Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2181340	04/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ut Health Rgv Clinical Laboratory	1214 W Schunior Street, Edinburg, 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	Based on an announced validation inspection from 4/02/2024 to 04/03/2024, the laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5300 - 42 C.F.R. 493.1240 Condition: Pre-analytic systems
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologist's (CAP) proficiency testing (PT) records from 2023 and 2024, review of the laboratory's personnel records, review of the laboratory policy and confirmed in interview, the laboratory failed to ensure that proficiency testing was performed by all personnel who routinely performed testing for 16 of 24 testing events reviewed. The findings were: 1. A review of the laboratory's College of American Pathologist's proficiency testing records from 2022 and 2023 revealed testing personnel number one as listed on Form CMS 209 performed the analysis of proficiency testing samples for 16 of 24 testing events reviewed. The events documented as performed by testing personnel number one were: CB-2023 General Chemistry/Therapeutic Drugs G-G 2023 Syphilis Serology S-B 2023 Diagnostic Immunology S2-B 2023 Special Immunology K-B 2023 Ligand - General U-B 2023 Urine Chemistry - General GH5-B 2023 HgA1C VM-B 2023 Viral Markers UDS-B 2023 Urine Drug Testing ESR1-A 2023 Erythrocyte Sed Rate Y-A 2023 Sex Hormones CGL-B 2023 Coagulation Limited FHG-B 2023 Hematology Auto Diff GH5-A 2023 HgA1C CM-B 2023 Clinical Microscopy VM-C 2023 Viral Markers 2. A review of the CMS209 revealed seven Testing personnel (TP). TP #1 (hire date 07/2022) TP #2 (hire date 02/2023) TP #3 (hire date (06/2023) TP #4 (hire date 06/2023) TP #5 (hire date 09/2023) TP #6 (hire

	date 09/2023) TP #7 (hire date 10/2023) 3. In review of the laboratory policy Proficiency Testing (SOP GEN.0020, effective 12/23/2020), it stated "survey specimens will be analyzed by the same primary method used for patient samples and by the personnel that routinely perform patient testing." It did not include that it would rotate surveys amongst testing personnel. 4. An interview with the administration liaison on 4/02/2024 at 1120 hours in the conference room confirmed the above 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 review of manufacturer's instructions, surveyor observation, review of patient test records and staff interview, the laboratory failed to meet the requirements for pre-analytic systems. The findings include: 1. The laboratory failed to ensure coagulation samples were transported to the facility at the temperature required by the manufacturer (refer to D5311 I.). 2. The laboratory failed to ensure thromboplastin samples were tested within 4 hours of collection (refer to D5311 II.). 3. The laboratory failed to have a mechanism in place to ensure chemistry samples were transported to the facility at the temperature required by the manufacturer (refer to D5311 III.).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on a review of the manufacturer's instructions for the Dade Innovin reagent, review of the Dade Actin FSL Activated PTT reagent, review of the laboratory's procedures for PT (prothrombin time) and PTT (partial thromboplastin time) testing, surveyor observation of patient samples received by the laboratory on 04/03/2024, and staff interview, the laboratory failed to ensure samples for coagulation testing were not transported to the facility at refrigerated temperatures. The findings include: 1. A review of the manufacturer's instructions for the Dade Innovin reagent (10873566GU11 Rev.03) under the section titled "Specimen Collection and Preparation" stated: "Do not store on ice or at 2 to 8C." 2. A review of the manufacturer's instructions for the Dade Actin FSL Activated PTT reagent (11541732 Rev.11) under the section titled "Storing the Specimen" stated: "Store in an unopened

tube at room temperature." And, "Do not store on ice." 3. A review of the laboratory's procedure titled "Prothrombin Time (PT) (Revised 08/31/2023) under the section titled "Handling conditions" stated: "The specimen should be transported at room temperature." And, "Specimens for PT assays can be maintained uncentrifuged or centrifuged with the plasma remaining on top of the cellular component in an unopened tube at room temperature for up to 24 hours." 4. A review of the laboratory's procedure titled "Activated Partial Thromboplastin Time (aPTT) (Revised: 8/31/2023) under the section titled "Handling conditions" stated: "The specimen should be transported at room temperature." And, "Cold temperatures are known to induce platelet aggregation and release platelet factor 4." 5. Surveyor observations on 04/03/2024 at 1415 hours in the laboratory revealed the laboratory received a coagulation sample 56306923 and part of a shipment of multiple samples. Surveyor observed the specimens were transported via a cooler with a minimum temperature of 1.57 C and maximum temperature of 12.88 C. An interview with the courier on 4/03/2024 at 1417 hours confirmed that he brought all specimens in a similar cooler with 2 ice packs daily. He placed them in their biohazard bags onto the cooler. 6. The laboratory reported performed the following number of coagulation tests in 2023: PT: 290 PTT: 219 7. Testing personnel number 5 and number 7 on 04/02 /2024 at 1430 hours in the processing area confirmed all samples were received by the laboratory inside a cooler with ice packs. They could not provide proof that the temperature of the coolers were acceptable for coagulation testing. II. Based on review of the manufacturer's instructions for the Dade Actin FSL Activated PTT reagent, review of the laboratory's procedures for PTT (partial thromboplastin time) testing, review of patient test records from November 2023 to January 2024, and staff interview, the laboratory failed to ensure PTT testing was performed within 4 hours of collection. The findings included: 1. A review of the manufacturer's instructions for the Dade Actin FSL Activated PTT reagent (11541732 Rev. 11) under the section titled "Storing the Specimen" stated: "Store at room temperature and test within 4 hours." 2. A review of the laboratory's procedure titled "Activated Partial Thromboplastin Time (aPTT) (Revised: 8/31/2023) under the section titled "Handling conditions" stated: "The whole blood specimen is checked for clot formation by gentle inversion and centrifuged and tested within 4 hours from the time of specimen collection." 3. A sampling of patient test results from November 2023 to January 2024 identified 16 of 23 samples where the time from collection to receipt by the laboratory exceeded 4 hours and thus, the samples were not tested within the required timeframe. They were: a) November 2023 Patient ID: 73326087 Date: 11/01 Collection time: 09: 06 am Received time: 01:22 pm Elapsed time: 4 hours 16 minutes Patient ID: 45254683 Date: 11/08 Collection time: 08:35 am Received time: 02:48 pm Elapsed time: 5 hours 53 minutes Patient ID: 515834067 Date: 11/08 Collection time: 02:59 pm Received time: 08:17 pm Elapsed time: 5 hours 18 minutes Patient ID: 1552681 Date: 11/16 Collection time: 11:45 am Received time: 07:10 pm Elapsed time: 7 hours 25 minutes Patient ID: 48051790 Date: 11/16 Collection time: 11:30 am Received time: 07:46 pm Elapsed time: 8 hours 16 minutes b) December 2023 Patient ID: 69443370 Date: 12/05 Collection time: 12:56 pm Received time: 07:17 pm Elapsed time: 6 hours 21 minutes Patient ID: 30306754 Date: 12/05 Collection time: 11:30 am Received time: 06:50 pm Elapsed time: 7 hours 20 minutes Patient ID: 30646053 Date: 12/06 Collection time: 11:11 am Received time: 06:35 pm Elapsed time: 7 hours 24 minutes Patient ID: 80445999 Date: 12/08 Collection time: 10:30 am Received time: 06:39 pm Elapsed time: 8 hours 9 minutes Patient ID: 86668067 Date: 12/13 Collection time: 12:31 pm Received time: 06:33 pm Elapsed time: 6 hours 2 minutes Patient ID: 8128086 Date: 12/14 Collection time: 01:45 pm Received time: 06:15 pm Elapsed time: 4 hours 30 minutes Patient ID: 50841581 Date: 12/20 Collection time: 08:48 am Received time: 01:55 pm Elapsed time: 5 hours 7 minutes

c) January 2024 Patient ID: 86131436 Date: 01/08 Collection time: 11:40 am Received time: 06:01 pm Elapsed time: 6 hours 21 minutes Patient ID: 24781257 Date: 001/09 Collection time: 09:30 am Received time: 01:39 pm Elapsed time: 4 hours 9 minutes Patient ID: 62749109 Date: 01/11 Collection time: 08:00 am Received time: 01:56 pm Elapsed time: 5 hours 56 minutes Patient ID: 26789740 Date: 01/16 Collection time: 10:25 am Received time: 06:34 pm Elapsed time: 8 hours 9 minutes 4. The laboratory director confirmed the findings in an interview conducted 04/04/2024 at 1400 hours in the conference room. 38387 III. Based on review of the manufacturer's instructions, laboratory policies, review of patient records, and confirmed in interview, the laboratory failed to establish and follow the preanalytic requirements for three of three testing observed: urinalysis, chemistry tests and cytology send out testing. A. Urinalysis B. Chemistry C. Cytology Findings included: A. Urinalysis 1. Review of Clinitek Novus Automated Urine Chemistry Analyzer Operator's Guide (11064810 Rev. B) under Testing the Patient Samples, it stated "With unpreserved samples, for the most accurate results, test within 2 hours of collection ...Allow the samples to reach room temperature if they were refrigerated." 2. Review of the laboratory policy Automated Urinalysis on Sysmex UN-Series (SOP Urine.0006, effective 09/01/2022) under Specimen Requirements, it stated, "uncentrifuged urine ...if analysis is not possible within one hour of collection, the urine may be refrigerated ...urine specimens that cannot be analyzed within an hour of collection or refrigerated must be transferred into a urinalysis preservative tube such as BD Vacutainer." 3. Surveyor observations on 04/03/2024 at 1415 hours in the laboratory revealed the laboratory received urine specimens unpreserved in various urine containers. Surveyor observed the specimens were transported via a cooler with a minimum temperature of 1.57 C and maximum temperature of 12.88 C. An interview with the courier on 4/03/2024 at 1417 hours confirmed that he brought all specimens in a similar cooler with 2 ice packs daily. He placed them in their biohazard bags onto the cooler. 4. Random review of urinalysis records from 04/03 /2024 confirmed the laboratory received and performed the following UA specimen received in an inappropriate temperature and beyond the two hours of collection. Patient Acc # 88278 collected 04/03/2024 at 0937 hours, received 1429 hours; elapsed time of 3 hours 52 minutes 5. In review of the laboratory records, the laboratory performed 289700 urinalysis testing annually. B. Chemistry Albumin 1. Review of the package insert for Dimension Albumin (Ref DF13, issue date 04/22/2019) under Specimen Collection and Handling it stated "specimens are stable for 8 hours at room temperature, 2 days at 2-8C. For longer storage, specimens may be frozen at -20 C or colder." 2. Review of the laboratory policy Dimension Albumin (SOP DIM.0001, effective 12/1/2022) under Specimen Requirements, it stated "specimens are stable for 8 hours at room temperature and for 2 days at 2 - 8 C." ALT 3. Review of the package insert for Dimension Alanine Aminotrasnsferase (Ref DF143, issue date 04/0/2019) under Specimen Collection and Handling it stated "separated samples are stable at 7 days refrigerated at 2-8 C. For longer storage, specimens may be frozen for 1 month at -20C or colder." 4. Review of the laboratory policy Dimension Alanine Aminotransferase (SOP Dim.0003, effective 12/01/2022) under Specimen Requirements, it stated "separated specimens are stable for 8 hours at room temperature and for 7 days at 2-8 C." ALP 5. Review of the package insert for Dimension Alkaline Phosphatase (Ref DF150, issue date 04/08/2019) under Specimen Collection and Handling, it stated "specimens are stable for 8 hours at room temperature, 7 days at 2-8 C and 6 months when frozen at -20 C or colder." 6. Review of the laboratory policy for Dimension Alkaline Phosphatase (SOP Dim.0002, effective date 12/01/2022) under specimen requirements, it stated "specimens are stable for 8 hours at room temperature, for 7 days at 2-8 C and for 6 months when frozen at -20 C." 7. Surveyor observations on 04/03/2024 at 1415 hours in the

	laboratory revealed the laboratory received the following chemistry specimens (Patient ID 75361017, 45680567, 32220127). Surveyor observed the specimens were transported via a cooler with a minimum temperature of 1.57 C and maximum temperature of 12.88 C. An interview with the courier on 4/03/2024 at 1417 hours confirmed that he brought all specimens in a similar cooler with 2 ice packs daily. He placed them in their biohazard bags onto the cooler. 8. Random review of laboratory records from 4/03/2024 confirmed the laboratory analyzed the following three specimens for ALB, ALT, ALP. Patient ID 75361017, 45680567, 32220127 C. Cytology 1. Review of the Instructions for Use for the Hologic PreservCyt Collection Medium (AW-23087-002 Rev.001, 03-2021) under Specimen Collection and Preparation, it stated "store PreservCyt Collection medium with gynecologic cytologic samples between 15 C and 30 C for up to 6 weeks." 2. Surveyor observations on 04/03 /2024 at 1415 hours in the laboratory revealed the laboratory received cytology specimens in PreservCyt Collection Medium. Surveyor observed the specimens were transported via a cooler with a minimum temperature of 1.57 C and maximum temperature of 12.88 C. An interview with the courier on 4/03/2024 at 1417 hours confirmed that he brought all specimens in a similar cooler with 2 ice packs daily. He placed them in their biohazard bags onto the cooler. 3. Random review of cytology records from 04/03/2024 confirmed the laboratory received and sent out the following cytology testing to a reference laboratory. Specimen ID DL249161M, DL249139M 4. In in interview with the laboratory director and liaison on 4/03/2024 at 1420 hours in the conference room confirmed the above findings. They acknowledged that the laboratory needed to monitor the temperature of the specimens and ensure they had a process in place to reject specimens not received in the correct temperature and/or within stability.
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 review of the laboratory client service manual and available policies, review of laboratory records, and confirmed in interview, the laboratory failed to provide documentation of specimen handling and transport for urinalysis, hematology, and chemistry testing. Findings included: 1. Review of the laboratory client service manual revealed no documentation of the required temperature for storage and transport for urinalysis, chemistry, and hematology testing. Cross refer to D5311 I, II-A, B. 2. An interview with the laboratory director on 04/03/2024 at 1320 hours in the conference room confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for performing platelet poor studies, review of the manufacturer's instructions for Dade Innovin reagent, review of laboratory's procedures for prothrombin testing, platelet poor studies from 2022 to 2024, and staff interview, the laboratory failed to ensure the studies were performed in the same manner as patient samples were processed. The findings included: 1. A review of the laboratory's procedure titled "Platelet Poor Plasma" (revised 8/30/2023) under the section titled "V. Procedure" determined: "Centrifuge for 10 minutes at 3200 rpm." 2. A review of the manufacturer's instructions for the Dade Innovin reagent (10873566GU11 Rev. 3) under the section titled "Specimen collection and preparation" determined: "Centrifuge the blood specimen at 1500 x g for no less than 15 minutes at room temperature." 3. A review of the laboratory's procedure titled "Prothrombin Time (PT)" (Revised:8/31/2023) under the section titled "Handling conditions" determined: "Centrifuge the capped specimen tube for a minimum of 15 minutes at 1500 g to consistently produce platelet poor plasma." 4. A review of the laboratory's platelet poor studies from 2022 to 2024 identified the laboratory processed study samples the following ways: a) 9/26/2022 Speed: no speed stated Time: 5 minutes b) No records for 2023 c) 3/27/2024 Speed: 3200 rpm Time: 10 minutes 5. Testing personnel number 5 (as listed on Form CMS 209) stated in an interview on 04/02/2024 at 1645 hours in the lab that prothrombin time samples were centrifuged at 3500 rpm for 15 minutes. 6. The laboratory reported performing 290 prothrombin time tests in 2023. 7. The Administration Liaison confirmed the findings on 04/03/2024 at 1430 hours in the conference room after her review of the records. She was unaware of the speed and time differences in the procedures and manufacturer's requirements. It was determined the laboratory's centrifuge could alternate between rpms and x g, but she was unable to state if 3500 rpm or 3200 rpm was equivalent to 1500 x g. Key rpm - revolutions per minute
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, patient records, and confirmed in interview, the laboratory failed to define how acceptability

	criteria for control materials would be determined and the corrective actions to take when quality control materials did not meet laboratory established acceptability criteria for all chemistry testing on the Dimension chemistry analyzer. The findings included: 1. In review of laboratory policies and procedures, the laboratory failed to define: (a) the process for establishing acceptability criteria for quality control materials (b) the process for documenting corrective actions taken when quality control results are outside of acceptable limits (c) the remedial process for assessing patient specimens back to the last acceptable quality control values when quality control results are outside of acceptable limits 2. Random review of chemistry quality control records from 2023 to 2024 revealed the following three corrective actions. 03 /08/2023 Albumin level 3 Biorad lot 45910, exp 03/31/2024 Result: 4.29 g/dL (acceptable range: 3.95 - 4.13 g/dL) corrective action: calibrate 01/07/2023 DBilirubin level 1, 3 Biorad lot 45910, exp 03/31/2024 Level 1 Result: 0.59 mg/dL (acceptable range: 0.15 - 0.25 mg/dL) Level 3 Result: 0.00 mg/dL (acceptable range: 1.78 - 1.98 mg/dL) corrective action: repeated level 1, level 3; inserted/edited data is not evaluated against QC rules. assay range dbi [dbilirubin] will repeat 09/18/2023 Vitamin B12 level 1, 3 Biorad 85320, exp 05/31/2024 Level 1 Result: 104 pg/mL (acceptable range: 215 - 265 pg/mL) Level 3 Result: 488 (acceptable range: 638 - 702 pg/mL) corrective action: L1 and L3 controls for VIT B12 still did not pass. Ran calibration; controls for level 1 and level 3 pass 3. Review of laboratory records revealed the laboratory performed 173,127 chemistry testing annually. 4. An interview with the laboratory liaison on 04/03/2024 at 1450 hours in the conference room confirmed the above findings. She acknowledged that they needed a step by step policy for quality control testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex CA-600 analyzer, review of the laboratory's procedures for establishing means and ranges for new lots of prothrombin and partial thromboplastin time quality control, review of the laboratory's quality control records from 2014, and staff interview, the laboratory failed to follow the manufacturer's instructions for verifying new lots of Prothrombin quality control material for 1 of 1 lots. The findings included: 1. A review of the manufacturer's instructions for the Sysmex CA-600 analyzer (Rev. 2.1, 2/6/2018) under the section titled "III. Quality Control" determined the manufacturer required the following: "A. Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols. B. Collect a minimum of 30 data points over multiple days and stability limits of control. C. Calculate the mean, 2 SD and 3 SD range. D. QC data for PTN and APTTN will be entered under QC Settings for PT and APTT when new reagent lot goes live for QC files to reflect the lot numbers in use." 2. A review of the laboratory's procedure "New Innovin Reagent Lot Validation" (Revised: 09/01/2023) under the section titled "Establishing the QC ranges" determined: "1. Run both levels of QC, Ci-TROL 1 and Ci-TROL 3 with the new lot of Innovin reagent during both shifts (AM QC and PM QC). 2. Collect a minimum of 20 points for each level, then calculate the 2 SD range using Microsoft Excel, EP Evaluator or any other

	appropriate software." 3. A review of the laboratory's procedure "New Actin Reagent Lot Validation" (Revised: 09/01/2023) under the section titled "Establishing the QC ranges" determined: "1. Run both levels of QC, Ci-TROL 1 and Ci-TROL 3 with the new lot of Actin reagent during both shifts (AM QC and PM QC). 2. Collect a minimum of 20 points for each level, then calculate the 2 SD range using Microsoft Excel, EP Evaluator or any other appropriate software." 4. A review of the laboratory's quality control records for new lots of Dade Ci-TROL controls (Lots: 564859 and 556563) from February 2024 determined the laboratory tested each level of quality control for each assay 19 times to establish the new mean and ranges. 5. The laboratory was asked to provide documentation of following the manufacturer's instructions. No documentation was provided. 6. The Administration liaison confirmed the findings in an interview conducted on 04/03/2024 at 1420 hours in the conference room. Key PTN - prothrombin time new lot PTTN - partial thromboplastin time new lot PT - prothrombin time PTT - partial thromboplastin QC - Quality Control SD - standard deviation
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of laboratory records from 2023 to 2024, and confirmed in interview, the laboratory failed to define correct temperature ranges for storage of chemistry quality control material per manufacturer's instructions for two of two Biorad quality control material observed. Findings included: 1. In review of the manufacturer's instructions for the Biorad controls under storage and stability, it stated "this product will be stable until the expiration date when stored unopened at -20 to -70 C." Biorad Liquichek Immunoassay Plus Control (level 85320, exp 5/31/2024) Biorad Liquichek Specialty Immunoassay Control (level 65000, exp 09/30/2026) 2. Surveyor observations on 04 /03/2024 at 0950 hours in the laboratory revealed the laboratory stored the following Biorad quality controls in Freezer #3: Biorad Liquichek Specialty Immunoassay Control lot 65003, exp 09/30/2026 Biorad Liquichek Immunoassay Control lot 85351, exp 02/28/2025 3. In review of the freezer temperature charts from 2023 to 2024 revealed the laboratory established the acceptable freezer temperature between -15 to -25 C. 4. Review of the laboratory records revealed the laboratory performed 173, 127 chemistry tests annually. 5. An interview with the laboratory liaison on 04/03/2024 at 1120 hours in the conference room confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's verification studies for D-dimer assay performed on the Sysmex CA-600, and staff interview, the laboratory failed to have documentation of verifying the reportable range. The findings include: 1. A review of the laboratory's verification studies performed in 2022 for the D-dimer assay performed on the Sysmex CA-600 analyzer determined the laboratory failed to have documentation of verifying the reportable range for the assay. 2. The laboratory was asked to provide documentation of performing the studies. No documentation was provided. 3. The laboratory reported performing 12 D-dimer tests in 2023. 4. The Administration Liaison confirmed the findings after the review of records in an interview conducted 04/02/2024 at 1440 hours in the conference room. II. Based on review of the laboratory's verification studies for Complete Blood Count (CBC) testing on the Sysmex XN-1000 hematology analyzer, review of patient test records, and staff interview, the laboratory failed to have documentation of verifying 2 of 2 patient normal ranges. The findings included: 1. A review of the laboratory's verification studies for CBC testing on the Sysmex XN-1000 hematology analyzer performed in 2023 determined the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of patient test records identified the following 2 patient normal ranges currently in use: a) Adults WBC 3.60 -10.60 RBC 3.80 - 5.20 HGB 12.0 - 15.0 HCT 35.0 - 39.0 MCV 80.0 - 100.0 MCH 26.0 -34.0 MCHC 32.0 - 36.0 RDW-CV 11.5 - 14.5 PLT 150 - 450 MPV 7.30 -12.0 Neutrophils% 50.0 - 70.0 Lymphocytes% 18.0 - 42.0 Monocytes% 2.0 - 11.0 Eosinophils% 1.0 -3.0 Basophils% 0.0 - 0.2 Neutrophils 1.70 -7.50 Lymphocytes 1.00 - 3.20 Monocytes 0.10 - 1.30 Eosinophils 0.00 - 0.30 Basophils 0.0 - 0.20 b) Pediatrics WBC 4.40 - 12.9 RBC 4.00 - 5.10 HGB 11.4 - 14.3 HCT 34.0 - 42.0 MCV 77.2 - 89.5 MCH 26.1 - 30.7 MCHC 32.4 - 34.9 RDW-CV 11.3 - 13.4 PLT 187 - 445 MPV 6.4 - 9.5 Neutrophils% 50.0 - 70.0 Lymphocytes% 18.0 - 42.0 Monocytes% 2.0 - 11.0 Eosinophils% 1.0 -3.0 Basophils% 0.0 - 0.2 Neutrophils 1.60 -7.80 Lymphocytes 1.60 - 5.30 Monocytes 0.30 - 0.90 Eosinophils 0.00 - 0.50 Basophils 0.0 - 0.10 3. The laboratory was asked to provide documentation of verifying the identified patient normal ranges. No documentation was provided. 4. The laboratory reported performing 5734 CBC tests in 2023. 5. The Laboratory Director confirmed the findings in an interview conducted on 04/02/2024 at 1500 hours in the conference room. Key WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW-CV - red cell distribution width PLT - platelet MPV - mean platelet volume
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 laboratory records from 2022 to 2024 and confirmed in interview, the laboratory failed to document two of two calibration verification for Sodium, Potassium, and Chloride testing on the Dimension chemistry analyzer in 2023. Findings included: 1. Review of the package insert for the Quiklyte Sodium, Potassium, and Chloride (Ref S600, issue date 07/19/2019), it stated that "the system performs a two point calibration in duplicate every 2 hours." 2. Review of laboratory records available revealed the laboratory performed two point calibrations and 2 levels of quality control daily for Sodium, Potassium, and Chloride; thus, requiring the calibration verification every 6 months. 3. Review of laboratory records available revealed no calibration verification for Sodium, Potassium, and Chloride for 2023. 4. An interview with the laboratory liaison on 04/03/2024 at 1640 hours in the conference room confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's hematology control records from September 2023 to January 2024, and staff interview, the laboratory failed to have documentation of verifying 3 of 3 lots of quality control material placed into use. The findings included: 1. A review of the laboratory's hematology quality control records for the Sysmex XP-1000 analyzer from September 2023 to January 2024 identified the following 3 lots of control placed into use: a) 3198 b) 3258 c) 3314 2. The laboratory

	was asked to provide documentation of verifying each of the lots prior to use. No documentation was provided. 3. The Administration Liaison confirmed the findings in an interview conducted 04/03/2024 at 1400 hours in the conference room. II. Based on review of the laboratory's sedimentation rate quality control records on the Sedimat 15 analyzer from May 2023 to October 2023, and staff interview, the laboratory failed to have documentation of verifying 3 of 3 lots of quality control material placed into use. The findings include: 1. A review of the laboratory's sedimentation rate quality control records from May 2023 to October 2023 identified the following 3 lots of control placed into use: a) 1150322 b) 1150422 c) 1150223 2. The laboratory was asked to provide documentation of verifying each of the lots prior to use. No documentation was provided. 3. The Laboratory Director confirmed the findings in an interview conducted 04/02/2024 at 1300 hours in the conference room. 38387 III. Based on review of the laboratory quality control records and patient test records from 2023 to 2024, and confirmed in interview, the laboratory failed to verify the acceptability of three of three quality control lots for chemistry (Albumin, Chloride, DBilirubin, Vitamin B12, and CRP) testing on the Dimension chemistry analyzer. Findings included: 1. Random review of the laboratory chemistry quality control records from 2023 to 2024 revealed the laboratory used the following acceptable ranges for the following five (Albumin, Chloride, DBilirubin, Vitamin B12, and CRP) analytes: Biorad lot 45910, exp 02/31/2024 Albumin acceptable ranges in 03/2023 Level 1: 2.24 - 2.38 g/dL Level 3: 3.95 - 4.13 g/dL Chloride acceptable ranges 03 /2023 Level 1: 73.5 - 75.98 mmol/L Level 3: 121.61 - 125.19 mmol/L DBilirubin acceptable ranges 01/2023 Level 1: 0.15 - 0.25 mg/dL Level 3: 1.78 - 1.98 mg/dL Biorad lot 85320 exp 05/31/2024 Vitamin B12 acceptable ranges 09/2023 Level 1: 215 - 265 pg/mL Level 3: 638 - 702 pg/mL Biorad lot 6900 exp 02/29/2024 CRP acceptable ranges 09/2023 Level 1: 0.82 - 0.98 mg/dL Level 3: 4.45 - 5.13 mg/dL 2. Review of laboratory records available revealed no documentation the laboratory verified the ranges above, prior to putting into use. 3. Review of laboratory policies revealed no policy in verifying the acceptable ranges for quality control. 4. Review of laboratory records revealed the laboratory performed 173, 127 chemistry testing annually. 5. In an interview with the laboratory liaison on 04/02/2024 at 1510 hours in the conference room, she stated that their policy is to start with the package insert ranges and then use the peer group data for acceptability.
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 laboratory policy, manufacturer's instructions, random review of Urinalysis quality control from 2023 and 2024, patient test results, and confirmed in interview, the laboratory failed to document two acceptable levels of quality control for each day of testing for one of ten days reviewed. Findings included: 1. In review of the laboratory policy Automated Urinalysis on Sysmex UN-Series (SOP Urine. 0006, effective 09/1/2022), it stated "when used with the Clinitek Novus and Clinitek Novus 10 Urinalysis Cassette, the Positive and Negative controls provide defined results for color, clarity, glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes." 2. In review of the manufacturer's instructions for the Clinitek Atlas Positive and Negative Control Strips for Urinalysis

	under expected results with Clinitek Novus Analyzer for both Positive and Negative Control "Clarity Clear" 3. Random review of urinalysis quality control from 2023 to 2024 revealed one of ten days when quality control was not acceptable. 4/14/2023 Positive Control (lot 0468022P) result "+" 4. Random review of patient testing from 04/14/2023 revealed the laboratory performed the following two patient for urinalysis. Patient ID74658, 74659 5. An interview with the laboratory liaison on 4/03/2024 at 1340 hours in the conference room confirmed the above 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 review of the laboratory's freezer #1 temperature log from December 2023 and staff interview, the laboratory failed to have documentation of performing corrective actions on 20 of 20 days when the maximum temperature exceeded the laboratory's acceptable range. The findings included: 1. A review of the laboratory's freezer #1 temperature log from December 2023 revealed the laboratory monitored the minimum and maximum temperature of the freezer. The acceptable ranges were: a) Minimum -25C b) Maximum -10C 2. Further review of the temperature records identified 20 of 20 test days were the documented maximum temperature was documented higher than -10C. They were: Date Temperature 12/1 -9.3C 12/4 -9.6C 12 /5 -9.3C 12/6 -9.3C 12/7 -9.3C 12/8 -9.3C 12/11 -9.3C 12/12 -9.6C 12/13 -9.6C 12/14 -9.6C 12/15 -9.6C 12/18 -9.6C 12/19 -9.6C 12/20 -9.2C 12/21 -9.2C 12/22 -9.4C 12 /26 -9.6C 12/27 -9.5C 12/28 -9.6C 12/29 -9.5C 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted 04/2/2024 at 1400 hours in the conference room.
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 quality control records and staff interview, the laboratory director failed to ensure new lots of quality control material were verified prior to use. The findings included: 1. The laboratory director failed to ensure 3 of 3 lots of hematology control material were verified prior to use (see D5469 I.). 2. The laboratory director failed to ensure 3 of 3 lots of sedimentation rate control material were verified prior to use (see D5469 II.). 3. The laboratory director failed to ensure 3

	of 3 lots of chemistry control material were verified prior to use (see D5469 I.). 4. The laboratory director failed to ensure two levels of quality control material was tested for urinalysis for 1 of 10 days (see D5481).