRIPTION A. KWIK-STIK: Each KWIK-STIK unit contains a lyophilized microorganism pellet, an ampoule of hydrating fluid, and an inoculating swab. Each device is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. KWIK-STIK microorganisms are 3 passages or fewer from the reference culture and are guaranteed to recover when processed using the recommended media and incubation requirements." 4. An interview with Testing Personnel #2 (as listed on Form CMS-209) confirmed the findings. He explained that quality control plates were restreaked on Wednesdays and the Thursday night shift technologist would perform the quality control testing. He also explained that the only time the KWIK-STIKs were used was if quality control was failing. He confirmed that the laboratory did not have a policy on the use of the KWIK-STIKs and that he was primarily going off of his memory on how to use of them. Key: ATCC - American Type Culture Collection CMS - Centers for Medicare and Medicaid Services 31968 II. Based on review of the manufacturer's instructions for the Streck ESR-Check Plus hematology control, surveyor observation of control material currently in use in the laboratory, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for the storage of the control material once placed into use. The findings were: 1. A review of the manufacturer's instructions for the Streck ESR-Check Plus hematology control (350680-2, 2018-11) revealed: "Working vials are to be stored at room temperature and may not be returned to refrigerated temperature for additional use." The instructions also stated that once opened, the controls would

	expire after 7 days at room temperature. 2. Surveyor observation of control material currently in use on 08/26/2021 at 13:05 hours revealed the laboratory was storing the controls in the refrigerator. The laboratory could not state how long the controls had been in use. 3. The laboratory performed quality control testing using these controls every day. 4. An interview with the general supervisor on 08/26/2021 at 13:07 hours in the laboratory revealed the facility routinely placed the control back in the refrigerator after each use. He stated the laboratory was unaware that it was required to be left at room temperature. This confirmed the findings. Key: ESR - erythrocyte sedimentation rate
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of establishing and monitoring an acceptable room humidity range in the room where epoc blood gas analyzers were in use for 55 days from July 1, 2021 to August 24, 2021 The findings included: Note: This is a repeat deficiency from the survey conducted 01/18-20/2021. 1. Review of the manufacturer's for the epoc System for performance of arterial blood gas under, "epoc Reader", it stated, "-The Reader must be used in relative humidity of less than 85% at 30 degrees Celsius, non condensing. The Reader's electronic QC checks leakage current within the Reader to detect compromised performance due to high humidity." 2. Review of the laboratory's environmental records from July 1, 2021 to August 24, 2021 found the laboratory did not establish or monitor an acceptable room humidity range according to the manufacturer's instructions. 3. Interview with the Technical Consultant on August 25, 2021 at 15:30 hours in the break room confirmed the findings. He stated that the data loggers were the back up system to the manual monitoring. However, when he retrieved the data logger analytics, he discovered that a range had not been entered. Without an acceptable range entered into the data logger system, it had no way of detecting times when humidity may have been out of range. Key: QC - quality control
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 surveyor direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for quality control reagents for 5 of 15 reagents observed in the chemistry refrigerator. The findings included: Note: This is a repeat deficiency from survey conducted January 18-20, 2021. 1. Surveyor observation made on August 23, 2021 at 14:30 hours in the laboratory found the following quality control reagents in the chemistry refrigerator with no open date and no revised expiration date. The reagents were not included in the posted list of revised expiration dates once open. Liquichek Therapeutic Drug Monitoring Control (TDM) Level 3 Lot 27753 Manufacturer expiration date: 09-30-2022 Open Date: 08-22-2021 (no revised expiration date) Liquichek Diabetes Control Level 1 Lot 55741 Manufacturer expiration date: 03-31-2023 Open Date: 08-06-2021 (no revised expiration date) Liquichek Diabetes Control Level 2 Lot 55742 Manufacturer expiration date: 03-31-2023 Open Date: 08-06-2021 (no revised expiration date) Liquichek Cardiac Markers Plus Control LT Level 1C Lot 99566 Manufactuer expiration date: 09-30-2021 No open date and no revised expiration date Liquichek Cardiac Markers Plus Control LT Level 3 Lot 67633 Manufactuer expiration date: 01-31-2023 No open date and no revised expiration date 2. Review of the manufacturer's instructions for BioRad quality control reagent, Therapeutic Drug Monitoring Control (TDM) Levels 1, 2, and 3 (5176-00, 2020-10) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 14 days 3. Review of the manufacturer's instructions for BioRad quality control reagent, Liquichek Diabetes Control Levels 1, 2, and 3 (5250-00, 2020-06) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 20 days Except Troponin I: 10 days." 4. Review of the manufacturer's instructions for BioRad quality control reagent, Liquichek Cardiac Markers Plus Control LT Levels 1, 2, 3, 1A and 1C (16000202-00, 2020-04) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 20 days Except Troponin I: 10 days." 5. Without documenting the open date or revised expiration dates, the laboratory had no means to ensure quality control materials were not used after their thawed expiration dates. a. Since revised expiration dates were not documented, it could not be determined if expired quality control materials were used when testing patients. 6. An interview with Testing Personnel #1 (as listed on Form CMS-209) on January 23, 2021 at 14:40 hours in the laboratory confirmed the findings. She agreed there were no open or revised expiration dates on the vials and without that information, laboratory staff had no way to determine if the quality control reagent was expired or not. Key: CMS - Centers for Medicare and Medicaid 31968 II. Based on review of the manufacturer's instructions for the Streck ESR-Check Plus hematology control, surveyor observation of control material currently in use in the laboratory, and staff interview, it was revealed the laboratory failed to follow the manufacturer's open vial stability for the control material. The findings were: 1. A review of the manufacturer's instructions for the Streck ESR-Check Plus hematology controls (350680-2, 2018-11) revealed: "Open-vial stability for this control is defined as the maximum number of continuous days a vial can be brought to room temperature and mixed for analysis on this system. Vials must be discarded at the lot expiration or the OVS expiration, whichever comes first. Working vials are to be stored at room temperature and may not be returned to refrigerated temperature for additional use." The instructions also stated that once opened, the controls would expire after 7 days at room temperature. 2. Surveyor observation of control material currently in use on 08/26/2021 at 13:05 hours revealed the laboratory was storing the controls (normal and abnormal) in the

	refrigerator. The laboratory did not monitor when the controls had been opened or how long the controls had been in use. 3. The laboratory performed quality control testing using these control every day. 4. An interview with the general supervisor on 08/26/2021 at 13:07 hours in the laboratory revealed the facility opened the control material and only monitored the lot expiration date. He stated the laboratory was unaware that the stability of the control changed once it was opened. This confirmed the findings. Key: ESR - erythrocyte sedimentation rate OVS - open vial stability
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on surveyor direct observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for quality control reagents for 5 of 15 reagents observed in the chemistry refrigerator. The findings included: Note: This is a repeat deficiency from follow-up survey conducted 01/18-20/2021. 1. Surveyor observation made on August 23, 2021 at 14:30 hours in the laboratory found the following quality control reagents in the chemistry refrigerator with no open date and no revised expiration date: Liquichek Therapeutic Drug Monitoring Control (TDM) Level 3 Lot 27753 Manufacturer expiration date: 09-30-2022 Open Date: 08-22-2021 (no revised expiration date) Liquichek Diabetes Control Level 1 Lot 55741 Manufacturer expiration date: 03-31-2023 Open Date: 08-06-2021 (no revised expiration date) Liquichek Diabetes Control Level 2 Lot 55742 Manufacturer expiration date: 03-31-2023 Open Date: 08-06-2021 (no revised expiration date) Liquichek Cardiac Markers Plus Control LT Level 1C Lot 99566 Manufactuer expiration date: 09-30-2021 No open date and no revised expiration date Liquichek Cardiac Markers Plus Control LT Level 3 Lot 67633 Manufactuer expiration date: 01-31-2023 No open date and no revised expiration date 2. Review of the manufacturer's instructions for BioRad quality control reagent, Therapeutic Drug Monitoring Control (TDM) Levels 1, 2, and 3 (5176-00, 2020-10) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 14 days 3. Review of the manufacturer's instructions for BioRad quality control reagent, Liquichek Diabetes Control Levels 1, 2, and 3 (5250-00, 2020-06) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 20 days Except Troponin I: 10 days." 4. Review of the manufacturer's instructions for BioRad quality control reagent, Liquichek Cardiac Markers Plus Control LT Levels 1, 2, 3, 1A and 1C (16000202-00, 2020-04) under, "Storage and Stability" it stated, "...Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: -All analytes: 20 days Except Troponin I: 10 days." 5. Without documenting the open date or revised expiration dates, the laboratory had no means to ensure quality control materials were not used after their thawed expiration dates. a. Since revised expiration dates could not be determined, it could not be determined if expired quality control materials were used when testing patients. 6. An interview with Testing Personnel #1 (as listed on Form CMS-209) on August 23, 2021 at 14:30 hours in the laboratory confirmed the findings. She agreed there were no

	open or revised expiration dates on the vials and without that information, laboratory staff had no way to determine if the quality control reagent was expired or not. II. Based on surveyor observation, review of manufacturer's instructions, review of quality control records, and confirmed in interview with facility personnel, the laboratory utilized expired Microbiologics quality control organisms to perform weekly quality control testing in microbiology from April 1 2021 to August 24, 2021 . The findings included: 1. Surveyor observation on August 24, 2021 at 13:20 hours in the Microbiology Department found the following random quality control Microbiologics KWIK-STIK microorganisms: Escherichia coli ATCC 35218 Lot 495-98-2 Expiration date: 06-30-2019 Enterococcus faecalis ATCC 29212 Lot 366-330-4 Expiration date: 10-31-2020 Escherichia coli ATCC 25922 Lot 335-494-1 Expiration date: 09-30-2020 Pseudomonas aeruginosa ATCC 27853 Lot 353-404-4 Expiration date: 06-30-2021 Klebsiella pneumoniae ATCC 33495 Lot 957-51-5 Expiration date: 01-30-2020 Staphylococcus aureus ATCC 43300 Lot 852-66-1 Expiration date: 12-31-2019 2. Review of the laboratory's quality control records found the laboratory performed weekly (each Thursday) sensitivity quality control testing using the following QC organisms: Escherichia coli ATCC 25922 Escherichia coli ATCC 35218 Pseudomonas aeruginosa ATCC 27853 Staphylococcus aureus ATCC 37213 Enterococcus faecalis ATCC 29212 3. Review of quality control records from April 1, 2021 to May 31, 2021 found the laboratory performed weekly quality control testing using expired quality control microorganisms. a. Weekly Gram negative quality control testing for sensitivities performed from April 1, 2021 to August 24, 2021 was performed using expired Escherichia coli ATCC 25922. b. Weekly Gram negative quality control testing for sensitivities performed from April 1, 2021 to August 24, 2021 was performed using expired Escherichia coli ATCC 35218. c. Weekly Gram negative quality control testing for sensitivities performed from July 1, 2021 to August 24, 2021 was performed using expired Pseudomonas aeruginosa ATCC 27853. d. Weekly Gram positive quality control testing for sensitivities performed from April 1, 2021 to August 24, 2021 was performed using expired Enterococcus faecalis ATCC 29212. 4. Review of patient records from August 2021 found the following patients were tested when expired quality control microorganisms were used (random sampling): Order # 70114 Result date: 08-10-2021 >100,000 Escherichia coli Order # 70088 Result date: 08-08-2021 >100,000 Serratia marcescens Order #71197 Result date: 08-12-2021 >100,000 Escherichia coli Order # 71108 Result date: 08-12-2021 >100,000 Enterobacter aerogenes Order # 72012 Result date: 08-15-2021 >100,000 Pseudomonas aeruginosa 5. An interview with the Technical Consultant on August 25, 2021 at 16:00 hours in his office confirmed the findings. He was not aware that the quality control microorganisms were expired. III. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview with facility personnel, the laboratory used expired CA Clean I to clean the Sysmex CA-600 probe for 56 days from July 1, 2021 to August 26, 2021. The findings included: 1. Surveyor observation made on August 26, 2021 at 16:40 hours in the laboratory found 1 bottle of CA Clean I in the refrigerator (expiration date: 06-30-2021). There was a pour over aliquot of CA Clean I on the analyzer. 2. Review of the manufacturer's instructions for CA Clean I (5431048Y, 02/2015) stated, "Intended use: The product is applied to cleanse the pipets used for fully automated blood coagulation analyzer." 3. Based on the expiration date on the bottle (06-30-2021), the reagent was expired for 56 days. 4. An interview with the Technical Consultant on August 26, 2021 at 17:45 hours in his office revealed that the reagent was on back order due to Covid. He was unable to provide an email or documentation from the manufacturer stating such prior to the exit conference on August 27, 2021.
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's verification studies, and staff interview, it was revealed the laboratory failed to have documentation of complete studies for: A) Beckman Coulter DxC 700 AU (serial number 2020051466) B) Beckman Coulter DxC 700 AU (serial number 2020021341) C) Beckman Coulter Access 2 (serial number 572386) D) Beckman Coulter Access 2 (serial number 572387) E) Desse Mini-Cube (serial number 1308) The findings include: A) DxC 700 AU (serial number 2020051466) 1. A review of the laboratory's verification records for the Beckman Coulter DxC 700 AU analyzer performed in January 2021 revealed the following 42 analytes were tested on the analyzer: Acetaminophen Hemoglobin A1c Albumin Alkaline Phosphatase Alanine Aminotransferase Ammonia Amylase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Carbamazepine Cholesterol Creatine Kinase Chloride CO2 Creatinine C-Reactive protein Direct Bilirubin Digoxin Ethanol Gentamicin Gamma-Glutamyl Transferase Glucose High density lipoprotein Potassium Lactate Lactate dehydrogenase Lipase Magnesium Sodium Phenobarbital Phenytoin Phosphorus Salicylate Total Bilirubin Total Protein Triglyceride Urine creatinine Urine Total Protein Uric Acid Valproic Acid Vancomycin 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for each of the 42 analytes identified. 3. The laboratory was asked to provide documentation of verifying patient normal ranges. No documentation was provided. 4. An interview with the general supervisor on 08/25/2021 at 1500 hours in the laboratory revealed the laboratory utilized the patient normal ranges provided by the manufacturer. He stated these ranges had not been verified as reflective of the facility's normal patient population. This confirmed the findings. B) DxC 700 AU (serial number 2020021341) 1. A review of the laboratory's verification records for the Beckman Coulter DxC 700 AU analyzer performed in August 2020 revealed the following 42 analytes were tested on the analyzer: Acetaminophen Hemoglobin A1c Albumin Alkaline Phosphatase Alanine Aminotransferase Ammonia Amylase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Carbamazepine Cholesterol Creatine Kinase Chloride CO2 Creatinine C-Reactive protein Direct Bilirubin Digoxin Ethanol Gentamicin Gamma-Glutamyl Transferase Glucose High density lipoprotein Potassium Lactate Lactate dehydrogenase Lipase Magnesium Sodium Phenobarbital Phenytoin Phosphorus Salicylate Total Bilirubin Total Protein Triglyceride Urine creatinine Urine Total Protein Uric Acid Valproic Acid Vancomycin 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for each of the 42 analytes identified. 3. The laboratory was asked to provide documentation of verifying patient normal ranges. No documentation was provided. 4. An interview with the general supervisor on 08/25/2021 at 1500 hours in the laboratory revealed the laboratory utilized the patient normal ranges provided by the manufacturer. He stated these ranges had not been verified as reflective of the facility's normal patient population.

	This confirmed the findings. C) Beckman Coulter Access 2 analyzer (serial number 572386) 1. A review of the laboratory's verification records for the Beckman Coulter DxC 700 AU analyzer performed in August 2020 revealed the following 12 analytes were tested on the analyzer: Creatine Kinase - muscle/brain Free Thyroxine Human Chorionic Gonadotropin Myoglobin T Uptake Troponin Thyroid Stimulating Hormone Prostate-specific antigen Parathyroid Testosterone Vitamin D 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of: a) accuracy for Prostate-specific antigen, testosterone, and vitamin D, and b) verifying patient normal ranges for each of the 12 analytes identified. 3. The laboratory was asked to provide documentation of accuracy and of verifying patient normal ranges. No documentation was provided. 4. An interview with the general supervisor on 08/25/2021 at 1535 hours in the laboratory revealed the laboratory utilized the patient normal ranges provided by the manufacturer. He stated these ranges had not been verified as reflective of the facility's normal patient population. His review of the accuracy studies confirmed accuracy had not been performed for Prostate-specific antigen, testosterone, and vitamin D. This confirmed the findings. D) Beckman Coulter Access 2 analyzer (serial number 572387) 1. A review of the laboratory's verification records for the Beckman Coulter DxC 700 AU analyzer performed in August 2020 revealed the following 12 analytes were tested on the analyzer: Creatine Kinase - muscle/brain Free Thyroxine Human Chorionic Gonadotropin Myoglobin T Uptake Troponin Thyroid Stimulating Hormone Prostate-specific antigen Parathyroid Testosterone Vitamin D 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of: a) accuracy for Prostate-specific antigen, testosterone, and vitamin D, and b) verifying patient normal ranges for each of the 12 analytes identified. 3. The laboratory was asked to provide documentation of accuracy and of verifying patient normal ranges. No documentation was provided. 4. An interview with the general supervisor on 08/25/2021 at 1535 hours in the laboratory revealed the laboratory utilized the patient normal ranges provided by the manufacturer. He stated these ranges had not been verified as reflective of the facility's normal patient population. His review of the accuracy studies confirmed accuracy had not been performed for Prostate-specific antigen, testosterone, and vitamin D. This confirmed the findings. E) Desse Mini-Cube (serial number 1308) 1. A review of the laboratory's verification records for the Desse Mini-Cube Sedimentation Rate analyzer performed in November 2019 revealed the laboratory failed to have documentation of performing precision studies. 2. The laboratory was asked to provide documentation of precision studies. No documentation was provided. 3. An interview with the general supervisor on 08/26/2021 at 0930 hours in his office - after his review of the records- confirmed the findings.
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 manufacturer's instructions for the Sysmex XT-1800i hematology analyzer, review of the manufacturer's instructions for the Beckman Coulter Access 2 analyzer, review of the laboratory's maintenance records, and staff interview, it was revealed the laboratory failed to have documentation of required

	maintenance. The findings include: A) Sysmex XT-1800i 1. A review of the manufacturer's instructions for the Sysmex XT-1800i hematology analyzer (Revised August 2004) under the section "12.1 Maintenance Schedule" revealed: "...Monthly Clean the sampler right rack pool, left rack pool, analysis line, and sample rack." 2. A review of the laboratory's Sysmex XT-1800i hematology maintenance records from February 2021 to July 2021 revealed the laboratory failed to have documentation of performing the required maintenance for 6 of 6 months. They were: February 2021 March 2021 April 2021 May 2021 June 2021 July 2021 3. The laboratory was asked to provide documentation of performing the monthly maintenance. No documentation was provided. 4. An interview with the general supervisor on 08/26/2021 at 1350 hours in his office -after his review of the records- confirmed the findings. B) Beckman Coulter Access 2 1. A review of the manufacturer's instructions for the Beckman Coulter Access 2 analyzer (C30219, 2018 Beckman Coulter, Inc.) revealed the following maintenance was required: a) Daily Check Zone Temperatures Check System Supplies Empty Liquid Waste Bottle System Backup Successful Inspect Fluidic Module Clean Probe Exteriors Prime Substrate Run Daily Clean System Perform Special Clean (if necessary) b) Weekly Clean Instrument Exterior Inspect Liquid Waste Bottle Check Waste Filter Bottle Inspect/Clean Primary Probe Replace /Clean Aspirate Probes Run System Check 2. A review of the laboratory's Beckman Coulter Access 2 maintenance records from February 2021 to July 2021 revealed the laboratory failed to have documentation of performing the required maintenance on the following days: a) serial number: 872386 April 1, 2021 April 2, 2021 April 24, 2021 April 25, 2021 April 27, 2021 June 2, 2021 July 1, 2021 July 2, 2021 Weekly April 24, 2021 b) serial number: 872387 February 5, 2021 July 1, 2021 July 2, 2021 July 15, 2021 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the general supervisor on 08/27/2021 at 0945 hours in the laboratory -after his review of the records- confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's calibration verification records, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification every six months for analytes requiring it on the Beckman Coulter DxC 700 AU analyzers. The findings include: 1. A review of the laboratory's instrumentation revealed the following analytes tested on each of the laboratory's Beckman Coulter DxC 700 AU analyzer which required calibration verification (less than 3 calibrators and less than 3 quality control levels tested twice daily): Albumin Alkaline Phosphatase Alanine Aminotransferase Ammonia Amylase Aspartate Aminotransferase Blood Urea Nitrogen Cholesterol Creatine Kinase Direct Bilirubin Gamma-Glutamyl Transferase Glucose High density lipoprotein Lactate Lipase Magnesium Phosphorus Total Bilirubin Total Protein Triglyceride Urine creatinine Urine Total Protein Uric Acid 2. A review of the laboratory's calibration records from 2020 and 2021 revealed the laboratory failed to have documentation of performing required calibration verifications on the following analytes: a) serial number 2020051466 (in use August 2020) ammonia lactate b) serial number 2020021341 (in use January 2021) Albumin Alkaline Phosphatase Alanine Aminotransferase Ammonia Amylase Aspartate Aminotransferase Blood Urea Nitrogen Cholesterol Creatine Kinase Direct Bilirubin Gamma-Glutamyl Transferase Glucose High density lipoprotein Lactate Lipase Magnesium Phosphorus Total Bilirubin Total Protein Triglyceride Urine creatinine Urine Total Protein Uric Acid 3. The laboratory was asked to provide documentation of performing the missing calibration verifications. No documentation was provided. 4. An interview with the general supervisor on 08/25/2021 at 1500 hours in the laboratory - after his review of the records- confirmed the findings.
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 manufacturer's instructions, quality control records, and confirmed in interview of facility personnel, the laboratory failed to have a mechanism in place to monitor quality control over time for the Siemens epoc Blood Gas analyzer for 2 of 2 lot numbers reviewed from May 1, 2021 to July 31, 2021. The findings included: Note: This is a repeat deficiency from follow up survey conducted 01/18-20/2021. 1. Review of quality of control records from May 1, 2021 to July 31, 2021 found no documentation of QC review over time. Lot numbers reviewed were: B038 B040 2. Interview with the Technical Consultant on August 24, 2021 at 15:00 hours in the break room confirmed the findings. He revealed that he would review the daily quality control monthly to make sure qc was being done daily and every 8 hours of testing, but was not monitoring it for shifts and trends or analytical issues over

	time. Key: QC - quality control 31968 II. Based on review of the laboratory's quality control records, review of the laboratory's test menu, and staff interview, it was revealed the laboratory failed to have documentation of monitoring controls over time to detect problems for 54 of 54 analytes. The findings include: 1. A review of the laboratory's test menu for testing performed on the Beckman Coulter DxC 700 AU chemistry analyzers revealed the following 42 analytes were tested on each of the two analyzers: Acetaminophen Hemoglobin A1c Albumin Alkaline Phosphatase Alanine Aminotransferase Ammonia Amylase Aspartate Aminotransferase Blood Urea Nitrogen Calcium Carbamazepine Cholesterol Creatine Kinase Chloride CO2 Creatinine C-Reactive protein Direct Bilirubin Digoxin Ethanol Gentamicin Gamma-Glutamyl Transferase Glucose High density lipoprotein Potassium Lactate Lactate dehydrogenase Lipase Magnesium Sodium Phenobarbital Phenytoin Phosphorus Salicylate Total Bilirubin Total Protein Triglyceride Urine creatinine Urine Total Protein Uric Acid Valproic Acid Vancomycin Instrument #1 (serial number 2020051466) was placed into use in August 2020 Instrument #2 (serial number 2020021341) was placed into use in January 2021 2. A review of the laboratory's test menu for testing performed on the Beckman Coulter Access 2 chemistry analyzers revealed the following 12 analytes were tested on each of the two analyzers: Creatine Kinase - muscle/brain Free Thyroxine Human Chorionic Gonadotropin Myoglobin T Uptake Troponin Thyroid Stimulating Hormone Prostate-specific antigen Parathyroid Testosterone Vitamin D Instrument #1 (serial number 572386) was placed into use in August 2020 Instrument #2 (serial number 572387) was placed into use in August 2020 3. A review of the laboratory's quality control records from August 2020 to July 2021 revealed the facility failed to have documentation of monitoring control values over time to detect errors and problems. 4. The laboratory was asked to provide documentation of monitoring control values over time. No documentation was provided. 5. An interview with the general supervisor on 08/27/2021 at 835 hours in the laboratory confirmed the findings.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on random review of laboratory's quality control (QC) records for rapid plasma regain (RPR)- a screening test for syphilis- for February, April and May of 2021, review of patient records for the same period, review of Becton Dickinson (BD) Macro-Vue RPR Card Test Kit manufacturer's package insert and interview with facility personnel, it was determined the laboratory failed to provide documentation of performing quality control on each day of testing for 4 of 50 days testing was performed. The findings were: 1. Random review of laboratory's QC records for RPR for February, April and May of 2021 it was revealed the laboratory failed to document QC on the following days: 02/12/2021 04/08/2021 05/03/2021 05/27/2021 2. Review of patient RPR testing records for February, April and May of 2021 revealed patient testing was performed on days QC was not documented as follows: 02/12/2021 Samples with Results: 10202987 - Non-Reactive (NR) 10202999 - NR 04/08/2021

	Samples with Results: 10206400 - NR 10206397 - NR 05/03/2021 Samples with Results: 10207896 - NR 05/27/2021 Samples with Results: 10209495 - NR 10209492 - NR 3. Review of BD Macro-Vue RPR Card Test Kit manufacturer's package insert revealed: "User Quality Control: Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." 4. In an interview on 08/25/2021 at 1105 hours in the break room the Technical Consultant (as documented on Form 209, signed by the laboratory director on 08/23/2021) stated that the RPR QC is performed each day of patient testing and should have been documented. This confirmed the 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: Based on review of laboratory policies, quality control records, and confirmed in interview of facility personnel, the laboratory failed to have a mechanism in place to verify new lot numbers of quality control for 2 of 2 lot numbers reviewed from July 1, 2021 to August 26, 2021 for quality control testing on the laboratory's two EPOC blood gas analyzers (Serial Number 18318 and Serial Number 18319). The findings included: Note: This is a repeat deficiency from the survey conducted 01/18-20/2021. 1. Review of the laboratory's policy titled, "New QC Verification" approved by the laboratory director (no approval date), it stated, "The laboratory will verify the QC material upon arrival. Each level of QC material will be run a total of, but no less than 10 repetitions per reporting instrument to validate the manufacturers [sic] assayed quality control ranges." 2. Review of laboratory records for lot numbers B038 found that controls were ran 19 times on both analyzers. However, only raw data was available for review. The raw data was not evaluated. The control was put into use in July 2021. 3. Review of laboratory records for lot numbers B040 found that controls were ran 19 times on both analyzers. However, only raw data was available for review. The raw data was not evaluated. The control was put into use in July 2021. 4. Interview with the Respiratory Therapy Manager on August 24, 2021 at 15:00 hours in his confirmed the findings. He confirmed that he had not had a chance to send the Technical Consultant the raw data for evaluation. Key: QC - quality control
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)

	(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on random review of the laboratory's media Quality Control (QC) records from January to June of 2021, review of the laboratory's Individualized Quality Control Plans (IQCPs) studies for 2019, 2020 and 2021, review of the laboratory's Bacteriology QC policies and procedures and interview with the staff it was determined the laboratory failed to check each new batch/lot of media for its ability to support growth and specific organism's selectivity for 12 of 12 media shipments reviewed. The findings were: 1. Review of the laboratory's media QC records from January to June of 2021 revealed the laboratory did not have documentation of checking each new batch of media for its ability to support growth and specific organism selectivity before or concurrent with initial use. The following media was received in the laboratory: Blood Agar - Received on 01/22/2021 Lot: 206103; Exp. 2021/02/24 Salmonella-Shigella Agar - Received on 01/22/2021 Lot: 212470; Exp. 2021/03/10 XLD Agar - Received on 01/22/2021 Lot: 215665; Exp. 2021/03/16 MacConkey Agar w/ Sorbitol- Received on 01/28/2021 Lot: 215663; Exp. 2021/03/16 MacConkey Agar - Received on 03/19/2021 Lot: 251761; Exp. 2021/05/10 Chocolate Agar - Received on 03/19/2021 Lot: 259406; Exp. 2021/05/25 Blood Agar - Received on 03/19/2021 Lot: 253073; Exp. 2021/05/07 Blood Agar - Received on 04/16/2021 Lot: 268288; Exp. 2021/06/03 MacConkey Agar - signed off on 04/16/2021 Lot: 268310; Exp. 2021/06/09 Blood Agar - Received on 05/26/2021 Lot: 290527; Exp. 2021/07/12 MacConkey Agar - Received on 05/26/2021 Lot: 282692; Exp. 2021/07 /05 Chocolate Agar - Received on 05/26/2021 Lot: 286716; Exp. 2021/07/13 2. Review of the laboratory's records revealed the laboratory did not develop IQCP for media. Therefore, each new batch/lot of media must be checked for its ability to support growth and specific organism's selectivity. 3. Review of the laboratory's Bacteriology QC policies and procedures revealed the policies and procedures did not address checking each new batch of media for its ability to support growth and specific organism selectivity. 4. In an interview on 08/24/2021 at 1000 hours in the laboratory the Testing Person #1 (as documented on CMS Form 209, signed by the laboratory director on 08/23/2021) stated that the laboratory did not develop IQCP for media. This confirmed the 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: Based on review of the manufacturer's instructions for the Streck ESR-Chex Plus controls, review of the laboratory's Sedimentation Rate quality control values from April 1, 2021 to August 26, 2021, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure quality control values were acceptable

	prior to reporting patient results. The findings include: 1. A review of the manufacturer's instructions for the Streck ESR-Chex Plus controls revealed the manufacturer had established the following acceptable ranges for the control material: Lot: 635 Normal control: 1 - 13 Abnormal control: 43 - 85 2. A review of the laboratory's Sedimentation Rate quality control records from April 1, 2021 to August 26, 2021 identified the following 2 of 148 days where the documented quality control result was outside the manufacturer's acceptable range: a) April 25, 2021 Normal control value: 14 b) May 26, 2021 Normal control value: 14 c) May 27, 2021 Normal control value: 14 d) May 29, 2021 Normal control value: 14 e) June 24, 2021 Normal control value: 14 f) August 1, 2021 Normal control value: 14 g) August 10, 2021 Normal control value: 14 3. A review of patient test records from April 1, 2021 to August 26, 2021 identified the following 7 of 148 patients whose samples were tested and reported on days of failed quality control: a) May 27, 2021 patient ID: 47239 b) August 10, 2021 patient ID: 71152 4. The laboratory was asked to provide documentation of acceptable control values prior to reporting the identified patient results. No documentation was provided. 5. A interview with the general supervisor on 08/26/2021 at 1328 hours in his office revealed the laboratory did not evaluate the controls for acceptability using the manufacturer's ranges or using ranges the laboratory had established. He stated the manufacturer's ranges were the ranges which should be used to evaluate the acceptability of the controls. This confirmed the findings.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on random review of the laboratory's weekly Quality Control (QC) for Antimicrobial Susceptibility Testing (AST) of Thermo Scientific Sensititre GN4F (for Gram negative microorganisms) and GPALL3F (for Gram positive microorganisms) panels, review of manufacturer package inserts for Sensititre AST panels, review of patient test reports for August 2021 and interview with the staff it was determined the laboratory failed to use all the appropriate control organism strains to check fully the test system's reactivity for specific resistance and/or inducibility of resistance (D Test) for 16 of 16 QC records reviewed. The findings were: 1. Random review of the laboratory's QC for AST revealed the laboratory was using the following strains of organisms to run QC on the Sensititre AST panels: GN4F Panel: Escherichia coli ATCC 25922 Escherichia coli ATCC 35218 Pseudomonas aeruginosa ATCC 27853 GPALL3F Panel: Staphylococcus aureus ATCC 29213 Enterococcus faecalis ATCC 29212 2. Review of the package inserts for the AST GN4F and GPALL3F Sensititre panels revealed the following additional strains of organisms are required to verify the system's reactivity of resistance and/or inducibility of resistance: GN4F Panel: Klebsiella pneumoniae ATCC 7000603 for Piperacillin/Tazobactam GPALL3F Panel: Staphylococcus aureus ATCC BAA 976 for D Test 1 and 2, and Cefoxitin screen

	Staphylococcus aureus ATCC BAA 977 for D Test 1 and 2 Enterococcus faecalis ATCC 51299 for Gentamycin and Streptomycin Note: D test 1 and 2, and Cefoxitin screen are used for determination of Clindamycin inducibility of resistance. 3. Review of laboratory's patient test results for August 2021 revealed that Piperacillin /Tazobactam, D test 1 and D test 2, and Cefoxitin screen are reported. The following is a sampling of the patient tests with those AST results: 10214297 - Pipera/Tazob = S 10214298 - Pipera/Tazob = S 10214525 - Pipera/Tazob = S 10214479 - Pipera/Tazob = S 10214499 - Pipera/Tazob = S 10214684 - Pipera/Tazob = S 10214927 - Pipera /Tazob = S 10214980 - Pipera/Tazob = I 10214984 - Pipera/Tazob = I 10215105 - Pipera/Tazob = S 10214267 - DTEST1=S; DTEST2 =S; FOXSCR=N 10215258 - DTEST1=S; DTEST2 =S; FOXSCR=R 10214326 - DTEST1=R; DTEST2 =R; FOXSCR=N 4. In an interview on 08/24/2021 at 1030 hours in the break room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/23/2021) stated that the laboratory does not perform QC on the additional microbial strains, and that he was not aware that it was required. This confirmed the findings. Key: DTEST1 = D Test 1 DTEST2 = D Test 2 FOXSCR = Cefoxitin screen Pipera/Tazob = Piperacillin/Tazobactam S = Susceptible I = Intermediate R = Resistant N = No interpretation for this antibiotic/organism combination QC - quality control ATCC = American Type Culture Collection
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 patient transfusion records for June to August of 2021, review of the facility's governing body policies for Patient Care Services, review of the laboratory's policies and procedures and interview with the staff, it was determined the laboratory failed to have policies in place to address investigation of potential transfusion reactions. The findings were: 1. Review of the laboratory's patient transfusion records found the laboratory performed transfusion reaction workups on the following patients: Patient 10214654 Transfusion reaction report on 08 /14/2021 Patient 10211502 Transfusion reaction report on 06/28/2021 2. Review of the facility's Patient Care Services' BLOOD/BLOOD COMPONENTS-TRANSUSION REACTIONS policy signed off by the members of the facility's governing body on 06/15/2021 revealed: a. "The registered nurse will complete the patient information portion of the transfusion reaction form and return it to the Blood bank along with blood component bag, the attached transfusion set and IV solutions when possible." And, "The Clinical Laboratory will perform "Partial Transfusion Reaction" work-up." b. This policy was not approved by the laboratory director. 3. Review of the laboratory's policies revealed there was no written policy/procedure in place for addressing investigation of potential transfusion reactions. 4. In an interview

	on 08/26/2021 at 0840 hours in the break room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/23/2021) stated that the laboratory performs a work-up and consults the laboratory director but does not have a written policy to address potential transfusion reactions. This confirmed the findings
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's policies, review of the laboratory's instrumentation and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual instrument comparisons in 2019 and 2020. The findings include: 1. A review of the laboratory's policy titled "Quality Assurance & Assessment Management Policy" (effective date: 08/10/2018) under the section titled "Comparison of Test Results" revealed: "If laboratory testing is performed using varying methodologies or instruments, then comparisons must be run twice a year to define the relationship between methods." 2. A review of the laboratory's instrumentation revealed the laboratory utilized 2 Beckman Coulter Access 2 analyzers which were placed into use in August 2020. Both instruments tested the following 12 analytes: Creatine Kinase - muscle/brain Free Thyroxine Human Chorionic Gonadotropin Myoglobin T Uptake Troponin Thyroid Stimulating Hormone Prostate-specific antigen Parathyroid Testosterone Vitamin D Thus, two instrument comparisons were required to have been performed. 3. The laboratory was asked to provide documentation of the instrument comparisons being performed. No documentation was provided. 4. An interview with the general supervisor on 08/27 /2021 at 0940 hours in the laboratory revealed instrument comparisons had not been performed. This confirmed the 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 the laboratory's blood products' freezer temperature charts for 2019, 2020 and 2021, review of the laboratory's policies and interview with the staff it

	was determined the laboratory failed to have documentation of performing corrective actions for 16 of 16 weeks when the Blood Bank freezer's continual monitoring system showed failures. The findings were: 1. Review of the laboratory's blood products' freezer temperature charts for 2019, 2020 and 2021 revealed freezer temperature recorder inconsistencies. A sampling of the findings included: a) Weekly chart starting on 02/24/2019 has stopped advancing after approximately 46 hours of recording. The rest of the chart was blank. No corrective action was documented. b) Weekly chart starting on 11/28/19 stopped recording after 6 days. No corrective action was documented. c) Weekly chart starting on 10/4/2020 showed a changed pattern of temperature oscillation, ranging from -26C to -32C, and increasing to -16C every 8 hours. This pattern continued until 01/08/2021 when it changed to its previous pattern with oscillation of -26C to -28C and every 8 hours increase in temperature to -24C. No corrective action was documented for any of the weekly charts from October 2020 to January 2021. 2. Review of the laboratory's Bood Bank; Freezer Preventive Maintenance policy signed into effect on 6/29/2018 under part III. PROCEDURE revealed: "Observe the chart recorder to determine that: a) It is on the proper day and time b) The chart is moving and the pen is tracking on the chart paper c) The temperature has monitored consistent and within acceptable limits and the tracing pattern has not changed" And, "Bring any problems or deviations to the attention of the Quality Specialist immediately." 3. In an interview on 08/26/2021 at 11:30 hours in the break room the Technical Consultant (as documented on CMS Form 209, signed by the laboratory director on 08/23/2021) confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on surveyor direct observation, review of manufacturer's instructions, review of laboratory environmental records, and confirmed in interview of facility personnel, revealed the laboratory failed to have documentation of performing corrective actions when the recorded refrigeration temperatures were outside the laboratory's established acceptable range for 8 of 55 days from July 1, 2021 to August 24, 2021. The findings included: Note: This is a repeat deficiency from the survey conducted 01/18-20/2021. 1. Direct observation by the surveyor on August 25, 2021 at 13:30 hours in the Respiratory Therapy Department refrigerator found the following random review of Eurotrol epoc GAS-ISE quality control materials: Level 1 Lot 266-1-B038 2 boxes (unopened) Level 3 Lot 266-3-B040 2 boxes (unopened) 2. Review of the manufacturer's instructions for Eurotrol blood gas controls stored in the refrigerator in the Respiratory Therapy Department stated, "Storage: Eurotrol epoc GAS-ISE Metabolites can be used until the expiry date as indicated on the labels on the ampules and outer box, if stored unopened a temperature of 2 to 8 degrees Celsius (35-46 degrees Fahrenheit) ..." 3. Review of the laboratory's refrigeration records from July 1, 2021 to August 24, 2021 found the laboratory documented an acceptable temperature range from 2 to 8 degrees Celsius. The laboratory documented temperatures out of range or did not document a temperature for the following 8 of 55 days from July 1, 2021 to August 24, 2021: July 20, 2021 1.5 degree Celsius July 29, 2021 no documentation August 8, 2021 1.1 degrees Celsius August 11, 2021 1.8 degrees Celsius August 12, 2021 no documentation August 18, 2021 1.5 degrees Celsius

	August 20, 2021 1.0 degrees Celsius August 22, 2021 no documentation 4. The laboratory was asked to provide documentation of performing corrective action when the temperatures were documented out of range or when no temperature was documented. No corrective action documentation was provided. 5. Interview with the Technical Consultant on August 25, 2021 at 15:30 hours in the break room confirmed the findings. He was not aware of the out of range and missing temperatures.
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 surveyor observation, review of laboratory policies, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of a written policy and procedure for an ongoing mechanism to monitor, assess, and correct when the blood bank refrigerator alarm was activated and hospital staff did not know procedures to follow for 1 of 1 alarm checks performed on August 26, 2021 (the date of the survey). The findings included: Note: The blood bank alarm for the facility is located at the nurse's station on the patient Medical/Surgery Unit. 1. Surveyor observation made on August 26, 2021 at 10:20 hours found the following blood products (PRBCs) stored in the Blood Bank refrigerator: O Positive: Unit # W1409 21 015983 Unit # W1409 21 079847 Unit # W1409 21 080033 Unit # W1409 21 079729 Unit # W1409 21 080041 Unit # W1409 21 079735 Unit # W1409 21 076087 A Positive: Unit # W1409 21 058418 Unit # W1409 21 056926 Unit # W1409 21 079826 Unit # W1409 21 078835 Unit # W0533 21 702081 Unit # W1409 21 016155 B Positive: Unit # W1409 21 075946 Unit # W1409 21 080391 Unit # W1409 21 078173 Unit # W1409 21 082829 AB Positive: Unit # W1409 21 004298 Unit # W1409 21 057070 A Negative: Unit # W1409 21 074191 Unit # W1409 21 080011 B Negative: Unit # W1409 21 079089 Unit # W1409 21 058461 At 10:29 hours the surveyor activated the blood bank refrigerator alarm and proceeded to the Medical /Surgery Unit where the alarm is set to go off. Beginning temperature was 3.4 degrees Celsius. At 10:35 hours the alarm activated. The temperatures was 6.1 degrees Celsius. At 10:35 hours on the Medical/Surgery Unit the Unit Secretary looked around to determine source of alarm. A nurse walked over to inquire about the alarm and asked what is was for and the unit secretary said, "I think it is for the blood." The nurse turned off the alarm and both walked away. No call was made to the laboratory. No call was made to the laboratory by 10:37 hours No call was made to the laboratory by 10:45 hours At 10:46 hours the surveyor asked the Unit Secretary what the alarm was for and what did they do when it goes off. She revealed that she thought it was for the blood in the laboratory. She went on to say since the nurse turned the alarm off, she assumed she had taken care of it. At 10:47 hours a call was made to the laboratory that the blood bank alarm had went off. 2. Review of laboratory policies revealed the laboratory did not have a policy for alarm checks for refrigerated blood products. a. There was no policy available for review to determine the frequency of performing audible alarm checks. b. There was no policy available for review to determine staff procedures once the alarm is activated. 3. An interview with the technical consultant on August 26, 2021 at 17:30 hours in his office confirmed he could not locate the policy for blood bank alarm checks. Key: PRBCs - packed red blood cells

D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient final reports, and confirmed in interview of facility personnel, revealed the laboratory failed to provide patient normal ranges for 2 of 3 sample types for blood gas analysis. The findings included: Note: This is a repeat deficiency from the survey conducted 01/18-20/2021. 1. Review of laboratory records from June, July, and August 2021 found the laboratory performs blood gas testing on the following sample types: Arterial Venous Cord Blood (venous and arterial) a. The laboratory's defined patient normal ranges for arterial blood gas results are as follows: pH 7.34 - 7.46 PCO2 35.0 - 45.0 PO2 77.0 - 97.0 HCO3 20.0 - 28.0 Base excess -0.3 - 3.0 O2 Saturation 95 - 98 2. Random review of patient reports from June, July, and August 2021 revealed all samples types were performed under the order for an arterial blood gas. The following patient samples were resulted with patient normal ranges for Arterial Blood Gas when a different sample type was tested: Order # 22077 Result date: 06-05-2021 Sample Type: Venous Order # 22968 Result date: 07-24-2021 Sample Type: Cord (venous) Order # 23505 Result date: 08-09-2021 Sample Type: Cord (venous) Order # 23609 Result date: 08-10-2021 Sample Type: Cord (arterial) Order # 23838 Result date: 08-16-2021 Sample Type: Cord (venous) 3. The laboratory was asked to provide documentation of providing patient normal ranges for the 2 additional patient sample types (venous and cord blood) tested. No documentation was provided. 4. An interview with the Technical Consultant on August 25, 2021 at 16:15 hours in his office confirmed the findings. He provided the studies for the additional sample types. However, when he pulled patient records in the CPSI system, he discovered that the incorrect test was ordered. He explained if a VBG (venous blood gas) was ordered and performed, it would pull up the correct patient normal ranges. Key: pH - measure of acid or base pO2 - partial pressure of oxygen pCO2 - partial pressure carbon dioxide HCO3 - bicarbonate O2 - oxygen CPSI - the laboratory's information system
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: Follow-up survey conducted 08/23-27/2021 CONDITION level deficiency remains uncorrected Based on surveyor observations, review of laboratory policies, manufacturer's instructions, review of quality control records, review of environmental records, patient reports, and confirmed in interview of facility personnel, the laboratory director failed to provided overall management and direction of the laboratory as evidenced by: Note: This is a repeat deficiency from the unannounced follow up survey conducted 01/18-20/2021. 1. The laboratory director failed to ensure verification studies were complete prior to patient testing (refer to

	D6013). 2. The laboratory director failed to ensure a quality control (QC) plan is established and maintained (refer to D6020). 3. The laboratory director failed to ensure there was a written policy for performance of blood bank alarm checks (refer to D6021). 4. The laboratory director failed to ensure patient reports included information necessary for interpretation (refer to D6026). 5. The laboratory director failed to ensure testing personnel had documentation of training prior to performing patient testing (refer to D6029). 6. The laboratory director failed to ensure approved procedure manuals are available to testing personnel (refer to D6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete (refer to D5421). Note: This is a repeat deficiency from the unannounced follow up survey conducted 01/18-20/2021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview it was revealed the laboratory director failed to ensure the facility's quality control program was developed and followed to provide quality services. Note: This is a repeat deficiency from the unannounced follow up survey conducted 01/18-20/2021. The findings include: 1. The laboratory director failed to ensure control values were monitored over time (refer to D5441). 2. The laboratory director failed to ensure control values were acceptable prior to patient results being reported (refer to D5481).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policies, review of laboratory records, and confirmed in interview of facility personnel, the laboratory director failed to ensure a quality assurance plan is established and maintained (refer to D5791).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient results, and confirmed in interview of facility personnel, the laboratory director failed to include pertinent information needed for interpretation (refer to D5807). Note: This is a repeat deficiency from the unannounced follow up survey conducted 01/18-20/2021.
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 of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure testing personnel had documentation of training prior to performing patient testing (refer to D6066).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies, and confirmed in interview of facility personnel, the laboratory director failed to ensure a procedure manuals are available to all testing personnel. The findings were: Note: This is a repeat deficiency from the survey conducted January 18-20, 2021 1. The following procedure manuals were unsigned by the current laboratory director: General Laboratory Microbiology 2. Interview with the Technical Consultant on August, 26, 2021 at 17:30 hours in his confirmed the findings. He confirmed that the laboratory is still working on getting policy and procedure manuals updated.
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 surveyor observations, review of laboratory records, and confirmed in interview of facility personnel, the technical consultant failed to provide technical oversight of the laboratory (refer to D6040, D6042, D6054, and D6055). Note: This is a repeat deficiency from the survey conducted January 18-20, 2021
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 the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure verification studies were complete (refer to D5421). The findings were: Note: This is a repeat deficiency from the survey conducted January 18-20, 2021
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 the laboratory's records and staff interview it was revealed the

	technical consultant failed to ensure the facility's quality control program was developed and followed to provide quality services. The findings were: Note: This is a repeat deficiency from the survey conducted January 18-20, 2021 1. The technical consultant failed to ensure control values were monitored over time (refer to D5441). 2. The technical consultant failed to ensure control values were acceptable prior to patient results being reported (refer to D5481).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments annually in 2019 and 2020 for 9 of 9 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 9 testing personnel. 2. A review of the laboratory's personnel records revealed each of the 9 testing personnel required annual competency assessments in 2019 and 2020. 3. The laboratory was asked to provide documentation of the competency assessments. No documentation was provided. 4. An interview with the general supervisor on 08/23/2021 at 1600 hours in his office revealed that competency assessment had not been performed in 2019 and 2020. This confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant assessing the competency of testing personnel after instrumentation changes and prior to them reporting patient results. The findings include: 1. A review of the laboratory's instrumentation changes in 2019, 2020, and 2021 revealed the laboratory placed the following new instruments into use: a) Desse Mini-Cube Sedimentation analyzer serial number 1308 placed in use: November 2019 b) Beckman Coulter DxC 700 AU analyzer serial number 2020021341 placed in use: August 2020 c) Beckman Coulter DxC 700 AU analyzer serial number 2020051466 placed in use: August 2020 d) Beckman Coulter Access 2 analyzer serial number 572386 placed in use: August 2020 e) Beckman Coulter Access 2 analyzer serial number 572387 placed in use: August 2020 2. The laboratory was asked to provide documentation of the technical consultant assessing the

	competency of nine testing personnel who performed testing on these analyzers prior to patient results being reported. No documentation was provided. 3. An interview with the general supervisor on 08/26/2021 at 1030 hours in his office revealed competency assessments for the new instrumentation had not been performed. This confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of training for 6 of 6 testing personnel who performed testing in the core laboratory. The findings include: 1. A review of the laboratory's instrumentation changes in 2019, 2020, and 2021 revealed the laboratory placed the following new instruments into use: a) Desse Mini-Cube Sedimentation analyzer serial number 1308 placed in use: November 2019 b) Beckman Coulter DxC 700 AU analyzer serial number 2020021341 placed in use: August 2020 c) Beckman Coulter DxC 700 AU analyzer serial number 2020051466 placed in use: August 2020 d) Beckman Coulter Access 2 analyzer serial number 572386 placed in use: August 2020 e) Beckman Coulter Access 2 analyzer serial number 572387 placed in use: August 2020 2. The laboratory was asked to provide documentation of training of 6 testing personnel who performed testing on these analyzers. No documentation was provided. 3. An interview with the general supervisor on 08/26/2021 at 1030 hours in his office revealed training was not documented. This confirmed the findings.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations that included a policy to ensure transfusion reactions were promptly identified and investigated (refer to D5559).
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)

	The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure testing personnel are performing tests as required (refer to D5411). The findings were: Note: This is a repeat deficiency from the survey conducted January 18-20, 2021
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments annually in 2019 and 2020 for 6 of 6 testing personnel who performed high complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 9 testing personnel. 2. A review of the laboratory's personnel records revealed each of the 6 of the 9 testing personnel required annual competency assessments in 2019 and 2020 for high complexity testing. 3. The laboratory was asked to provide documentation of the competency assessments. No documentation was provided. 4. An interview with the general supervisor on 08/23/2021 at 1600 hours in his office revealed that competency assessment had not been performed in 2019 and 2020. This confirmed the findings.