Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301189	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Urology Centers Of Alabama, Pc	3485 Independence Drive, Birmingham, AL	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) (2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed to enroll in an approved Proficiency Testing program for the Urine Sediment analysis. This was noted for two of the three events in 2024 and two of the three events in 2025. The findings include: 1. A review of the API PT records revealed no evidence of enrollment in a proficiency testing program for the 2024 Event 2 and Event 3, and 2025 Event 1 and 2 in the Urine Sediment analysis. No evidence of alternative accuracy verification procedure was available for review. 2. During the Day 1 exit conference at 5:00 PM on 06-10-2026, the Laboratory Director and the GS confirmed the above findings.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-

	approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records and interviews with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed ensure PT results were submitted before the due date and to implement a mechanism to verify the accuracy of Sperm Count analysis, a non-regulated assay. The findings include: Refer to D2127 Refer to D2130
D2127	HEMATOLOGY CFR(s): 493.851(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the API (American Proficiency Institute) Proficiency Testing (PT) records and interviews with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed to ensure PT results were submitted before the due date specified by API. This was noted for one of the three 2025 Hematology PT events. The findings include: 1. A review of the API PT records revealed a blank score due to "Failure to participate" on the 2025 Hematology Second Event. 2. During the Day 1 exit conference at 5:00 PM on 06-10-2026, the Laboratory Director and the GS confirmed the above findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records and interviews with the Laboratory Director (LD) and the General Supervisor (GS), the laboratory failed to implement a mechanism to verify the accuracy of Sperm Count analysis, a non-regulated assay. The surveyor noted the PT failures occurred in two consecutive events out of six from 2024 to 2025. The findings include: 1. A review of the API PT records revealed the Sperm Count analysis were unsuccessful for the following events: a) 2024 Hematology Third Event, 50 percent b) 2025 Hematology First Event, 50 percent 2. A review of the Performance Review and

	Corrective action revealed documentation the re-analysis was in range. 3. During the Day 1 exit conference at 5:00 PM on 06-10-2026, the Laboratory Director and the GS confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Policy and Procedure Manual, a lack of Abbott i-STAT ionized Calcium Validation Records, Quality Control (QC) Records, a lack of Calibration Records, and interview with the Laboratory Director and the General Supervisor (GS), who is also the Testing Personnel 1 (TP1) the laboratory: 1. failed to ensure no out-of-date equipment will be utilzed in the laboratory. 2. failed to perform Abbott i-STAT required validation studies during implementation. 3. failed to perform maintenance and function checks according to manufacturer's instructions. 4. failed to perform or late performance of Calibration-Verification (C-V). 5. failed to established an IQCP for the ionized Calcium testing on the i-STAT analyzer. Findings include: 1. Refer to 5417 2. Refer to D5421 3. Refer to D5429 and D5431 4. Refer to D5439 5. Refer to D5445
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observations during the laboratory tour, reviews of the refrigerator and freezer thermometers in the Chemistry and Hematology testing locations, and an interview with the General Supervisor (GS), who is also the Testing Personnel 1 (TP1), the laboratory failed to ensure in date thermometers were utilized to monitor the refrigerator and freezer temperatures where the reagents, controls and calibrators were stored. The surveyor noted three of the six thermometers had the due dates in 2024. The findings include: 1. Based on direct observation of the refrigerator and freezer thermometers during the laboratory tour at approximately 9:28 AM revealed three of the thermometers had the following due dates. A) Refrigerator with Hematology Controls, due March 28, 2024, SN221385043 B) Refrigerator with the Auto UA Controls and Calibrators, due January 30, 2024, SN221197337 C) Freezer with the Chemistry/ImmunoAssay Controls and Calibrators, due March 28, 2024, SN221385044 2. During the laboratory tour, the surveyor could not read the freezer and refrigerator temperatures because the thermometer reading fluctuated due to the defective chord connection. 3. During the Day 1 exit conference at 5:00 PM on 06-10-2026, the Laboratory Director and the GS confirmed the above findings.

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a lack of the Abbott i-STAT install validation records and interviews with the Laboratory Director (LD) and General Supervisor (GS). who is also Testing Personnel 1 (TP1), the laboratory failed to provide documentation of the validation studies. Surveyor noted there was no evidence of documentation for the i-STAT ionized Calcium testing from the date of the last survey, 04-25-2024, to the date of the current survey, 06-11-2026. Findings included: 1. A review of the Abbott Abbott i-STAT Chemistry analyzer validation process revealed no documentation of the following required verification studies. A) Accuracy B) Precision C) Reportable Range 2. The LD and the GS confirmed the above findings during the Day 2 exit conference on 06-11-2026 at 2:30 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter (B/C) AU-480, AU-5820, DxI 600, and Sysmex XN-550 Maintenance Logs, the BC AU-480 User's Guide and an interview with the General Supervisor (GS), also the Testing Personnel 1 (TP1), the laboratory failed to document the quarterly and preventive maintenances (PM) as per manufacturer's requirements. The surveyor noted two of the four quarterly maintenances required were not documented in 2025 for the AU 480 and no 2024-2026 annual PM documentations were avalible for review during the survey. The findings include: 1. A review of the B/C AU-480 Maintenance Logs revealed a place to document the quarterly maintenance for the analyzer. Staff had no documentation it was performed in July and October 2025. 2. A review of the BC AU-480 User's Guide revealed the manufacturer's maintenance copy of the log and the following requirements under Section 8. A) Maintenance Log, page 8-7 B) Quarterly, page 8-15 8.6.1 Clean the Air Filters. 8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring. 8.6.3 Replace the Wash Solution Roller Pump Tubing. 3. A review of the B/C AU 480, AU 5820, DxI 600 and Sysmex XN-550 maintennace logs revealed missing PM documentation for 2024-2026. 4. During the Day 1 exit conference at 5:00 PM on 06-10-2026, the Laboratory Director and the GS confirmed the above findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on reviews of the i-STAT maintenance logs, the ABBOTT i-STAT System Manual, pipette service records and an interview with the General Supervisor (GS), also the Testing Personnel 1 (TP1), the laboratory failed to perform and document function checks required by the manufacturer every six months on the i-STAT analyzer from the previous survey on 04-25-2024 to the current survey on 06-11-2026. The findings include: 1. A review of the i-STAT maintenance logs revealed no documentation of the manufacturer's required function checks for the Thermal Probe every six months. 2. A review of the i-STAT System Manual on page 14-17 revealed the following, "...Thermal Probe Check: Check the thermal probes on the i-STAT 1 Analyzer as follows: ...4. Interpretation of the thermal probe check value: Acceptable: a value from -0.1 to +0.1, inclusive... Documentation of Results: ... use the form included in this section of the manual to record the results." 3. The laboratory was unable to provide documentation of the thermal probes checks and pipette service records during the survey. 4. The Laboratory Director and the GS confirmed the above findings during the Day 2 exit conference on 06-11-2026 at 2:30 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Abbott i-STAT Chemistry analyzer calibration, Beckman Coulter (B/C) AU480 and an interview of the General Supervisor (GS), who is also the Testing Personnel 1 (TP1), the laboratory failed to fulfill CLIA Calibration-Verification (C-V) regulatory requirements by performing at least three levels of QC twice a day or implementing C-V procedures at least every six months. The surveyor

	noted no documentation of five of the five C-Vs due from the date of the previous survey on 04-25-2024 to the current survey on 06-11-2026. The findings include: 1. A review of the calibration records for the ionized Calcium on the Abbott i-STAT and B /C AU 480 Chemistry analyzers revealed the following. a) no C-V performed in the Abbott i-STAT for the past 24 months. b) interval of C-V performance in the B/C AU 480 was greater than six months, performed 09-04-2024, 04-02-2025, 12-02-2025, none for 2026 at the time of the survey. 2. During the Day 2 exit conference on 06-11-2026 at approximately 2:18 PM, the Laboratory Director and the GS/TP1 confirmed the above findings. GS/TP1 stated the ionized Calcium on the i-STAT was tested under waived category since it was implemented over 10 years ago and the B/C AU 480 was late due to material shipment issues. GS promised to email communication documentation of the C-V shipment issues.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on reviews of the Policy and Procedure manual for the Chem8+ ionized Calcium testing on the ABBOTT i-STAT analyzer, a workbook on the Step By Step Guide in Developing an Individualized Quality Control Plan (IQCP) and an interview with the General Supervisor (GS), who is also the Testing Personnel 1 (TP1) the surveyor determined the laboratory failed to establish a complete IQCP, which included the three required steps: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. The surveyor noted the Risk Assessment Step was missing in the IQCP from the date of the previous survey on 04-25-2024 to the current survey on 06-11-2026. The findings include: 1. A review of the Policy and Procedure manual for ABBOTT i-STAT analyzer revealed a lack of an IQCP for the ionized Calcium testing. 2. A further review of the Policy and Procedure manual revealed a workbook from the Center for Medicare and Medicaid Services indicating the three required steps, Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment when the laboratory developed an IQCP tailored to its unique testing, environment and patients. 3. An interview of the GS/TP1 during Day 2 exit conference on 06-11-2026 at 2:30 PM revealed the laboratory had considered the Abbott i-STAT ionized Calcium testing under waived category, hence, no IQCP required.
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 lack of validation records, review of the Policy and Procedure (P&P) manual, a review of the Testing Personnel (TP) records and an interview with the Laboratory Director (also serving as the Technical Supervisor (TS)/ Technical Consultant (TC) and the General Supervisor (GS), also the Testing Personnel 1 (TP1), the surveyor determined the Laboratory Director (LD) failed to perform the following responsibilities. The findings include: a) Refer to D6013 b) Refer to D6020 c) Refer to D6029 d) Refer to D6031
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on a review of the Abbott i-STAT Chemistry analyzer records and an interview with the General Supervisor (GS), also the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to ensure the ionized Calcium testing on the Abbott i-STAT was verified for pertinent performance characteristics of the method. The findings include: 1. A lack of the Abbott i-STAT validation records revealed the LD failed to ensure selected test methodology was verified for accuracy, precision and reportable range prior to patient testing. 2. During the Day 2 exit conference on 06-11-2026 at 2:30 PM, the LD/TC/TS confirmed the above findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 a review of the Policies and Procedures and an interview with the Laboratory Director (LD), also the Technical Supervisor (TS), Technical Consultant (TC), the LD failed to establish and maintain a Quality Assessment program to assure the quality of laboratory services provided. This was noted from the date of the last survey, 04-25-2024, to the date of the current survey, 06-11-2026. The findings include: 1. A review of Policies and Procedures revealed no evidence of a Quality Assurance Plan for the facility. 2. During the Day 2 exit conference on 06-11-2026 at 2:30 PM, the LD/TC/TS confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

	This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the General Supervisor (GS), also the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to ensure TP listed on the CMS 209 form (Laboratory Personnel Report) provided education documentation. This was noted for two of the nine testing personnel. The findings include: 1. A review of the personnel records revealed no education documentation for TP8 and TP9. 2. During the Day 2 exit conference on 06-11-2026 at 2:30 PM, the above-mentioned findings were reviewed and confirmed with the GS/TP1 and LD. The surveyor agreed that the laboratory could submit the documentation by 06-15-2026 at the latest, however no additional records were emailed to the surveyor.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on lack of new or updated Standard Operating Procedure (SOP) and an interviews with Laboratory Director (LD), also the Technical Supervisor (TS) /Technical Consultant (TC), and General Supervisor (GS), also Testing Personnel 1 (TP1), the LD failed to ensure a written and approved policies and procedures for the new and revised test methodologies performed in the laboratory were available for the staff during the testing process. The findings include: 1. A review of the Procedure Manual revealed a lack of written and approved SOP for the new and/or revised test procedures. 2. The LD/TS/TC and GS/TP1 confirmed the above findings during the exit conference on 06-11-2026 at 2:30 PM