Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2176501	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Privia Medical Group Of North Texas Laboratory	2909 Lackland Rd, Fort Worth, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1240 Pre-Analytic Systems 493.1403 Laboratory Director, (moderate complexity) 493.1409 Technical Consultant, (moderate complexity) 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 Southern Operations Branch-Dallas 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. The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory.
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 direct observation, review of manufacturer's instructions, review of laboratory policies, patient test reports, and staff interview, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for establishing a stability for patient complete blood count (CBC) specimens prior to testing on the Sysmex XN-9000 analyzer for 34 of 34 specimens in 2022 (03/2022). Refer to D5311 I. 2. The laboratory failed to follow its own written policy in providing a correct collection time for 4 of 23 patients (random sampling) when tested on the Sysmex XN-9000 hematology analyzer in 03/2022. Refer to D5311 II. 3. The laboratory failed to ensure temperature of specimens received into the laboratory from offsite clients were within manufacturer's requirements for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. Refer to D5311 III. 4. The laboratory failed to have a system in place for documenting the time specimens were received in the laboratory from outside clinics for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03 /08/2022. Refer to D5313. 5. The laboratory failed to ensure specimen storage and preservation requirements of all tests were included in instructions for outside clients. 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: I. Based on review of laboratory policy, manufacturer's instructions, direct observation, patient test reports, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for establishing a stability for patient complete blood count (CBC) specimens prior to testing on the Sysmex XN-9000 analyzer for 34 of 34 specimens in 2022 (03/2022). Findings: 1. Review of the laboratory's policy "SYS 2 PROCEDURE - CBC Sysmex" revealed: "Specimen Requirements... A. Acceptable Specimen: Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant. B. Unacceptable specimens including those listed below must be recollected: 1. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens should be checked visually for obvious clots prior to sampling by the analyzer. 2. Grossly hemolyzed samples. 3. Samples drawn above an IV line. 4. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins. C. Stored Specimen Stability: Stored at 2-8C for up to 48 hours. 1. EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability. 2. Sample stability at room temperature (18-26C) is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours, which may be minimized by refrigeration." 2. Review of manufacturer's instructions from the Sysmex Implementation Manual stated the following: "Introduction ... Section 3 Method Verification Protocols ... It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies (CAS assists with data reduction) Sensitivity Studies (See Application Manual) Reference Range Verification (See Application Manual) Stability Study (See Application Manual) Mixing Study

(See Application Manual) Typically, integration studies are performed on new analyzers to verify and document satisfactory analyzer performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy requirements over and above what is contained in these protocols." Review of the Stability Study section from the Application Manual stated: "Stability Study (for Customer Reference Only) Stability studies may be performed to determine the readiness of a sample for CBC, differential and reticulocyte count analysis. Short term stability may be performed with fresh samples drawn and analyzed at intervals within one (1) hour. Long term stability is conducted under storage conditions and over a period of time, defined by the laboratory as acceptable for specimen analysis. Typical long term studies include analysis of room temperature (18-26C) and refrigerated (4C) samples at intervals from zero to 48, 56 or 72 hours." Review of the Sysmex XN-9000 Instructions for Use manual page 9-4 stated the following: "9.2 Prepare the sample ... 9.2.1 Sample types and handling ... Handling whole blood Collect venous blood with anti-coagulant (EDTA-2K or EDTA-3A). Draw the specified amount of blood as per the package insert of the tube to be used. The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2-8C until it can be analyzed." 3. During an interview on 03/08/2022 at 9:05 am, the Technical Consultant stated that he did not know if the stability studies were performed on the Sysmex XN-9000 hematology analyzer. During the exit interview on 03/09/2022 at 4:00 pm, the Technical Consultant confirmed that the laboratory failed to perform the stability studies. 4. During a tour of the laboratory on 03/07/2022 at 1:45 pm, the surveyor observed 7 EDTA-2K (lavender) specimen tubes from multiple outside clinics delivered by a courier in a soft-shell cooler bag with one small ice pack and one large ice pack. These specimens were cool to the touch. The courier had another large rolling cooler containing 3 large specimen bags. The specimen bags held 81 EDTA-2K (lavender) specimen tubes. The cooler did not have any ice packs. These specimens were warm to the touch. The courier was asked if the coolers had been validated to maintain refrigerated (2-8C) and room (18-26C) temperatures, she stated "no" and that they were her own personal coolers. The specimens were sorted and placed in the refrigerator for later processing by the processer. At 3:05 pm, another courier arrived with 57 EDTA-2K (lavender) specimen tubes from other outside clinics in a larger shoulder cooler bag with no ice packs. These specimens were warm to the touch. The courier was asked if the coolers had been validated to maintain and room temperature (18-26C), he stated "no" and that the cooler was his own personal cooler. The specimens were sorted and placed in the refrigerator for later processing by the processer. During a tour of the laboratory on 03 /08/2022 at 2:30 pm, the surveyor observed 105 EDTA-2K (lavender) specimen tubes from multiple outside clinics delivered by a courier in a large rolling cooler with two frozen ice packs. These specimens were cool to the touch. The specimens were sorted and placed in the refrigerator for later processing by the processer. The following sampling of specimens were analyzed on the Sysmex XN-9000, after they were processed: Patient ID: NPG3991241- collection date/time 03/07/2022 8:10 am, analyzed time 4:50 pm, 7 hours 11 mins elapsed time from time of collection to analysis Patient ID: NPG3992112- collection date/time 03/07/2022 10:06 am, analyzed time 5:58 pm, 7 hours 52 mins elapsed time from time of collection to analysis Patient ID: NPG3991916- collection date/time 03/07/2022 8:56 am, analyzed time 6:00 pm,97 hours 6 mins elapsed time from time of collection to analysis Patient ID: NPG3991940- collection date/time 03/07/2022 9:55 am, analyzed time 6:10 pm, 8 hours 15 mins elapsed time from time of collection to analysis Patient ID: NPG3992281- collection date/time 03/07/2022 10:44 am, analyzed time 5:59 pm, 7 hours 15 mins elapsed time from time of collection to analysis Patient ID:

NPG3992109- collection date/time 03/07/2022 10:17 am, analyzed time 6:07 pm, 8 hours 10 mins elapsed time from time of collection to analysis Patient ID: NPG3992172- collection date/time 03/07/2022 10:35 am, analyzed time 5:58 pm, 6 hours 13 mins elapsed time from time of collection to analysis Patient ID: NPG3992346- collection date/time 03/07/2022 11:01 am, analyzed time 6:00 pm, 7 hours 1 min elapsed time from time of collection to analysis Patient ID: NPG3992204- collection date/time 03/07/2022 10:23 am, analyzed time 6:01 pm, 8 hours 22 mins elapsed time from time of collection to analysis Patient ID: NPG3991889- collection date/time 03/07/2022 8:40 am, analyzed time 6:01 pm, 9 hours 21 mins elapsed time from time of collection to analysis Patient ID: NPG3991486- collection date/time 03/07/2022 9:04 am, analyzed time 4:54 pm, 7 hours 50 mins elapsed time from time of collection to analysis Patient ID: NPG3987616- collection date/time 03/07/2022 8:55 am, analyzed time 6:05 pm, 9 hours 10 mins elapsed time from time of collection to analysis Patient ID: NPG3988605- collection date/time 03/07/2022 8:22 am, analyzed time 6:04 pm, 7 hours 42 mins elapsed time from time of collection to analysis Patient ID: NPG3982897- collection date/time 03/07/2022 10:20 am, analyzed time 6:06 pm, 7 hours 46 mins elapsed time from time of collection to analysis Patient ID: NPG3991880- collection date/time 03/07/2022 9:07 am, analyzed time 6:04 pm, 6 hours 53 mins elapsed time from time of collection to analysis Patient ID: NPG3991962- collection date/time 03/07/2022 9:39 am, analyzed time 6:04 pm, 8 hours 25 mins elapsed time from time of collection to analysis Patient ID: NPG3992133- collection date/time 03/07/2022 10:25 am, analyzed time 6:01 pm, 7 hours 36 mins elapsed time from time of collection to analysis Patient ID: NPG3992179- collection date/time 03/07/2022 9:46 am, analyzed time 6:00 pm, 8 hours 14 mins elapsed time from time of collection to analysis Patient ID: NPG3991903- collection date/time 03/07/2022 9:35 am, analyzed time 4:55 pm, 7 hours 20 mins elapsed time from time of collection to analysis Patient ID: NPG3994745- collection date/time 03/08/2022 10:34 am, analyzed 8:10 pm, 9 hours 46 minutes elapsed time from time of collection to analysis Patient ID: NPG3994274- collection date/time 03/08/2022 9:00 am, analyzed 9:35 pm, 12 hours 35 minutes elapsed time from time of collection to analysis Patient ID: NPG3992885- collection date/time 03/08/2022 10:17 am, analyzed 9:32 pm, 11 hours 15 minutes elapsed time from time of collection to analysis Patient ID: NPG3994525- collection date/time 03/08/2022 10:01 am, analyzed 8:19 pm, 10 hours 18 minutes elapsed time from time of collection to analysis Patient ID: NPG3994843- collection date/time 03/08/2022 10:47 am, analyzed 8:18 pm, 9 hours 31 minutes elapsed time from time of collection to analysis Patient ID: NPG3994402- collection date/time 03/08/2022 9:38 am, analyzed 7:56 pm, 10 hours 18 minutes elapsed time from time of collection to analysis Patient ID: NPG3993359- collection date/time 03/08/2022 9:06 am, analyzed 7:55 pm, 10 hours 49 minutes elapsed time from time of collection to analysis Patient ID: NPG3991448- collection date/time 03/08/2022 8:26 am, analyzed 7:54 pm, 11 hours 28 minutes elapsed time from time of collection to analysis Patient ID: NPG3992073- collection date/time 03/08/2022 7:51 am, analyzed 7:55 pm, 12 hours 4 minutes elapsed time from time of collection to analysis Patient ID: NPG3989104- collection date/time 03/08/2022 9:48 am, analyzed 7:53 pm, 10 hours 5 minutes elapsed time from time of collection to analysis Patient ID: NPG3994382- collection date/time 03/08/2022 9:22 am, analyzed 7:57 pm, 10 hours 35 minutes elapsed time from time of collection to analysis Patient ID: NPG3994489- collection date/time 03/08/2022 10:00 am, analyzed 7:56 pm, 8 hours 56 minutes elapsed time from time of collection to analysis Patient ID: NPG3994365- collection date/time 03/08/2022 9:23 am, analyzed 8:12 pm, 10 hours 49 minutes elapsed time from time of collection to analysis Patient ID: NPG3973699- collection date/time 03/08/2022 10:10 am, analyzed 8:12 pm, 8

hours 2 minutes elapsed time from time of collection to analysis Patient ID: NPG3994702- collection date/time 03/08/2022 10:27 am, analyzed 8:08 pm, 9 hours 41 minutes elapsed time from time of collection to analysis The laboratory did not ensure their written preanalytical requirements were consistent with manufacturer's preanalytical requirements. The laboratory extended the specimen stability beyond manufacturer's instructions for the above CBC specimens analyzed on the Sysmex XN-9000 analyzer. The laboratory could not provide studies to support the extended stability as stated in their laboratory policy. II. Based on direct observation, review of the laboratory's procedure manual, patient test reports and confirmed in interview, the laboratory failed to follow its own written policy in providing a correct collection time for 4 of 23 patients (random sampling) when tested on the Sysmex XN-9000 hematology analyzer in 03/2022. Findings included: 1. Review of the laboratory's policy "Specimen Collection Procedure" revealed: "Procedure ... 3. Label the specimens: a. Label the specimen IMMEDIATELY, do NOT leave exam room or phlebotomy area without labeling the specimen!... c. PRINT the full name, DOB, collection date and time, and initials of the person collecting the specimen, using indelible ink. d. NOTE: INCORRECTLY LABELED SPECIMENS, by CLIA REGULATIONS, MUST BE REJECTED. The patient will be required to return for recollection ... 5. Collection in Copia ... g. ENSURE THAT ALL REQUESTED TESTS ON THE REQUISITION ARE FOUND ON THE COLLECT SAMPLES PAGE ... 2. Make additions or deletions as needed, so that the requisition matches the tests ordered in Copia. Make sure the Collection date and time is accurate, then click "Save"." 2. During a tour on 03/07/2022 at 1:45 p.m. a contracted courier was observed delivering offsite patient specimens. The courier possessed three coolers containing offsite patient samples consisting of: 1 large rolling cooler containing no ice packs and 3 large clear biohazard bags of specimens, 1 hard top small plastic cooler containing dry ice in a plastic bag and 5 small clear biohazard bags of specimens and 1 soft shell cooler with two solid ice packs and 2 clear biohazard bags of specimens and one fecal container. The courier proceeded to unpack the large rolling cooler and placed the 3 large clear biohazard bags of specimens in black bins on the floor. The specimens received were: 93 SST (serum separator tubes), 81 lavender tubes, 55 urine conical tubes, 4 Aptima Multitest Swab Transport Media, 3 Fisher Transport Swabs (strep culture pregnancy), 20 Thin Preps, and 1 formalin vial. These specimens were warm to the touch. The courier unpacked the hard top small cooler and placed the frozen specimens in the accession area freezer. The frozen specimens received were: 1 fecal container and 2 SST. These specimens were frozen. The courier then unpacked the soft-shell cooler and placed the 5 small clear biohazard bags of specimens in the accession area refrigerator. The refrigerated specimens received were: 3 SST, 4 lavender, 4 green urine cups, 1 white urine tube, and 2 grey urine tubes. These specimens were cool to the touch. During a tour 03/07/2022 at 3:05 p.m. patient samples delivered by contract courier were observed to be delivered in one large shoulder cooler with no ice packs. The courier placed the specimens in black bins on the floor. The specimens received were: 73 SST, 57 lavender, 7 grey urine tubes, 5 Thin Preps, and 1 Aptima Multitest Swab Transport Media. These specimens were warm to the touch. 3. A random review of CBC test reports from 03 /07/2022 (observation times for specimens received in the laboratory were 1:45 pm and 3:05 pm) revealed the following: Patient NPG3992079 Order Date: 03/07/2022 9: 23 am Collected: 03/07/2022 3:14 pm Patient NPG3992171 Order Date: 03/07/2022 9: 42 am Collected: 03/07/2022 5:16 pm Patient NPG3992836 Order Date: 03/07/2022 11:55 am Collected: 03/07/2022 5:44 pm Patient NPG3991949 Order Date: 03/07 /2022 8:54 am Collected: 03/07/2022 5:38 pm The above collection times from the final reports were NOT accurate collection times. These collection times on the final reports were the times the specimens were processed into the laboratory. 4. During an

interview on 03/08/2022 at 11:40 am, the Technical Consultant confirmed the above findings. 44278 III. Based on direct observation, review of manufacturer's instructions, laboratory policy, client services policy, patient test requisitions, and confirmed in interview, the laboratory failed to ensure temperature of specimens received into the laboratory from offsite clients were within manufacturer's requirements for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08 /2022. Findings Included: 1. During a tour on 03/07/2022 at 1:45 p.m. a contracted courier was observed delivering offsite patient specimens. The courier possessed three coolers containing offsite patient samples consisting of: 1 large rolling cooler containing no ice packs and 3 large clear biohazard bags of specimens, 1 hard top small plastic cooler containing dry ice in a plastic bag and 5 small clear biohazard bags of specimens and 1 soft shell cooler with two solid ice packs and 2 clear biohazard bags of specimens and one fecal container. At 1:50 p.m. the contracted courier was asked if the above coolers transporting patient specimens were validated for specimen transport. The courier stated the coolers were not validated and were also for her personal use and resided at her home. The courier proceeded to unpack the large rolling cooler and placed the 3 large clear biohazard bags of specimens in black bins on the floor. The specimens received were: 93 SST (serum separator tubes), 81 lavender tubes, 55 urine conical tubes, 4 Aptima Multitest Swab Transport Media, 3 Fisher Transport Swabs (strep culture pregnancy), 20 Thin Preps, and 1 formalin vial. These specimens were warm to the touch. The courier unpacked the hard top small cooler and placed the frozen specimens in the accession area freezer. The frozen specimens received were: 1 fecal container and 2 SST. These specimens were frozen. The courier then unpacked the soft-shell cooler and placed the 5 small clear biohazard bags of specimens in the accession area refrigerator. The refrigerated specimens received were: 3 SST, 7 lavender, 4 green urine cups, 1 white urine tube, and 2 grey urine tubes. These specimens were cool to the touch. During an interview on 03/07/2021 at 01:50 p.m., the laboratory technical supervisor (TS 1) was asked if the temperature of the specimens was documented when specimens arrived at the facility. He stated "no". The supervisor was asked if the facility had performed shipping studies to validate the temperature of the coolers transporting specimens from offsite clients. He stated "no" and that the facility did not possess coolers and used the coolers provided by a contracted courier. The supervisor was also asked how many cold packs were used in shipping and if dry ice was used to ship frozen specimens. He stated that he did not know how many cold packs or dry ice was used in shipping. During a tour 03/07/2022 at 3:05 p.m. patient samples delivered by contract courier were observed to be delivered in one large shoulder cooler with no ice packs. The courier placed the specimens in black bins on the floor. The specimens received were: 73 SST, 57 lavender, 7 grey urine tubes, 5 Thin Preps, and 1 Aptima Multitest Swab Transport Media. These specimens were warm to the touch. During a tour on 03/08/2022 at 2:30 p.m. offsite patient samples delivered by contract courier were observed to be delivered in one large rolling cooler with two frozen ice packs. The courier placed the specimens in black bins on the floor. The specimens received were: 144 SST, 105 lavender, 38 Thin Preps, 22 urine conical tubes and 38 grey urine tubes. The specimens were cool to the touch. During an interview with the contracted courier on 03/08/2022 at 2:35 p.m., the courier stated she would "sometimes put ice packs" with the room temperature samples in situations when it was warm outside or there are numerous samples being shipped. The courier stated she was not trained on site specific patient specimen shipping requirements. 2. Review of manufacturer's instructions for Roche Cobas CO2 (Bicarbonate) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability: 7 days at 4-8 C; 40 hours at 15-25 C; 6

months -20 to -80 C" Manufacturer's instructions for Roche Cobas TP2 (Total Protein) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability: 6 days at 20-25 C; 4 weeks at 4-8 C; 1 year at -20 C" Manufacturer's instructions for Roche Cobas PHOS2 (Phosphorus) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 24 hours at 15-25 C; 4 days at 2-8 C; 1 year at -15 to -25 C Stability in urine: 6 months at 2-8 C" Manufacturer's instructions for Roche Cobas UA2 (Uric Acid) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 7 hours at 4-8 C; 3 days at 20-25 C; 6 months at -20 C Stability in urine: 4 days at 20-25 C" Manufacturer's instructions for Roche Cobas A1C (Hemoglobin A1C) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 3 days at 15-25 C; 7 days at 2-8 C; 6 months at -15 to -20 C" Manufacturer's instructions for Sysmex XN-9000 CBC analysis revealed the following: "9.2.1 Sample types and handling Handling whole blood: ...The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store in a refrigerator at 2-8 C until it can be analyzed." Manufacturer's instructions for Thin Prep revealed the following: "Storage Store PreservCyt Solution with cytologic sample intended for Thin Prep Pap testing between 15C (59F) and 30C (86F) for up to 6 weeks." Manufacturer's instructions for Aptima Multitest Swab Specimen Collection Kit revealed the following: "Kit Storage Requirements Store collection kit at room temperature (15C to 30C)." The instructions mentioned above were a sampling of analytes tested by the laboratory. All analytes included instructions for storage requirements. 3. Review of laboratory policy, "CO2 (Bicarbonate)" (Approved by the Laboratory Director on 02/16/2022) stated the following: "Specimen Collection and Preparation Stability: 7 days at 4-8 C; 40 hours at 15-25 C; 6 months -20 to -80 C" Laboratory policy, "Total Protein" (Approved by the Laboratory Director on 03/03/2022) stated the following: "Specimen Collection and Preparation Stability: 6 days at 20-25 C; 4 weeks at 4-8 C; 1 year at -20 C" Laboratory policy, "Phosphorus" (Approved by the Laboratory Director on 03/03/2022) stated the following: "Specimen Collection and Preparation Stability in serum: 24 hours at 15-25 C; 4 days at 2-8 C; 1 year at -15 to -25 C Stability in urine: 6 months at 2-8 C" Laboratory policy, "Uric Acid" (Approved by the Laboratory Director on 02/25/2022) stated the following: "Specimen Collection and Preparation Stability in serum: 7 hours at 4-8 C; 3 days at 20-25 C; 6 months at -20 C" Laboratory policy, "Hemoglobin A1c" (Approved by the Laboratory Director on 02/25/2022) stated the following: "Specimen Collection and Preparation Stability in whole blood: 3 days at 15-25 C; 7 days at 2-8 C; 6 months at -15 to -20 C" Laboratory policy, "CBC Sysmex" (Approved by the Laboratory Director on 04/06 /2021) stated the following: "Specimen Requirements ...B. Unacceptable Specimens including those listed below must be recollected: ...C. Stored Specimen Stability: Stored at 2-8 C for up to 48 hours... 2. Sample stability at room temperature (18-26 C) is 24 hours." 4. Review of laboratory client services policy, "Specimen Collection" (Approved by Laboratory Director on 08/06/2020) provided to offsite clients for specimen collection and transport requirements, revealed the following: "Storage and Transportation: a. Make sure lids are tight in order to avoid spills. b. Put requisition /paperwork/extra labels in outside pouch of bio-transport bag. This will prevent the

	requisition from being ruined in the event the specimen leaks. c. If specimen is not going to be sent to the lab immediately, confirm the proper temperature (room temperature, refrigerated, or frozen) for interim storage until specimen can be sent. d. During hot summer days, make sure specimens are shipped to the lab in cool containers. e. Do not leave specimens overnight without confirming with the lab the proper way of handling the specimens for delayed testing." The laboratory failed to ensure temperature of specimens received into the laboratory from offsite clients were within defined acceptability range and manufacturer's requirements for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. 5. Review of patient requisitions and final reports revealed temperatures were not documented for specimens received on 03/07/2022 (observation times 1:45 p.m. and 3:05 pm.) and on 03/08/2022 (observation time 2:30 p.m.). The following random sampling of patient samples were received on 03/08/2022 (observation time 2:30 p.m.) for testing on the Roche Cobas chemistry and/or Sysmex hematology analyzers: a. Patient ID: NGP3994525 Received date: 03/08/2022; Received time: 7:34 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. b. Patient ID: NGP3994843 Received date: 03/08/2022; Received time: 7:30 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. c. Patient ID: NGP3994702 Received date: 03/08/2022; Received time: 7:12 p.m. Tests Ordered: CBC (Complete Blood Count) Specimen disposition was not documented. d. Patient ID: NGP3982885 Received date: 03/08/2022; Received time: 8:11 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. e. Patient ID: NGP3994274 Received date: 03/08/2022; Received time: 8:09 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. f. Patient ID: NGP3973669 Received date: 03/08/2022; Received time: 6:59 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. g. Patient ID: NGP3994402 Received date: 03/08/2022; Received time: 5:59 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. h. Patient ID: NGP3994365 Received date: 03/08/2022; Received time: 7:00 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. i. Patient ID: NGP3994382 Received date: 03/08/2022; Received time: 7:06 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. j. Patient ID: NGP3989104 Received date: 03/08/2022; Received time: 6: 44 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis (Consisting of CO2 and TP) Specimen disposition was not documented. Note: During the duration of inspection, the Roche Cobas chemistry analyzers were not processing samples due to analyzer malfunction. The laboratory did not have a system in place to document disposition of patient specimens that included the temperature of environment in which specimens were transported from outside clients to arrival in laboratory and correct environmental storage of specimens during transport according to manufacturer's requirements for accurate and reliable test results. 6. During an interview with the laboratory representatives on 03/07/2022 at 01:50 p.m., Technical Supervisor-1 (TS-1) stated the contracted courier coolers were not validated for specimen transport. This confirmed the above findings.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:
Based on direct observation, patient test reports, and confirmed in interview, the laboratory failed to have a system in place for documenting the time specimens were received in the laboratory from outside clinics for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. Findings Included: 1. During a tour on 03/07/2022 at 1:45 p.m. a contracted courier was observed delivering offsite patient specimens. The courier possessed three coolers containing offsite patient samples consisting of: 1 large rolling cooler containing no ice packs and 3 large clear biohazard bags of specimens, 1 hard top small plastic cooler containing dry ice in a plastic bag and 5 small clear biohazard bags of specimens and 1 soft shell cooler with two solid ice packs and 2 clear biohazard bags of specimens and one fecal container. The courier proceeded to unpack the large rolling cooler and placed the 3 large clear biohazard bags of specimens in black bins on the floor. The specimens received were: 93 SST (serum separator tubes), 81 lavender tubes, 55 urine conical tubes, 4 Aptima Multitest Swab Transport Media, 3 Fisher Transport Swabs (strep culture pregnancy), 20 Thin Preps, and 1 formalin vial. These specimens were warm to the touch. The courier unpacked the hard top small cooler and placed the frozen specimens in the accession area freezer. The frozen specimens received were: 1 fecal container and 2 SST. These specimens were frozen. The courier then unpacked the soft-shell cooler and placed the 5 small clear biohazard bags of specimens in the accession area refrigerator. The refrigerated specimens received were: 3 SST, 4 lavender, 4 green urine cups, 1 white urine tube, and 2 grey urine tubes. These specimens were cool to the touch. During an interview on 03/07/2021 at 01:50 p.m., the Technical Supervisor (TS 1) was asked if the time the specimens were received in the laboratory was documented and he stated "no". During a tour 03/07/2022 at 3:05 p.m. offsite patient samples delivered by contract courier were observed to be delivered in one large shoulder cooler with no ice packs. The courier placed the specimens in black bins on the floor. The specimens received were: 73 SST, 57 lavender, 7 grey urine tubes, 5 Thin Preps, and 1 Aptima Multitest Swab Transport Media. These specimens were warm to the touch. During a tour on 03/08/2022 at 2:30 p.m. offsite patient samples delivered by contract courier were observed to be delivered in one large rolling cooler with two frozen ice packs. The courier placed the specimens in black bins on the floor. The specimens received were: 144 SST, 105 lavender, 38 Thin Preps, 22 urine conical tubes and 38 grey urine tubes. The specimens were cool to the touch. 2. Review of patient final reports revealed receipt times in the laboratory were not documented accurately for specimens received on 03/07/2022 (observation times 1:45 p.m. and 3:05 pm.) and on 03/08/2022 (observation time 2:30 p.m.). The following random sampling of patient samples were received on 03/08/2022 (observation time 2:30 p.m.) for testing on the Roche Cobas chemistry and/or Sysmex hematology analyzers: a. Patient ID: NGP3994525 Received date: 03/08/2022; Received time: 7:34 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis b. Patient ID: NGP3994843 Received date: 03/08/2022; Received time: 7:30 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis c. Patient ID: NGP3994702 Received date: 03/08/2022; Received time: 7:12 p.m. Tests Ordered: CBC (Complete Blood Count) d. Patient ID: NGP3982885 Received date: 03/08/2022; Received time: 8:11 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis e. Patient ID: NGP3994274 Received date: 03/08/2022; Received time: 8:09 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis f. Patient ID: NGP3973669 Received date: 03/08/2022; Received time: 6:59 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis g. Patient ID:

	NGP3994402 Received date: 03/08/2022; Received time: 5:59 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis h. Patient ID: NGP3994365 Received date: 03/08/2022; Received time: 7:00 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis i. Patient ID: NGP3994382 Received date: 03/08 /2022; Received time: 7:06 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis j. Patient ID: NGP3989104 Received date: 03/08/2022; Received time: 6:44 p.m. Tests Ordered: CBC (Complete Blood Count); Chemistry Analysis Note: During the duration of the inspection, the Roche Cobas chemistry analyzers were not processing samples due to analyzer malfunction. The laboratory did not have a system in place to ensure accurate documentation of the time specimens were received in the laboratory from outside clinics. 3. During an interview on 03/08/2022 at 11:40 a.m., the Technical Supervisor-1 confirmed the above 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 review of manufacturer's instructions, laboratory policy, client service's manual, patient records, and confirmed in interview, the laboratory failed to ensure specimen storage and preservation requirements of all tests were included in instructions for outside clients. Findings Included: 1. Review of manufacturer's instructions for Roche Cobas CO2 (Bicarbonate) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability: 7 days at 4-8 C; 40 hours at 15-25 C; 6 months -20 to -80 C" Manufacturer's instructions for Roche Cobas TP2 (Total Protein) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability: 6 days at 20-25 C; 4 weeks at 4-8 C; 1 year at -20 C" Manufacturer's instructions for Roche Cobas PHOS2 (Phosphorus) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 24 hours at 15-25 C; 4 days at 2-8 C; 1 year at -15 to -25 C Stability in urine: 6 months at 2-8 C" Manufacturer's instructions for Roche Cobas UA2 (Uric Acid) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 7 hours at 4-8 C; 3 days at 20-25 C; 6 months at -20 C Stability in urine: 4 days at 20-25 C" Manufacturer's instructions for Roche Cobas A1C (Hemoglobin A1C) Reagent revealed the following: "Specimen collection and preparation- It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory. Stability in serum: 3 days at 15-25 C; 7 days at 2-8 C; 6 months at -15 to -20 C" Manufacturer's instructions for CBC Reagent revealed the following: Laboratory policy, "CBC Sysmex" (Approved by the Laboratory Director on 04/06 /2021) stated the following: "Specimen Requirements ..B. Unacceptable Specimens including those listed below must be recollected: ..C. Stored Specimen Stability:

	Stored at 2-8 C for up to 48 hours.. 2. Sample stability at room temperature (18-26 C) is 24 hours." Manufacturer's instructions for Thin Prep revealed the following: "Storage Store PreservCyt Solution with cytologic sample intended for ThinPrep Pap testing between 15C (59F) and 30C (86F) for up to 6 weeks." 2. Review of laboratory policy, "CO2(Bicarbonate" (Approved by the Laboratory Director on 02/16/2022) stated the following: "Specimen Collection and Preparation Stability: 7 days at 4-8 C; 40 hours at 15-25 C; 6 months -20 to -80 C" Laboratory policy, "Total Protein" (Approved by the Laboratory Director on 03/03/2022) stated the following: "Specimen Collection and Preparation Stability: 6 days at 20-25 C; 4 weeks at 4-8 C; 1 year at -20 C" Laboratory policy, "Phosphorus" (Approved by the Laboratory Director on 03/03/2022) stated the following: "Specimen Collection and Preparation Stability in serum: 24 hours at 15-25 C; 4 days at 2-8 C; 1 year at -15 to -25 C Stability in urine: 6 months at 2-8 C" Laboratory policy, "Uric Acid" (Approved by the Laboratory Director on 02/25/2022) stated the following: "Specimen Collection and Preparation Stability in serum: 7 hours at 4-8 C; 3 days at 20-25 C; 6 months at -20 C" Laboratory policy, "Hemoglobin A1c" (Approved by the Laboratory Director on 02/25/2022) stated the following: "Specimen Collection and Preparation Stability in whole blood: 3 days at 15-25 C; 7 days at 2-8 C; 6 months at -15 to -20 C" Laboratory policy, "CBC Sysmex" (Approved by the Laboratory Director on 04/06 /2021) stated the following: "Specimen Requirements ..B. Unacceptable Specimens including those listed below must be recollected: ..C. Stored Specimen Stability: Stored at 2-8 C for up to 48 hours.. 2. Sample stability at room temperature (18-26 C) is 24 hours." The instructions mentioned above were a sampling of analytes tested by the laboratory. All analytes included instructions for storage requirements. 3. Review of laboratory client services policy, Specimen Collection" (Approved by Laboratory Director on 08/06/2020) provided to offsite clients for specimen collection and transport requirements, revealed the following: "Storage and Transportation: a. Make sure lids are tight in order to avoid spills. b. Put requisition/paperwork/extra labels in outside pouch of bio-transport bag. This will prevent the requisition from being ruined in the event the specimen leaks. c. If specimen is not going to be sent to the lab immediately, confirm the proper temperature (room temperature, refrigerated, or frozen) for interim storage until specimen can be sent. d. During hot summer days, make sure specimens are shipped to the lab in cool containers. e. Do not leave specimens overnight without confirming with the lab the proper way of handling the specimens for delayed testing." The client services policy did not include specific storage, stability, and preservation requirements of specimens. 4. Review of patient requisitions revealed 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03 /08/2022, were received by the laboratory without following manufacturer's instructions for specimen storage and preservation. Refer to D5311, I and D5311, III. The following is a random sampling of patient samples received on 03/08/2022: Patient ID: NGP3994525; NGP3994843; NGP3994642; NGP3982885; NGP3994274; NGP3993179; NGP3994402; NGP3994210; NGP3995013; NGP3994358; NGP3993359; NGP3981448; NGP3982073; NGP3989104; NGP3994382; NGP3994489; NGP3973669; NGP3994745; NGP3994702 5. During an interview with the Technical Supervisor (TS-1) on 03/07/2022 at 10:20 a.m., TS-1 confirmed the laboratory failed to ensure specimen storage and preservation requirements of all tests were included in instructions for outside clients.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks

	may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient reports and confirmed in staff interview, the laboratory failed to follow its own written policy for reporting platelet estimates for 4 of 11 patients in 2022 (random review 03/2022). Findings included: 1. Review of the laboratory's policy titled "Performance of Manual Differential", revealed: "Platelet Estimate, Clumps, and Giant Platelet Reporting 1. Examine the slide on the 100X oil objective in the evenly dispersed fields of 100-160 RBCs. 2. Count the platelets in 10 fields. Determine the mean to the nearest tenth by dividing the total number of platelets counted by 10. 3. Calculate the PLT estimate: mean X 20,000 = PLT/uL. The estimate should match the instrument count +/- 20%. If the quantitative platelet count is between 75,000/uL and 300,000/uL, the estimate should correlate within 26,000/uL. If not, ask that the patient be recollected. 4. If platelets are clumped, report the platelet estimate if it can be accurately counted." 2. A random review of patient manual differential reports from March 2022 revealed the laboratory failed to follow their own policy for reporting platelet estimates as follows: 03/02/2022 Patient ID: NGP3986371 Test: Platelet Estimation; Result: Normal Test: Platelet Clumping; Result: 1+ Patient ID: NGP3986603 Test: Platelet Estimation; Result: Normal Test: Platelet Clumping; Result: 2+ 03/03/2022 Patient ID: NGP3986984 Test: Platelet Estimation; Result: Normal Test: Platelet Clumping; Result: 2+ 03/08/2022 Patient ID: NGP3993361 Test: Platelet Estimation; Result: Normal Test: Platelet Clumping; Result: 1+ 3. During an interview on 03/09/2022, Testing Person-3 (TP-3) stated that platelet estimations were not documented on the patient's test reports and the terms "normal", "decreased" and "increased" were reported for platelet estimations.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, review of operator's manual, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for the Roche Cobas 6000 analyzer for 2 of 2 months in 2022 (random review 01/2022 and 02/2022). Findings Included: 1. During a tour of the facility on 03/09/2022 at 02:30 p.m., the inspector observed three Roche Cobas 6000 chemistry analyzers in the laboratory clinical room. 2. Review of Roche Cobas 6000 Operator's Manual (Version 8.2), revealed the following environmental operating specifications for the Roche Cobas 6000 Chemistry analyzers: "Specifications: Environmental conditions The following environmental conditions should be followed in order to ensure correct operation of this system: Ambient Temperature During Operation: 18 to 32 C" 3. Review of laboratory environmental logs for 01/2022 and 2/2022 revealed the clinical room temperature

	range was 15-30 C. The laboratory failed to ensure room temperature ranges were within operating specifications for the Roche Cobas 6000 analyzers for 2 of 2 months in 2022. 4. During an interview with the Technical Supervisor (TS-2) on 03/08/2022 at 02:48 p.m., the TS-2 confirmed the above findings. II. Based on direct observation, review of operator's manual, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within operating specifications for the Siemens Hematek 3000 Hematology Slide Stainer for 2 of 2 months in 2022 (random review 01/2022 and 02/2022). Findings Included: 1. During a tour of the facility on 03/09/2022 at 02:30 p.m., the inspector observed a Siemens Hematek 3000 Hematology Slide Stainer in the laboratory clinical room. 2. Review of Siemens Hematek 3000 Hematology Slide Stainer (Version 1.3) operator's manual revealed the following: "Technical Specifications Environmental Operating temperature: 18 to 30 C" 3. Review of laboratory environmental logs for 01/2022 and 2/2022, revealed the clinical room temperature range was 15-30 C. The laboratory failed to ensure room temperature ranges were within operating specifications for the Siemens Hematek 3000 Hematology Slide Stainer for 2 of 2 months in 2022. 4. During an interview with the Technical Supervisor (TS-2) on 03/08/2022 at 02:50 p. m., the TS-2 confirmed the above findings. III. Based on direct observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature ranges were within storage specifications for the Harleco Wright Blood Smear Stain for 2 of 2 months in 2022 (random review 01/2022 and 02/2022). Findings Included: 1. During a tour of the facility on 03/09/2022 at 02:30 p.m., the inspector observed the Harleco Wright Blood Smear Stain stored in the laboratory clinical room. 2. Review of manufacturer's instructions for the Harleco Wright Blood Smear Stain revealed the following: "Storage 15-25 C" 3. Review of laboratory environmental logs for 01/2022 and 2 /2022, revealed the clinical room temperature range was 15-30 C. The laboratory failed to ensure room temperature ranges were within manufacturer's storage specifications for the Harleco Wright Blood Smear Stain for 2 of 2 months in 2022. 4. During an interview with the Technical Supervisor (TS-2) on 03/10/2022 at 04:30 p. m., the TS-2 confirmed the above findings. IV. Based on direct observation, review of operator's manual, laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room humidity ranges were within operating specifications for the Tissue Tek VIP 6 Processor for 2 of 2 months in 2022 (random review 01/2022 and 02/2022). Findings Included: 1. During a tour of the facility on 03/10/2022 at 10: 15 a.m., the inspector observed the Tissue Tek VIP 6 Processor (Serial Number: 60300072-1008) stored in the anatomical pathology (AP) room. 2. Review of the operator's manual for the Tissue Tek VIP 6 Processor revealed the following: "2.2 Environmental Factors As with all electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature and humidity should be held relatively constant ... The ambient operating humidity range is 30-85% relative humidity." 3. Review of laboratory environmental logs for 01/2022 and 2 /2022, revealed the AP room humidity range was 20-85%. The laboratory failed to ensure room humidity ranges were within operating specifications for the Tissue Tek VIP 6 Processor for 2 of 2 months in 2022. 4. During an interview with the Laboratory Director (LD) on 03/10/2022 at 04:30 p.m., the LD confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations, review of records, and interview with the Laboratory Director, the laboratory failed to ensure three of three tissue marking stains were not expired when used in processing histopathology specimens. The findings included: 1. At 13:41 hours on 3/9/2022 in the histopathology laboratory, the surveyor observed the following expired tissue marking stains located at the grossing station: Tissue Marking Dye - Blue Expired 2021 - 05-01 Tissue Marking Dye - Red Expired 2020 - 06-01 Tissue Marking Dye - Yellow Expired 2021 -03-01 2. Based on review of patient testing records, the laboratory performed 1,668 histopathology tests annually. 3. In an interview at 13:45 hours on 3/9/2022 in the office, the Laboratory Director confirmed the tissue marking stains had exceeded their expiration date.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per patient testing day for the Vaginal Microbial Identification Test on the BD Affirm analyzer for 9 of 13 testing days in February 2022. Findings Included: 1. Review of laboratory policy titled, "BD Affirm" (Approved by the Laboratory Director on 10/12/2021) revealed the following: "Quality Control- External quality controls will be performed once per week using TVS-01 (Positive Control) and TVS-02 (Negative Control)." The laboratory did NOT have an Individualized Quality Control Plan (IQCP) to support its reduction in frequency to once per week. 2. Review of laboratory BD Affirm quality control records revealed the following days external quality control was performed in February 2022: 02/07/2022; 02/14/2022; 02/21/2022; 02/28/2022 3. Review of laboratory, "BD Affirm VPIII Microbial Identification Testing Test: Laboratory Testing Log" revealed the following patients performed on days external negative and positive quality controls were not performed prior to patient testing: Date Patient Test Performed: a. 02/01/2022 Patient ID: 220311673; 220311352; 220310937 b. 02/05 /2022 Patient ID: 220330809; 220331282 c. 02/08/2022 Patient ID: 220380854; 220381094; 220381613; 229381537; 220401503; 220400997 d. 02/11/2022 Patient ID: 220411672; 220411042; 220411155; 220411423 e. 02/15/2022 Patient ID: 220450864; 220450994; 220451056; 220451089 f. 02/17/2022 Patient ID: 220470539; 220471270; 220471416; 220471419 g. 02/18/2022 Patient ID: 220471560; 220480702 h. 02/22/2022 Patient ID: 220521586; 220520903 i. 02/25 /2022 Patient ID: 220540466; 220540599 The laboratory failed to document external negative and positive control material at least once per patient testing day for the Vaginal Microbial Identification Test on the BD Affirm analyzer for 9 of 13 testing days in February 2022. 4. During an interview with the Technical Supervisor (TS-2) on 03/08/2022 at 02:30 p.m., the TS-2 confirmed the above findings.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for peripheral blood smears for 97 of 97 days in 2021 (random review 10/2021 through 12/2021) and 40 of 40 days in 2022 (01/2022 through 03/2022). Findings included: 1. Review of the laboratory's policy "SYS 2 PROCEDURE - CBC Sysmex" revealed: "Quality Control ... B. Review the blood smears microscopically for acceptability. 1. Relatively even distribution of cellular elements. 2. Acceptable morphology within the working area. 3. None or very little artifact of the cell morphology, (e.g., "punched-out" RBCs, smashed WBCs). 4. None, or very little stain precipitate or debris. 5. The staining is consistent and imparts the characteristic cytoplasmic color differences and distinct nuclear chromatic patterns of the whole spectrum of blood cells. Acceptable stains will display the following characteristics. a. RBCs should be pink to orange. There should be good differentiation between normochromic, hypochromic and polychromatic cells. b. Lymphocytes will display dark to purple nuclei with varying shades of blue cytoplasm. c. Neutrophils will display dark purple nuclei, with light pink cytoplasm and lilac granules. d. Monocytes will show lighter purple nuclei. The cytoplasm of the monocytes will be gray-blue with reddish granules. e. Eosinophils will show bright orange granules in the cytoplasm. f. Basophils will display dark blue granules in the cytoplasm. g. Platelets will be violet to purple. 6. If smear quality is unsatisfactory, clean, or if necessary, replace the spreader glass. If still unable to obtain an acceptable smear, refer to the SP-Series Implementation Manual Troubleshooting Section ... 7. Document results on the Patient's CBC printout and save in the monthly file." 2. Review of the "Sysmex SP-10 Daily Control Observations" log revealed the following: The log had two columns titled "Macroscopic" and "Microscopic". The "Macroscopic" column had three sub-columns titled "Length, Edge and Consistency". The "Microscopic" column had three sub-columns titled "RBCs, WBCs and Platelets". Each day QC was documented with a "checkmark" under each column. The laboratory failed to specify what the "checkmark" indicated. The following dates in 2021 and 2022 (random review) were observed to be documented with a "checkmark": 2021 October: 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 18, 19, 20, 21, 22, 25, 26, 27, 28, 29 November: 2, 3, 4, 5, 6, 9, 10, 11, 12, 13, 16, 17, 18, 19, 20, 23, 24, 25, 30 December: 1, 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 24, 28, 29, 30, 31 2022 January: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 31 February: 1, 2, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 25, 28, March: 1, 2, 3, 4, 7 The laboratory failed to document the staining characteristics for the peripheral blood smears. 3. Review of test volume records provided by the laboratory included a total annual volume of 472 peripheral blood smears. 4. During an interview on 03/08/2022 at 10:32 am, the Technical Consultant confirmed the above findings. 44278 II. Based on review of manufacturer's instructions, laboratory policy, quality control (QC) records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for

	Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides on each day of patient testing for 10 of 10 months in 2020 (March 2020-December 2021) 12 of 12 months in 2021 and 2 of 2 months in 2022 (January 2022- February 2022). Findings Included: 1. Review of manufacturer's instructions for the "MasterTech Routine H&E Staining" revealed the following: "This procedure stains cell nuclei and cytoplasm. Results: Nuclei: Blue Cytoplasm: Pink" 2. Review of laboratory policy titled, "Hematoxylin and Eosin (H&E)"(Approved by the Laboratory Director on 02/20/2020) revealed the following: "Quality Controls: Quality check will be done on a daily basis, in the form of a control H&E slide. The control slide will be reviewed by qualified personnel to ensure the stain works properly." The laboratory failed to specify the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics prior to patient testing. 3. Random review of laboratory "Daily H&E QC Forms" (2020, 2021 and 2022) revealed the following: "H & E Control Acceptable (yes/no): Yes Legend: Check mark or A- Stain is acceptable X or N- Stain is not acceptable" Each day of patient testing the H&E QC Forms were marked as "Yes" by the testing personnel. The laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for 10 of 10 months in 2020 (March 2020-December 2020), 12 of 12 months in 2021 and 2 of 2 months in 2022 (January 2022- February 2022). 4. During the exit conference with the Laboratory Director (LD) at 04:15 p.m. on 03/09 /2022, the LD confirmed the above findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, chemistry quality control (QC) logs, QC corrective action documentation, patient records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable QC run to ensure accurate and reliable test results for 81 of 81 patients tested on 12/22/2021. Findings Included: 1. Review of laboratory policy titled "Quality Control (Clinical Laboratory)" (Reviewed by Laboratory Director on 01/28/2021) revealed the following: "C. Quality Control Review 1. Daily Review- All quality control data must be verified for acceptability by the testing personnel prior to releasing patient results. If the expected results are not achieved, patient results must not be released. Testing personnel are expected to begin the troubleshooting process. If testing personnel are not able to bring quality control results within acceptable limits, the supervisor must be consulted. The testing personnel or supervisor must document corrective actions as appropriate. ...5. If the Run Is Rejected a. Do not run the assay or release patient results for the assay which has been rejected. b. Repeat the control once to eliminate random error as the cause for the rejected control run. c. When simply repeating the control fails to produce satisfactory results, the following steps should be taken: 1.

	Verify the age and viability of the control 2. Reconstitute and run the new control 3. Verify the age and viability of the reagent 4. An expired reagent should be discarded 5. Verify the age and viability of the calibrators and recalibrate 6. Troubleshoot instrument d. Prudent judgement must be exercised in order to resolve the problem as efficiently as possible. The Department Supervisor should be notified at step c-6. e. All control values that cause a run to be rejected must be recorded on the Control Out of Limits Documentation Log and/or in the quality control software program. This documentation must also include the corrective action taken." The laboratory policy failed to state how to evaluate patients when test systems adjustments were made for QC failures since the last acceptable QC run. 2. Review of laboratory Chemistry QC logs, corrective action documentation and patient results revealed test system adjustments performed for the following QC test event in December 2021: Bio-Rad MulitQual QC Levels 1,2,3; Lot Number: 56680; Expiration Date:11/30/2023 Date Performed: 12/23/2021 QC Failures and Troubleshooting Analyte: BUN- Levels 2 and 3 Gluc- Levels 2 and 3 Uric Acid- Levels 1, 2 and 3 ALP- Levels 2 and 3 ALT- Levels 2 and 3 Calibrate the Analyte: Recalibrate all Rerun QC: Yes Supervisor Review: Signed by Technical Supervisor-2 on 12/23/2021 3. The following 20 randomly reviewed patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run when test system adjustments were performed (12/22/2021): a. Analytes: BUN; Gluc; Uric Acid; ALP; ALT Patient ID: 213560184; 213560410; 211750864; 213560146 b. Analytes: BUN; Gluc; ALP; ALT Patient ID: 213560214; 213560124; 213330244; 213560033; 213560154; 213560162; 213560084; 213560367; 213560256; 213560285; 213560350; 213560006; 213550320; 213540352; 213560260; 213560549; 213560596; 213541027; 213560604; 213560636 4. During an interview on 03/08/2022 at 11:05 am, in the laboratory office, the Laboratory Technical Supervisor-2 (TS-2) confirmed that all patients tested on 12/22/2021 were not evaluated since the last acceptable QC run when test system adjustments were performed on the chemistry analyzer. Word Key: ID- Identification BUN- Blood Urea Nitrogen Gluc- Glucose ALP- Alkaline phosphatase ALT- Alanine transaminase
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 observations, review of freezer temperature records, and interview with the Technical Consultant, the laboratory failed to document corrective actions when freezer temperatures were outside acceptable limits for the storage of chemistry quality control materials for 75 of 103 days reviewed between October 2021 and January 2022. The findings included: 1. Based on surveyor observations at 13:00 hours on 3/9/2022, the surveyor observed the following quality control materials stored in Freezer 1: Bio-Rad Liquichek Immunoassay Plus Control, levels 1-3 - 18 packages Storage: -20C to -70C Bio-Rad Liquid Unassayed Multiqual, Levels 1-3, 3 full packages and 3 partial packages Storage: -20C to -70C Bio-Rad Amplichek STI nucleic acid controls - 4 boxes Storage: -20C to -70C 2. Based on review of temperature records, the acceptable freezer temperatures for Freezer 1 were defined as -20C to -30C. Temperatures were outside of acceptable ranges for 27 of 31 days in October 2021 23 of 30 days in November 2021 16 of 21 days recorded in December

	2021 9 of 21 days recorded in January 2022 3. In an interview at 13:10 hours on 3/9 /2022 in the office, the Technical Supervisor 2 (as listed on the CMS-209 laboratory personnel report) stated the laboratory had tried adjusting the freezer, changed thermometers to troubleshoot, experimented with different placement of the thermometers, and had ultimately had to order a new freezer, which had just arrived but was not currently in use for storage of quality control materials.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the submitted Centers for Medicare and Medicaid (CMS) 116 Application, random review of histopathology final patient reports and confirmed in staff interview, it was revealed that the laboratory failed to ensure the laboratory address for all tests performed was documented on the final patient reports or in the EMR(electronic medical record) for 10 of 10 patients randomly reviewed in March 2022. Findings Included: 1. Review of CMS 116 application submitted at the time of survey revealed the following address for the laboratory: 2909 Lackland Rd Ft. Worth, TX 76116 2. Random review of histopathology patient final reports revealed the following 10 of 10 reports in March 2022 that did not include the physical address of the laboratory: Patient ID: 22-005-0000069; 22-047-0000031; 22-059-0000159; 22-06-0000076; 21-060-0000132; 22-020-0000063; 22-027-0000124; 22-062-0000104; 22-062-0000097; 22-018-0000127 3. During an interview with the Laboratory Director (LD) at 11:15 a.m. on 03/09/2022, the LD confirmed the final patient reports did not include the address of the laboratory. This confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policies, client services policy, patient test requisitions and final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The Laboratory Director failed to ensure requirements were met for pre-analytic systems. Refer to D6007.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policies, client services policy, patient test requisitions and final reports, and confirmed in interview, the Laboratory Director failed to ensure requirements were met for pre-analytic systems as evidence by: 1. The laboratory failed to follow manufacturer's instructions for establishing a stability for patient complete blood count (CBC) specimens prior to testing on the Sysmex XN-9000 analyzer for 34 of 34 specimens in 2022 (03/2022). Refer to D5311 I. 2. The laboratory failed to follow its own written policy in providing a correct collection time for 4 of 23 patients (random sampling) when tested on the Sysmex XN-9000 hematology analyzer in 03/2022. Refer to D5311 II. 3. The laboratory failed to ensure temperature of specimens received into the laboratory from offsite clients were within manufacturer's requirements for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08 /2022. Refer to D5311 III. 4. The laboratory failed to have a system in place for documenting the time specimens were received in the laboratory from outside clinics for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. Refer to D5313. 5. The laboratory failed to ensure specimen storage and preservation requirements of all tests were included in instructions for outside clients. Refer to D5317.
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 direct observation, review of manufacturer's instructions, laboratory policies, client services policy, patient test requisitions and final reports, and confirmed in interview, the Technical Consultant failed to provide technical oversight, as evidenced by: 1. The Technical Consultant failed to provide technical and scientific oversight. Refer to D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory.

	This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policies, client services policy, patient test requisitions and final reports, and confirmed in interview, the Technical Consultant failed to provide technical and scientific oversight, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for establishing a stability for patient complete blood count (CBC) specimens prior to testing on the Sysmex XN-9000 analyzer for 34 of 34 specimens in 2022 (03/2022). Refer to D5311 I. 2. The laboratory failed to follow its own written policy in providing a correct collection time for 4 of 23 patients (random sampling) when tested on the Sysmex XN-9000 hematology analyzer in 03/2022. Refer to D5311 II. 3. The laboratory failed to ensure temperature of specimens received into the laboratory from offsite clients were within manufacturer's requirements for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. Refer to D5311 III. 4. The laboratory failed to have a system in place for documenting the time specimens were received in the laboratory from outside clinics for 455 of 455 samples received on 03/07/2022 and 347 of 347 on 03/08/2022. Refer to D5313. 5. The laboratory failed to ensure specimen storage and preservation requirements of all tests were included in instructions for outside clients. Refer to D5317.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy CMS (Center for Medicare & Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate and document performance for 1 of 9 Testing Persons (TP-3) responsible for moderate complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the laboratory's policy titled "Competency and Training" revealed: "Competency Assessment ... G. Who Can Assess Competency? The Laboratory Director must ensure that the individuals performing competency assessment are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing. Competency assessments are delegated by the Laboratory Director to qualified Manager, Supervisors, and testing personnel. The qualifications for individuals to perform competency assessments in this laboratory are ... 2. Testing personnel performing moderate complexity testing must be assessed by an individual meeting the qualifications of a technical consultant for moderate complexity testing. Technical consultant requirements: Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least two years of experience in nonwaived testing in the designated specialty or subspecialty area of service." 2. Review of the submitted CMS 209 form revealed Testing Person-3 (TP-3) listed to perform moderate complexity testing. 3. Review of personnel records from 2021 revealed the following: TP-3 Training documentation for "Chemistry" and "Hematology": training date 01/2021 6-Month Competency Assessment for "Chemistry" and "Hematology": 05/13/2021 Evaluator: Signed by Testing Person-8 who was NOT listed on the CMS-209 as the Technical Consultant Annual Competency Assessment for "Chemistry" and "Hematology": 12/15/2021 Evaluator:

	Signed by Testing Person-8 who was NOT listed on the CMS-209 as the Technical Consultant The TC failed to evaluate and document performance at least semiannually during the first year of patient testing. 4. During an interview on 03/07/2022 at 11:41 am, Testing Person-3 confirmed the above findings.
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy CMS (Center for Medicare & Medicaid Services) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance for 1 of 9 Testing Persons (TP-3) responsible for high complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the laboratory's policy titled "Competency and Training" revealed: "Competency Assessment ... G. Who Can Assess Competency? The Laboratory Director must ensure that the individuals performing competency assessment are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing. Competency assessments are delegated by the Laboratory Director to qualified Manager, Supervisors, and testing personnel. The qualifications for individuals to perform competency assessments in this laboratory are: 1. Testing personnel performing high complexity testing must be assessed by an individual meeting Technical Supervisor or General Supervisor's requirements for high complexity testing. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year experience with high complexity testing. Associates degree in a laboratory science or medical technology program with at least two years' experience in with high complexity testing." 2. Review of the submitted CMS 209 form revealed Testing Person-3 (TP-3) listed to perform high complexity testing. 3. Review of personnel records from 2021 revealed the following: TP-3 Training documentation for "Molecular": training date 01/2021 6-Month Competency Assessment for "Molecular": 05/13/2021 Evaluator: Signed by Testing Person-8 who was NOT listed on the CMS-209 as the Technical Supervisor Annual Competency Assessment for "Molecular": 12/13/2021 Evaluator: Signed by Testing Person-8 who was NOT listed on the CMS-209 as the Technical Supervisor The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 4. During an interview on 03/07/2022 at 11:41 am, Testing Person-3 who was also the Technical and General Supervisor for molecular testing stated she was the only technical/general supervisor and therefore had Testing Person-8 perform her competency assessments. This confirmed the above findings.