

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0690713	(X3) Date Survey Completed 08/14/2024
Name of Provider or Supplier Urology Austin Pllc	Street Address, City, State 8701 N Mopac Expy, Ste 370, Austin, 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, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to verify the accuracy of urine cytology diagnostic interpretations at least twice annually for two of two years reviewed in 2022, 2023, and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled General Laboratory Policy.006 Proficiency Testing, reviewed 05/08/2024, under Pathology stated, "The laboratory is enrolled in the CAP PIP and NGC PT programs as part of the pathologist assessment program. All PT materials are processed and reported to CAP by the pathologist. CAP documents are retained and matched with results from CAP when received. After review by the medical director, they are filed in the CAP PT binder. Urology Austin coordinates testing with [name redacted] for interpretation of slides evaluated utilizing Fluorescent In-Situ Hybridization (FISH). [Name redacted] provides Urology Austin with actual CAP material that has been completed by their laboratory. The Urology Austin pathologist reads the smears and reports results to [name redacted]. A report is then received from [name redacted] documenting our findings and how we scored in comparison to their graded results. [Name redacted] provides two to three sets of</p>

challenge slides per calendar year for our interpretation to satisfy the Alternative PT Assessment. Any discordance with [name redacted] results require corrective action similar to that outlined in this policy for CAP PT specimens." The procedure did not address accuracy assessments for urine cytology diagnostic interpretations. B. Review of accuracy assessments for urine cytology diagnostic interpretations showed none in 2022, 2023, and to date in 2024. C. Review of the pre-survey paperwork titled Derivation of Test Count Totals had an estimated annual test volume for urine cytology at 3,402. D. Interview with the Laboratory Director on August 12, 2024 at 1620 hours in the office confirmed the findings. II. Based on review of the laboratory's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to verify the accuracy of UroVysion fluorescence in situ hybridization (FISH) diagnostic interpretations for urine bladder cancer at least twice annually for one of two years reviewed in 2022, 2023, and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled General Laboratory Policy.006 Proficiency Testing, reviewed 05/08/2024, under Pathology stated, "The laboratory is enrolled in the CAP PIP and NGC PT programs as part of the pathologist assessment program. All PT materials are processed and reported to CAP by the pathologist. CAP documents are retained and matched with results from CAP when received. After review by the medical director, they are filed in the CAP PT binder. Urology Austin coordinates testing with [name redacted] for interpretation of slides evaluated utilizing Fluorescent In-Situ Hybridization (FISH). [Name redacted] provides Urology Austin with actual CAP material that has been completed by their laboratory. The Urology Austin pathologist reads the smears and reports results to [name redacted]. A report is then received from [name redacted] documenting our findings and how we scored in comparison to their graded results. [Name redacted] provides two to three sets of challenge slides per calendar year for our interpretation to satisfy the Alternative PT Assessment. Any discordance with [name redacted] results require corrective action similar to that outlined in this policy for CAP PT specimens." B. Review of accuracy assessments for FISH diagnostic interpretations showed no results/evaluations of the assessments performed in 2023, and no accuracy assessments to date in 2024. C. Review of the pre-survey paperwork titled Derivation of Test Count Totals had an estimated annual test volume for FISH at 547. D. Interview with the Laboratory Director on August 12, 2024 at 1620 hours in the office confirmed the findings.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory's reference guide, temperature logs, stability study, patient reports, observation, requisition slips, weather app, pre-survey paperwork, and interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems in Cytology, Endocrinology, and Hematology (see 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 the laboratory's policies and procedures, laboratory's reference guide, observation, requisition slips, pre-survey paperwork, and interview, the laboratory failed to follow their own procedure for specimen transport for Urine Cytology specimens for 22 out of 22 samples observed on 08/14/2024. Findings follow. A. Review of the laboratory's policy and procedure titled UA Laboratory. Cytology.002 Cytology Fixative, reviewed 03/15/2023, stated, "Store specimens with Fixative Solution between 4-30 degrees Celsius (39-86 degrees Fahrenheit). Preferred storage and shipping conditions are on ice packs." B. Review of the laboratory's policy and procedure titled UA Laboratory.Cytology.003 Procedure For Receiving Cytology Specimens, reviewed 03/15/2023, under Procedure stated, "Specimens should be kept and properly stored in the clinics designated area to await transportation by courier. Specimens collected at all Urology Austin sites transported to the UA laboratory via Urology Austin's courier or contracted courier. Each site enters date, patient name, and type of specimens being sent daily in the 'Laboratory Specimen Log' sheet. The person entering the information initials the sheet. 1. Each specimen is checked against the specimen log to ensure all specimens listed are received... 2. Specimen are transported as to ensure specimen integrity. Daily temperatures for transport are recorded by the courier and temperature documents are reviewed each month by the Laboratory Supervisor. 3. Lab personnel will receive specimens and compare to Laboratory Specimen Log sheet in the presence of the courier to ensure all specimens are received..." The policy and procedure did not specify temperature requirements at pick-up, during transit, or drop-off. C. Review of the laboratory's policy and procedure titled General Laboratory Policy.022 Specimen Transport and Tracking, reviewed 09/07/2022, stated, "Specimens collected for testing must be transported such that there is no compromise in the quality of a sample to be analyzed. Quality results start with quality specimen collection, proper storage, and proper transport to the laboratory. Failure at any stage may lead to sample integrity compromise, possibly causing erroneous results. From the moment a specimen is collected, processed for storage, stored for pickup, and transported from clinics to the laboratory, the quality must remain intact. Submitting clinics must follow all steps outlined in General Laboratory Policy.021 (Laboratory Guidelines for Clinics). Urology Austin couriers, as well as contracted courier services, are involved with clinic specimen pickup and transport to the laboratory." Under Specimen Logs stated, "...Couriers will go to each assigned clinic location to pick up specimens. Specimens stored according to storage requirements (refrigerated, room temperature, or frozen) will be retrieved..." Under Transport to the Laboratory stated, "The courier will place specimens into the transport container. The container must meet all requirements outlined in the Exposure Control Plan, Appendix A, Courier Services Utilized for Specimen Transport requirements, Training and Documentation. Specimens must be transported under the same conditions as storage requirements, e. g., specimens requiring storage at room temperature must be transported at room

temperature." Specimen/Test Storage & Stability Transport "Cytology specimens Room Temperature Room Temperature" The policy and procedure did not define room temperature range in Celsius/Fahrenheit. D. Review of the laboratory's reference guide titled Urology Austin Central Laboratory Guide under Urine Cytology, Uro17, UroVysion Fish, Cytology & UroVysion FISH stated, "...5. Place the container with the mixed urine-preservative into a biohazard specimen transport bag and seal. Place the Allscripts Demographics and Urology Austin Pathology Requisition (triplicate form) in the outer sleeve of the bag (never inside with the specimen). 6. Place the sealed biohazard specimen transport bag containing the specimen, demographics and requisition into the labeled Cytology box provided. 7. Store and transport specimen at room temperature." E. Interview with the courier on August 13, 2024 at 1435 hours in the laboratory confirmed he did not monitor the temperature of the specimens transported at room temperature. Interview with the courier on August 13, 2024 at 1645 hours in the laboratory confirmed he did not document specimen temperature during transport. F. Surveyor observed on 08/14/2024 at 1400 hours urine Cytology specimens packaged to be sent to [name redacted] by FedEx as listed by requisition number and date of collection (no time of collection on slip) without ice packs: 1. 37190 08/12/2024 2. 37203 08/12/2024 3. 40584 08/12/2024 4. 41227 08/12/2024 5. 41420 08/12/2024 6. 41421 08/12/2024 7. 30827 08/13/2024 8. 30828 08/13/2024 9. 33206 08/13/2024 10. 37288 08/13/2024 11. 40272 08/13/2024 12. 40329 08/13/2024 13. 40330 08/13/2024 14. 40587 08/13/2024 15. 40589 08/13/2024 16. 41225 08/13/2024 17. 41226 08/13/2024 18. 41271 08/13/2024 19. 41419 08/13/2024 20. 40326 08/14/2024 21. 41224 08/14/2024 22. 41270 08/14/2024 G. Review of the pre-survey paperwork titled Derivation of Test Count Totals had an estimated annual test volume for urine Cytology at 3,402. H. Interview with the administrative assistant on 08/14/2024 at 1400 hours confirmed it was laboratory practice for the clinic to add the urine 2:1 with preservative, and it is received in the laboratory without ice packs, stored at room temperature in the lab, and is shipped the following day to [name redacted] by FedEx for the technical component without ice packs or any shipping temperature indicators. I. It was laboratory practice that the cytology slides to come back to the laboratory for diagnostic interpretation by the laboratory director. II. Based on review of the manufacturer's instructions, laboratory's policies and procedures, laboratory's reference guide, observation, requisition slips, pre-survey paperwork, and interview, the laboratory failed to follow their own procedure for specimen transport for UroVysion fluorescence in situ hybridization (FISH) for 10 out of 10 samples observed on 08/14/2024. Findings follow. A. Review of the manufacturer's package insert UroVysion Bladder Cancer Kit, April 2020, under Intended Use stated "The UroVysion Bladder Cancer Kit is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer." And under Specimen Collection and Transport stated, "The UroVysion Kit is designed for use on voided urine specimens. Perform urine collection at the physician's office. Mix voided urine 2:1 with preservative: Carbowax or PreservCyt preservatives are recommended. Transfer up to 50 mL centrifuge tube or other tightly-capped plastic container. Use of any other preservative must be validated by the individual laboratory. If urine is not shipped immediately after collection, refrigerate immediately and ship via overnight courier within 24 hours. The preferred storage and shipping conditions are on ice packs, but specimens may be stored and shipped at temperatures up to 25 degrees Celsius. Urine stored in Carbowax or PreservCyt under these conditions has been shown to be stable for 1 week; however, it is recommended that specimens be processed to the point of fixed cell pellets within 72 hours of collection. Performance characteristics of the UroVysion test under any other conditions must be determined and validated by the user." B. Review of the

laboratory's policy and procedure titled UA Laboratory.Cytology.002 Cytology Fixative, reviewed 03/15/2023, stated, "Store specimens with Fixative Solution between 4-30 degrees Celsius (39-86 degrees Fahrenheit). Preferred storage and shipping conditions are on ice packs." The laboratory's policy exceeded the manufacturer's storage and shipping requirements of 25 degrees Celsius. C. Review of the laboratory's policy and procedure titled UA Laboratory.Cytology.003 Procedure For Receiving Cytology Specimens, reviewed 03/15/2023, under Procedure stated, "Specimens should be kept and properly stored in the clinics designated area to await transportation by courier. Specimens collected at all Urology Austin sites transported to the UA laboratory via Urology Austin's courier or contracted courier. Each site enters date, patient name, and type of specimens being sent daily in the 'Laboratory Specimen Log' sheet. The person entering the information initials the sheet. 1. Each specimen is checked against the specimen log to ensure all specimens listed are received... 2. Specimen are transported as to ensure specimen integrity. Daily temperatures for transport are recorded by the courier and temperature documents are reviewed each month by the Laboratory Supervisor. 3. Lab personnel will receive specimens and compare to Laboratory Specimen Log sheet in the presence of the courier to ensure all specimens are received..." The policy and procedure did not specify temperature requirements at pick-up, during transit, or drop-off. D. Review of the laboratory's policy and procedure titled General Laboratory Policy.022 Specimen Transport and Tracking, reviewed 09/07/2022, stated, "Specimens collected for testing must be transported such that there is no compromise in the quality of a sample to be analyzed. Quality results start with quality specimen collection, proper storage, and proper transport to the laboratory. Failure at any stage may lead to sample integrity compromise, possibly causing erroneous results. From the moment a specimen is collected, processed for storage, stored for pickup, and transported from clinics to the laboratory, the quality must remain intact. Submitting clinics must follow all steps outlined in General Laboratory Policy.021 (Laboratory Guidelines for Clinics). Urology Austin couriers, as well as contracted courier services, are involved with clinic specimen pickup and transport to the laboratory." Under Specimen Logs stated, "...Couriers will go to each assigned clinic location to pick up specimens. Specimens stored according to storage requirements (refrigerated, room temperature, or frozen) will be retrieved..." Under Transport to the Laboratory stated, "The courier will place specimens into the transport container. The container must meet all requirements outlined in the Exposure Control Plan, Appendix A, Courier Services Utilized for Specimen Transport requirements, Training and Documentation. Specimens must be transported under the same conditions as storage requirements, e. g., specimens requiring storage at room temperature must be transported at room temperature." Specimen/Test Storage & Stability Transport "Cytology specimens Room Temperature Room Temperature" The policy and procedure did not define room temperature range in Celsius/Fahrenheit. E. Review of the laboratory's reference guide titled Urology Austin Central Laboratory Guide under Urine Cytology, Uro17, UroVysion Fish, Cytology & UroVysion FISH stated, " ...5. Place the container with the mixed urine-preservative into a biohazard specimen transport bag and seal. Place the Allscripts Demographics and Urology Austin Pathology Requisition (triplicate form) in the outer sleeve of the bag (never inside with the specimen). 6. Place the sealed biohazard specimen transport bag containing the specimen, demographics and requisition into the labeled Cytology box provided. 7. Store and transport specimen at room temperature." F. Interview with the courier on August 13, 2024 at 1435 hours in the laboratory confirmed he did not monitor the temperature of the specimens transported at room temperature. Interview with the courier on August 13, 2024 at 1645 hours in the laboratory confirmed he did not document specimen temperature during transport. G. Surveyor observed on 08/14/2024 at 1400 hours FISH specimens

packaged to be sent to [name redacted] by FedEx as listed by requisition number and date of collection (no time of collection on slip) without ice packs: 1. 37190 08/12/2024 2. 37203 08/12/2024 3. 30827 08/13/2024 4. 37288 08/13/2024 5. 40329 08/13/2024 6. 40330 08/13/2024 7. 41271 08/13/2024 8. 41413 08/13/2024 9. 40272 08/13/2024 10. 40326 08/14/2024 H. Review of the pre-survey paperwork titled Derivation of Test Count Totals had an estimated annual test volume for FISH at 547. I. Interview with the administrative assistant on 08/14/2024 at 1400 hours confirmed it was laboratory practice for the clinic to add the urine 2:1 with preservative, and it is received in the laboratory without ice packs, stored at room temperature in the lab, and is shipped the following day to [name redacted] by FedEx for the technical component without ice packs or any shipping temperature indicators. J. It was laboratory practice that the FISH picture comes back to the laboratory for diagnostic interpretation by the laboratory director. III. Based on review of the manufacturer's instructions, laboratory's policies and procedures, interview, observation, requisition slips, temperature logs, test reports, pre-survey paperwork, and interview, the laboratory failed to follow their own procedure for specimen transport for testosterone for 10 out of 10 samples observed on 08/13/2024. Findings follow. A. Review of the manufacturer's package insert Cobas Elecsys Testosterone II, 07/2023, under Specimen collection and preparation stated, "Stable for 1 week at 2-8 degrees Celsius, 6 months at -20 degrees Celsius (+/- 5 degrees Celsius). Freeze only once." B. Review of the laboratory's policy and procedure titled Chemistry.cobas e 411.008 Elecsys Testosterone II, reviewed 01/23/2023, under Specimen stated, " ... The specimen is then stored at 2-8 degrees Celsius until transported and during transit to the laboratory. Upon receipt and initial processing into the laboratory, the specimen is then stored at 2-8 degrees Celsius until tested. Specimen stability is one week at 2-8 degrees Celsius, up to 6 months when stored at -20 degrees Celsius (+/- 5 degrees Celsius). Freeze only once. There is no manufacturer statement of claim for stability at room temperature." C. Review of the laboratory's policy and procedure titled General Laboratory Policy.022 Specimen Transport and Tracking, reviewed 09/07/2022, stated, "Specimens collected for testing must be transported such that there is no compromise in the quality of a sample to be analyzed. Quality results start with quality specimen collection, proper storage, and proper transport to the laboratory. Failure at any stage may lead to sample integrity compromise, possibly causing erroneous results. From the moment a specimen is collected, processed for storage, stored for pickup, and transported from clinics to the laboratory, the quality must remain intact. Submitting clinics must follow all steps outlined in General Laboratory Policy.021 (Laboratory Guidelines for Clinics). Urology Austin couriers, as well as contracted courier services, are involved with clinic specimen pickup and transport to the laboratory." Under Specimen Logs stated, "...Couriers will go to each assigned clinic location to pick up specimens. Specimens stored according to storage requirements (refrigerated, room temperature, or frozen) will be retrieved...." Under Transport to the Laboratory stated, "The courier will place specimens into the transport container. The container must meet all requirements outlined in the Exposure Control Plan, Appendix A, Courier Services Utilized for Specimen Transport requirements, Training and Documentation. Specimens must be transported under the same conditions as storage requirements, e.g., specimens requiring storage at room temperature must be transported at room temperature." Specimen/Test Storage & Stability Transport "Testosterone 2-8 degrees Celsius up to 7 days Refrigerated (Cold Packs)" The policy and procedure did not define "refrigerated" transport temperature range in Celsius/Fahrenheit. D. Interview with technical consultant #1 (as listed on the CMS Form 209) on 08/13/2024 at 1445 on the phone with the courier during his route stated the thermometer in the insulated bag was at 16 degrees Celsius. E. Surveyor observed on 08/13/2024 at 1645 hours the courier was

dropping off specimens and the thermometer in his insulated bag with ice packs was read at 13 degrees Celsius. The following samples were in the bag: Accession number Test Picked up from clinic Date & time of collection 1. 718446 Testosterone 1:00 pm 08/13/2024 at 8:22 am 2. 718532 Testosterone 1:00 pm 08/13/2024 at 8:55 am 3. 718558 Testosterone 1:00 pm 08/13/2024 at 9:10 am 4. 718623 Testosterone 1:00 pm 08/13/2024 at 10:01 am 5. 718678 Testosterone 1:00 pm 08/13/2024 at 10:14 am 6. 718764 Testosterone 2:00 pm 08/13/2024 at 12:15 pm 7. 718479 Testosterone 2:45 pm 08/13/2024 at 8:38 am 8. 718688 Testosterone 2:45 pm 08/13/2024 at 10:19 am 9. 718752 Testosterone 4:12 pm 08/13/2024 at 11:52 am 10. 718803 Testosterone 4:12 pm 08/13/2024 at 2:58 pm F. Surveyor observed on August 13, 2024 at 1650 hours in the laboratory using personal temperature gun, the temperature of the insulated bag and "refrigerated" specimens was 13 degrees Celsius. G. Review of the Specimen Transport Temperature Log from January 2024 to May 2024 showed the daily logged temperatures were between 15 to 30 degrees Celsius. The acceptable range was above the manufacturer's requirements. H. Review of the test reports for the above samples showed testing was completed and reported on 08/13/2024. I. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 45,831 in endocrinology. J. Interview with the courier on August 13, 2024 at 1645 hours would document the insulated bag thermometer temperature on the Specimen Transport Temperature Log, but thought the acceptable temperature range in the insulated bag with ice packs was 15-30 degrees Celsius and confirmed he did not document specimen temperature during transport.

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 policies and procedures, verification of performance specifications, presurvey paperwork, and interview, the laboratory failed to verify the performance specifications for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for normal reference ranges for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled General laboratory Policy.031 New Instrument or New Assay Protocol, reviewed 09/09/2022, stated, "... When any new instrument or piece of equipment is purchased, or when a new assay is considered for in-house testing, guidelines must be in place to ensure all required protocols are followed. This includes any regulatory requirements consistent with best laboratory practices." and under New Instrumentation/Equipment, Major Service or Relocation stated, "The laboratory must verify the performance of all instruments and equipment prior to initial use, after major maintenance or service, and after major relocation to ensure they continue to function according to manufacturer specifications. Instrument/equipment performance verification (NOT to be confused with validation or verification of the test method performance specifications) ..." The policy and procedure did not define what was required for the verification of performance specifications when validating new instrumentation or assays. B. Review

of the verification of performance specifications for the Sysmex XN-530, 04/05/2024 (elapsed time four months), showed no verification of the normal reference range. The normal range study was requested on August 13, 2024 at 1100 hours but not provided. C. Review of the verification of performance specifications for the Sysmex XN-330 (in excess of two years) showed no verification of the normal reference range. D. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 31,550 for Hematology. E. Interview with the former testing person on August 13, 2024 at 1100 hours confirmed the normal reference range study had not been performed, that they were using [name redacted] reference ranges and the Laboratory Director had approved them. II. Based on review of the laboratory's policies and procedures, verification of performance specifications, presurvey paperwork, and interview, the laboratory failed to verify the performance specifications for Testosterone, Beta Human Chorionic Gonadotropin, Prostate Specific Antigen (PSA), Free PSA, Estradiol, Alpha Feto Protein, Sex Hormone Binding Globulin (SHBG), Prolactin, Luteinizing Hormone (LH), and Follicular Stimulating Hormone (FSH) for normal reference range using the Roche Cobas e411 for 16 of 16 months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled General laboratory Policy.031 New Instrument or New Assay Protocol, reviewed 09/09/2022, stated, "... When any new instrument or piece of equipment is purchased, or when a new assay is considered for in-house testing, guidelines must be in place to ensure all required protocols are followed. This includes any regulatory requirements consistent with best laboratory practices." and under New Instrumentation/Equipment, Major Service or Relocation stated, "The laboratory must verify the performance of all instruments and equipment prior to initial use, after major maintenance or service, and after major relocation to ensure they continue to function according to manufacturer specifications. Instrument/equipment performance verification (NOT to be confused with validation or verification of the test method performance specifications) ..." The policy and procedure did not define what was required for the verification of performance specifications when validating new instrumentation or assays. B. Review of the verification of performance specifications for the Roche Cobas e411 , 03/24 /2023 (elapsed time 16 months), showed no verification of the normal reference range. The normal range study was requested on August 13, 2024 at 1240 hours but not provided. C. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 45,831 in Endocrinology. D. Interview with the former testing person on August 13, 2024 at 1240 hours confirmed the normal reference range study had not been performed, that they were using [name redacted] reference ranges and the Laboratory Director had approved them. III. Based on review of the manufacturer's instructions, the laboratory's policy and procedure, stability study, patient reports, presurvey paperwork, and interview, the laboratory failed to ensure an extended specimen stability study was performed for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for nine out of 10 outpatient samples observed on 08/13/2024. Findings follow. A. Review of the Sysmex XN-530/XN-330 Basic Operation manual, AK803790 09/2021, on page 120 at 4.3 Preparing Samples, for Handling Whole Blood stated, "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 to 8 degrees Celsius until it can be analyzed..." The manufacturer did not define the stability of the CBC beyond 4 hours after collection. B. Review of the Sysmex XN-530/XN-330 General Information manual, BV237179 09/2021, on page 58 at Chapter 5 Instrument Specifications stated, "Long term stability is determined by comparing the results of the initial analysis (within 2 hours of collection) to results from samples stored at controlled room and refrigerated temperature for 48 hours..." C. Review of

the laboratory's policy and procedure titled Heme Policy .015 Sysmex XN-530-Specimen Requirements, under C. Specimen Stability stated, "1. EDTA blood samples are optimal when testing is performed within 4 hours of collection at 18-25 degrees Celsius. a. If sample cannot be tested with 4 hours, refrigerate at 2-8 degrees Celsius for up to 48 hours.... 3. Samples that have not been refrigerated are stable at room temperature (18 to 25 degrees Celsius) for up to 24 hours." D. The laboratory's specimen stability study was requested on August 13, 2024 at 1155 hours but not provided. E. Random review of patient reports from the afternoon courier drop off on 08/12/2024 and 08/13/2024 revealed 9 out of 10 exceeded the manufacturer's stability of 4 hours as listed by Sample No, date and time of collection, date and time of run, and elapsed time: Sample Number Test Collection date and time Run date and time Elapsed Time 1. 718228 H&H 08/12/2024 at 11:07 am 08/13/2024 at 8:05 am 20 hours, 58 minutes 2. 718223 H&H 08/12/2024 at 10:57 am 08/13/2024 at 8:04 am 21 hours, 7 minutes 3. 718200 CBC 08/12/2024 at 10:41 am 08/13/2024 at 1:52 pm 27 hours, 11 minutes 4. 718192 H&H 08/12/2024 at 10:31 am 08/13/2024 at 8:05 am 21 hours, 34 minutes 5. 718134 H&H 08/12/2024 at 8:51 am 08/13/2024 at 8:04 am 23 hours, 13 minutes 6. 718622 CBC 08/13/2024 at 10:01 am 08/13/2024 at 5:19 pm 7 hours, 18 minutes 7. 718557 CBC 08/13/2024 at 9:10 am 08/13/2024 at 6:03 pm 8 hours, 53 minutes 8. 718679 H&H 08/13/2024 at 10:14 am 08/13/2024 at 5:18 pm 7 hours, 4 minutes 9. 718478 H&H 08/13/2024 at 8:38 am 08/13/2024 at 5:18 pm 8 hours, 40 minutes NOTE: It was laboratory practice for the afternoon drop-off to be run the following day. Specimens 6-9 were run 08/13/2024 because the tech stayed later than normal. F. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 31,550 for Hematology. G. Interview with the courier on August 12, 2024 at 1650 hours acknowledged when he dropped off specimens at 4:30 pm, they would put the specimens in the refrigerator for testing the following day. H. Interview with technical consultant #2 (as listed on the CMS form 209) on August 13, 2024 at 1420 hours confirmed a stability study to establish the extended specimen stability of the CBC was not performed.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the quality control (QC) records, patient query, patient reports, slide tracking logs, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Uro17 Immunocytochemical (ICC) stain used for the detection of bladder cancer in urine specimens for three of three days reviewed. Finding follow. A. Quality control records for Uro17 were requested on August 13, 2024 at 1625 but not provided. B. Review of a patient query showed Uro17 testing began 03/18/2024 (elapsed time four months 26 days). C. Random review of patient reports showed the following dates without the documentation of QC: Accession # Date Reported 1. 3207423-2024 03/30/2024 2. 3207902-2024 04/03/2024 3. 3213724-2024 05/14/2024 D. Review of the Daily Slide

	<p>Tracking Form from 03/25/2024 to 04/17/2024 showed the date the above slides (at C) were created and sent to the laboratory with 69 patients tested: Accession # Total # of patients Created and sent 1. 3207423-2024 22 03/25/2024 2. 3207902-2024 15 03/27/2024 3. 3213724-2024 32 04/17/2024 E. Interview with the Histopathology Manager on August 13, 2024 at 1625 hours confirmed the Laboratory Director had not been documenting quality control for the Uro17 test.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies and procedures, interview, observation, requisition slips, temperature logs, stability study, patient reports, verification of performance specifications, pre-survey paperwork, and interview, the Laboratory Director failed to provide technical and scientific oversight of the laboratory for two of two years reviewed. Findings follow. 1. The Laboratory Director failed to monitor and evaluate the overall quality of the preanalytic systems; and correct problems in testing performed in Endocrinology for 10 out of 10 samples reviewed (refer to D6007). 2. The Laboratory Director failed to ensure the verification of performance specifications was performed for normal reference range for two of two new instruments and the extended specimen stability for the Complete Blood Count (CBC) for nine out of 10 outpatient samples observed (refer to D6013).</p>
<p>D6007</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies and procedures, interview, observation, requisition slips, temperature logs, test reports, pre-survey paperwork, and interview, the Laboratory Director failed to monitor and evaluate the overall quality of the preanalytic systems; and correct problems in testing performed in Endocrinology for 10 out of 10 samples reviewed. Findings follow. 1. The Laboratory Director failed to ensure the laboratory followed their own procedure for specimen transport for testosterone for 10 out of 10 samples received on 08/13/2024 (see D5311 III).</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory's policies and procedures, verification of performance specifications, stability study, patient reports, presurvey paperwork, and interview, the Laboratory Director failed to ensure the verification of performance specifications was performed for normal reference range for two of two new instruments and the extended specimen stability for the Complete Blood Count (CBC) for nine out of 10 outpatient samples observed. Findings follow.
1. The Laboratory Director failed to ensure the laboratory verified the performance specifications for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for normal reference ranges for two of two years reviewed (see D5421 I). 2. The Laboratory Director failed to ensure the laboratory verified the performance specifications for Testosterone, Beta Human Chorionic Gonadotropin, Prostate Specific Antigen (PSA), Free PSA, Estradiol, Alpha Feto Protein, Sex Hormone Binding Globulin (SHBG), Prolactin, Luteinizing Hormone (LH), and Follicular Stimulating Hormone (FSH) for normal reference range using the Roche Cobas e411 for 16 of 16 months reviewed (see D5421 II). 3. The Laboratory Director failed to ensure an extended specimen stability study was performed for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for nine out of 10 outpatient samples observed on 08/13/2024 (see D5421 III).

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, laboratory's policies and procedures, interview, observation, requisition slips, temperature logs, test reports, pre-survey paperwork, and interview, the Technical Consultant failed to provide technical and scientific oversight of the laboratory for testing performed in Endocrinology for 10 out of 10 samples reviewed. Findings follow. 1. The Technical Consultant failed to ensure the laboratory followed their own procedure for specimen transport for testosterone for 10 out of 10 samples received on 08/13/2024 (see D5311 III).

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
 Based on review of the manufacturer's instructions, laboratory's policies and procedures, verification of performance specifications, stability study, patient reports, presurvey paperwork, and interview, the Technical Consultant failed to ensure the verification of performance specifications was performed for normal reference range for two of two new instruments. Findings follow. 1. The Technical Consultant failed to ensure the laboratory verified the performance specifications for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for normal reference ranges for two of two years reviewed (see D5421 I). 2. The Technical Consultant failed to ensure the laboratory verified the performance specifications for Testosterone, Beta Human Chorionic Gonadotropin, Prostate Specific Antigen (PSA), Free PSA, Estradiol, Alpha Feto Protein, Sex Hormone Binding Globulin (SHBG), Prolactin, Luteinizing Hormone (LH), and Follicular Stimulating Hormone (FSH) for normal reference range using the Roche Cobas e411 for 16 of 16 months reviewed (see D5421 II). 3. The Technical Consultant failed to ensure an extended specimen stability study was performed for the Complete Blood Count (CBC) on the Sysmex XN-530/XN-330 for nine out of 10 outpatient samples observed on 08/13/2024 (see D5421 III).

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
 Based on review of manufacturer's instructions, laboratory's policies and procedures, laboratory's reference guide, observation, requisition slips, pre-survey paperwork, quality control (QC) records, patient query, patient reports, slide tracking logs, and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings follow. 1. The Laboratory Director failed to ensure the laboratory performed quality laboratory services for all aspects of test performance, including the preanalytic phase of testing for two of two urine cytology tests observed on 08/14/2024 (refer to D6082). 2. The Laboratory Director failed to ensure the laboratory documented the intended reactivity to ensure predictable staining characteristics for the Uro17 Immunocytochemical (ICC) stain used for the detection of bladder cancer in urine specimens for three of three days reviewed (refer to D6093).

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's instructions, laboratory's policies and procedures, laboratory's reference guide, observation, requisition slips, pre-survey paperwork, and

interview, the Laboratory Director failed to ensure the laboratory performed quality laboratory services for all aspects of test performance, including the preanalytic phase of testing for two of two urine cytology tests observed on 08/14/2024. Findings follow. 1. The Laboratory Director failed to ensure the laboratory followed their own procedure for specimen transport for Urine Cytology specimens for 22 out of 22 samples observed on 08/14/2024 (see D5311 I). 2. The Laboratory Director failed to ensure the laboratory followed their own procedure for specimen transport for UroVysion fluorescence in situ hybridization (FISH) for 10 out of 10 samples observed on 08/14/2024 (see D5311 II).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the quality control (QC) records, patient query, patient reports, slide tracking logs, and interview, the laboratory director failed to ensure the laboratory documented the intended reactivity to ensure predictable staining characteristics for the Uro17 Immunocytochemical (ICC) stain used for the detection of bladder cancer in urine specimens for three of three days reviewed (see D5601).

D6112

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, laboratory's policies and procedures, laboratory's reference guide, observation, requisition slips, pre-survey paperwork, and interview, the technical supervisor failed to provide technical and scientific oversight of the laboratory for two of two urine cytology tests observed on 08/14/2024. Findings follow. 1. The technical supervisor failed to ensure the laboratory followed their own procedure for specimen transport for Urine Cytology specimens for 22 out of 22 samples observed on 08/14/2024 (see D5311 I). 2. The technical supervisor failed to ensure the laboratory followed their own procedure for specimen transport for UroVysion fluorescence in situ hybridization (FISH) for 10 out of 10 samples observed on 08/14/2024 (see D5311 II).