Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675621	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Uthet Urology Tyler	700 Olympic Plaza Circle Suite 700, Tyler, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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 in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from American Association of Bioanalysts (AAB) for 2020 and 2021, and staff interview it was determined the laboratory failed to document required signatures attesting to the routine integration of the samples into the patient workload for 2 of 12 PT records reviewed. Findings included: 1. Review of the laboratory's PT records from AAB for 2020 and 2021 revealed: "Attestations The undersigned analyst attests that the samples were tested in the same manner as patient samples" 2. Further review of the PT records revealed no attestation signatures for the following PT events: Q3 Chemistry 2020 Tested 09/23/2020 Q3 Nonchemistry 2020 Tested 9/24/2020 3. In an

	interview on 03/15/2022 at 1005 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), after review of the data, confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's accuracy verification records for Urine Microscopy for 2019, 2020 and 2021 and staff interview it was determined the laboratory failed to document at least twice annually accuracy verification for 3 of 6 required verification intervals. Findings included: 1. Review of the laboratory's accuracy verification records for Urine Microscopy for 2019, 2020 and 2021 revealed accuracy verification was performed as follows: January 2019 January 2020 January 2021 2. The laboratory was asked to provide documentation of the required second accuracy verification for each year and no such documentation was provided. 3. In an interview on 03/15/2022 at 1145 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), after review of the data, confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from American Association of Bioanalysts (AAB) for 2020 and 2021, and staff interview it was determined the laboratory failed to document PT results' review for 6 of 12 PT events. Findings included: 1. Review of the laboratory's PT records from AAB for 2020 and 2021 revealed the following 6 of 12 PT events did not have evidence of documentation of PT results' review: Q3 Chemistry 2020 Q3 Nonchemistry 2020 Q1 Chemistry 2021 Q2 Chemistry 2021 Q3 Chemistry 2021 Q3 Nonchemistry 2021 2. In an interview on 03/15/2022 at 1010 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), after review of the data, confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's calibration verification records for its Abbott Architect i1000 chemistry analyzer for 2020 and 2021, and staff interview it was determined the laboratory failed to have policies in place addressing calibration verification for 5 of 5 analytes requiring calibration verification. Findings included: 1. Review of laboratory's policies revealed there was no policy in place addressing calibration verification requirements for analytes that required calibration verification. 2. Review of the calibration verification records for the laboroatory's Architect i1000 chemistry analyzer for 2020 and 2021 revealed the following 5 of 5 analytes did not have documentation of calibration verification: Prolactin Total PSA Free PSA FSH TSH 3. In an interview on 03/15 /2022 at 1245 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), stated that she was not aware of an existing policy addressing caibration verification. This confirmed the findings. Legend: PSA = Prostate-specific antigen FSH = Folicle stimulating ormone TSH = Thyroid stimulating hormone
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies, review of laboratory's calibration verification records for its Abbott Architect i1000 chemistry analyzer for 2020 and 2021, and staff interview it was determined the laboratory failed to document calibration verification at least once every 6 months for 3 of 3 calibration verification intervals reviewed. Findings included: 1. Review of laboratory's policies revealed there was no policy in place addressing calibration verification frequency for analytes tested on the Architect i1000 chemistry analyzer which required calibration verification. These analytes were: Prolactin Total PSA Free PSA FSH TSH 2. Review of the calibration verification records for the laboroatory's Architect i1000 chemistry analyzer for 2020 and 2021 revealed calibration verification was performed as follows: 08/27/2020 The only calibration verification for 2020 05/03/2021 9 month interval from last calibration verification 12/02/2021 7 month interval from last calibration verification 3. In an interview on 03/15/2022 at 1245 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), after review of the data, confirmed the findings. Legend: PSA = Prostate-specific antigen FSH = Folicle stimulating ormone TSH = Thyroid stimulating hormone
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of sampling of the laboratory's Daily Room Temperature & Humidity Logs for March to May of 2020 and staff interview it was determined the laboratory failed to document corrective action for 29 of 92 reviewed days when room temperatures were out of laboratory defined range. Findings included: 1. Review of a sampling of the laboratory's Daily Room Temperature & Humidity Logs for March to May of 2020 revealed the laboratory defined room temperature as 18-25C. 2. Further review of the logs revealed room temperature was out of defined range on the following days: Date: Temperature: 03/01/2020 17.6C 03/02/2020 17.9C 03/07/2020 17.2C 03/10/2020 17.6C 03/14/2020 17.2C 03/16/2020 17.4C 03/17/2020 17.4C 03/21 /2020 17.9C 03/28/2020 17.2C 04/03/2020 17.2C 04/18/2020 17.3C 04/24/2020 17.3 C 04/27/2020 17.7C 04/28/2020 17.8C 05/02/2020 17.9C 05/09/2020 19.9C 05/10 /2020 26.0C 05/16/2020 17.9C 05/17/2020 25.3C 3. The laboratory was asked to provide documentation of corrective action for the out of range temperatures and no such documentation was provided. 4. In an interview on 03/15/2022 at 1130 hours in the office testing person number 1 (as described on submitted Form 209, signed by laboratory director on 03/10/2022), after review of the data, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records, review of calibration verification records for the Architect i1000 chemistry analyzer for 2020 and 2021 and staff interview it was determined the laboratory's QA failed to identify issues with calibration verification. Refer to D5439.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from American Association of Bioanalysts (AAB) for 2020 and 2021, and staff interview it was determined the laboratory director failed to ensure PT results were reviewed as required. Refer to D5221.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment (QA) records, review of calibration verification records for the Architect i1000 chemistry analyzer for 2020 and 2021 and staff interview it was determined the laboratory director failed to ensure QA was established regarding calibration verification requirements. Refer to D5791.