Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0685192	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Triangle Urology Associates	205 Frasier Street, Durham, NC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of reagent package insert, review of operator's manual for the Clinitex Status, lack of documentation and interviews with technical consultant (TC) and nursing staff 11/13/25, the laboratory failed to follow manufacturer's instructions for the performance of urinalysis testing on the Clinitex Status. At approximately 10:30 a.m. surveyor observed two Clinitex Status analyzers in the nursing station at the facility. Surveyor also observed a nurse performing testing on the one of the Clinitex Status analyzers utilizing the Siemens Multistix 10 SG Reagent Strips. 1. The laboratory failed to monitor and document the temperature and humidity of the nursing station. Findings: a. Review of package insert for the Siemens Multistix 10 SG reagent strips revealed "STORAGE:...Store at temperatures between 15-30 C (59-86F).". b. Review of operator's manual for the Clinitex Status revealed under Specifications, "Ambient Operating Temperature Range 18C to 30C (64F to 86F) and Ambient Operating Humidity Range 18% to 80% Relative Humidity.". c. Review of laboratory records revealed no documentation the laboratory had monitored the temperature and humidity of the nursing station. 2. The laboratory failed to perform quality control (QC) as required for the Siemens Multistix 10 SG reagent strips. Findings: a. Review of package insert for the Siemens Multistix 10 SG reagent strips revealed "QUALITY CONTROL:...Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days.". b. Review of laboratory records revealed no documentation the laboratory had performed quality control as required. Interview with a nurse at approximately 10:45 a.m. confirmed the

	nurses perform urinalysis testing on the Clinitex Status analyzer. Interview with TC at approximately 10:45 confirmed the nurses perform urinalysis testing on the Clinitex Status analyzer. They stated they perform the testing every day.
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 Clinical Laboratory Improvement Amendment (CLIA) certificate database, review of 2024 and 2025 laboratory records, lack of documentation and interview with technical consultant (TC) 11/13/25, the laboratory failed to verify the accuracy of the urine microscopic and semen analysis testing at least twice annually since the provider performed microscopy procedure(PPMP) testing began in August of 2024. Findings: Review of CLIA certificate database revealed the laboratory's CLIA certificate was changed to a PPMP certificate August of 2024 and then changed to a certificate of compliance in March of 2025. Review of 2024 and 2025 laboratory records revealed no documentation of a verification of accuracy for urine microscopic and semen analysis (PPMP) testing. Interview with TC at approximately 12:15 p.m. confirmed the laboratory had no documentation of a verification of accuracy for the urine microscopic and semen analysis (PPMP) testing. She stated she was not responsible for the testing performed by the providers.
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 laboratory policy, review of 2025 Sciteck proficiency testing (PT) results, and interview with technical consultant (TC) 11/13/25, the laboratory failed to perform and document corrective action for unacceptable PT results. Findings: Review of laboratory policy "Procedure for Handling PT Samples" revealed "6. 6.1 Any unacceptable results on a PT Survey must be documented and investigated by the laboratory...6.2 Process for Investigation of Problems: 6.2.1 Review the original files and check for any clerical errors...If an error was found, document and provide an explanation. 6.2.2...re-run the sample(s) in question. 6.2.3 If results from the re-run were acceptable, document and provide an explanation for the change. 6.2.4 If results are still unacceptable: 6.2.4.1 Check quality of any calibrators and controls being used....6.3 Documentation: 6.3.1 Include documentation of the intended results. 6.3.2 Document what was done to correct problem and an explanation of the process. ...". Review of Sciteck PT result forms revealed "Results for this proficiency testing event were evaluated based on the accuracy of each laboratory's reported findings compared to the overall consensus average. A margin of +/- 20% was applied to determine acceptable performance.". Review of 2025 "Sciteck PT AutoUA Quant A Survey Graded Results" revealed the following 11 PT results that were unacceptable by a margin of +/- 20% with no documented corrective action: a. Raw Values - Sample AUA 1 - Albumin and Urobilinogen. b. Raw Values - Sample AUA 2 - Urobilinogen. c. Raw Values - Sample AUA 5 - Hemoglobin and Leukocyte. d. Normalized -

	Sample AUA 1 - Hemoglobin and Albumin. e. Normalized - Sample AUA 2 - Hemoglobin. f. Normalized - Sample AUA 4 - Hemoglobin. g. Normalized - Sample AUA 5 - Hemoglobin and Leukocyte. Review of 2025 "Sciteck PT AutoUA Quant B Survey Graded Results" revealed the following 8 PT results that were unacceptable by a margin of +/- 20% with no documented corrective action: a. Raw Values - Sample AUA-06 - Hemoglobin, Total Protein and Urobilinogen. b. Raw Values - Sample AUA-08 - Urobilinogen. c. Normalized - Sample AUA-06 - Total Protein. d. Normalized - Sample AUA-07 - Hemoglobin and Nitrite. e. Normalized - Sample AUA-08 - Urobilinogen. Interview with TC at approximately 1:15 p.m. confirmed no corrective action was performed or documented for the unacceptable PT results. They stated the instructions state a minimum score of 70% was required for a passing score, and they were unaware that unacceptable results for an analyte would require corrective action and documentation not just the final score.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2025 AU680 quality control (QC) records, lack of documentation and interview with technical consultant (TC) 11/13/25, the laboratory failed to ensure two levels of QC were within range prior to reporting patient test results approximately 37 of 74 days reviewed. Findings: Review of laboratory policy "Urinalysis Introduction and Quality Assurance Protocol" revealed under section 7 "Quality Controls: 7.1 There are five QC's each with different concentrations. Before any patients are run, the screening technologist verifies that all QC's are run and report an acceptable value. If the values are unacceptable: 7.1.1 Analyze a fresh aliquot of the failed QC. 7.1.2 If repeated results are acceptable, begin run. 7.1.3 If repeated results are unacceptable, recalibrate assay with fresh calibrators. Rerun all necessary QC samples of that assay after this calibration. If results are acceptable, begin run. If any are unacceptable, notify Technician.". Review of 2025 AU680 QC records revealed the following days in which either 1 or 2 levels of QC for an analyte was not within range prior to reporting patient test results; a. August 2025, analyte Urobilinogen; 08/19. b. September 2025, analyte Urobilinogen; 09/09 and analyte Hemoglobin; 09/05, 09/08, 09/09, 09/10, 09/11, 09/12, 09/16, 09/23, 09/24, 09 /25, 09/26, 09/29, and 09/30. c. October 2025, analyte Hemoglobin; 10/01, 10/03, 10 /08, 10/09, 10/15, 10/16, 10/21, 10/22, 10/23, 10/24, 10/28, 10/29, 10/30, and 10/31. b. November 2025, analyte Hemoglobin; 11/04, 11/05, 11/07, 11/10, 11/11, 11/12, and 11/13. During interview with TC at approximately 11:45 p.m., the TC stated when QC was not within range she would call technical support and when she did they told her it was okay to perform patient testing. The TC also stated that problems seemed to begin with the new type of reagents sent from the manufacturer.
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 laboratory procedures, review of 2025 temperature and humidity logs, lack of documentation and interview with technical consultant (TC) 11/13/25, the laboratory failed to document corrective action when refrigerator temperatures exceeded the acceptable range for the storage of the AU 680 reagents. 2025 Refrigerator temperatures were out of range 14 of 14 days in February, 17 of 21 days in March, 5 of 23 days in April. Findings: Review of laboratory procedure "Urinalysis Introduction...", revealed REAGENTS...Reagent kits...Storage 2-10 C, Refrigerated or on instrument...". Review of laboratory procedure "Monitoring Temperature-Dependent Equipment" revealed "1. Refrigerators and Freezers...if acceptable temperature ranges for refrigerators and/or freezers are exceeded, reagents, controls, calibrators, etc. must be evaluated for possible adverse effects. Results should be included in the Reagent Validation Records log." Review of 2025 refrigerator temperature logs revealed the following dates in which the temperature had exceeded 2-10 C and no corrective action was documented. a. 2/10 - 2/15, 2/17 - 2/19, 2/21 and 2/24 - 2/28; 14 of 14 days. b. 3/3 - 3/7, 3/10 - 3/14, 3/18, 3/19, 3/24 and 3/26 - 3/28; 17 of 21 days. c. 4/2, 4/7, 4/8, 4/11 and 4/16; 5 of 23 days. Review of laboratory records revealed no documentation of corrective action when refrigerator temperatures had exceeded the acceptable range. Interview with TC at approximately 12:45 p.m. confirmed there was no documentation of corrective action.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2025 Sciteck proficiency testing (PT) results, and interview with technical consultant (TC) 11/13/25, the laboratory director (LD) failed to ensure the laboratory's corrective action plan for unacceptable PT results was followed. Findings: See D5221.
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 review of laboratory procedure, review of personnel training records, lack of

	documentation and interview with technical consultant (TC) 11/13/25, the laboratory director (LD) failed to ensure training was documented and/or completed for 1 of 2 testing personnel (TP) who perform testing on the AU680 analyzer. Findings: Review of laboratory procedure "Training and Training Verification" revealed "2. New hires must be trained in laboratory procedure before attempting to perform analysis, report results, or perform any other laboratory function....b. Initial training must be documented...signed and dated by the trainer and trainee...". Review of laboratory personnel training records revealed no documentation of training for TP #3. Interview with TC at approximately 12:00 p.m. confirmed there was no documentation of training for TP #3. They stated they had trained them to fill in, but the training was not documented.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of 2024 and 2025 laboratory personnel records, lack of documentation and interview with technical consultant (TC) 11/13/25, the laboratory director (LD) failed to ensure a competency assessment policy or procedure was established for the TC's duties and responsibilities. The LD also failed to ensure a competency assessment policy or procedure was established for testing personnel (TP) who perform urine microscopic and semen analysis (PPMP) testing and failed to ensure competency assessments were performed for 3 of 3 TP who perform PPMP testing since August of 2024. 1. The LD failed to ensure a competency assessment policy or procedure was established for the TC's duties and responsibilities. Findings: Review of laboratory policies and procedures revealed no policy or procedure for the competency assessment of the TC. Interview with TC at approximately 12:00 p.m. confirmed the laboratory had not established a procedure or policy for the assessment of the TC's duties and responsibilities. 2. The LD failed to ensure a competency assessment policy or procedure was established for the TP who perform urine microscopic and semen analysis (PPMP) testing and failed to ensure TP competency assessments were performed for the urine microscopic and semen analysis (PPMP) testing since August of 2024. Review of laboratory policies and procedures revealed no policy or procedure for the competency assessment of the TP who perform urine microscopic and semen analysis (PPMP) testing. Review of 2024 and 2025 laboratory records revealed no documentation of a competency assessments for 3 of 3 TP, TP #4, TP #5 and TP #6 since August of 2024. During interview with TC at approximately 12:30 p. m. the TC stated they were unsure who was responsible for the competency assessments of the TP who perform the urine microscopic and semen analysis (PPMP) testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with technical consultant (TC) 11/13/25, the laboratory director (LD) failed to specify in writing the responsibilities and duties of the technical consultant (TC) and failed to specify in writing the examinations and/or testing each individual is authorized to perform. 1. The LD failed to specify in writing the responsibilities and duties of the technical consultant (TC) since they began employment approximately January of 2025. Findings: Review of laboratory records revealed no documentation the LD specified in writing the responsibilities and duties of the TC. Interview with TC at approximately 11:30 a.m. confirmed the LD did not specify in writing their duties and responsibilities. The TC stated they have an old job description from a previous procedure manual, but there was no documentation the LD had specified in writing their duties and responsibilities as TC since their employment began. 2. The LD failed to specify in writing the examinations and/or testing each individual is authorized to perform. Findings: Review of laboratory records revealed no documentation the LD specified in writing the examinations and/or testing each individual is authorized to perform. Interview with TC at approximately 11:30 a.m. confirmed their was no documentation the LD had specified in writing the examinations and/or testing each individual is authorized to perform. They also stated testing personnel (TP #2 and the TC) perform testing on the AU680 and the LD and other providers (TP #4, #5 and #6) perform urine microscopic and semen analysis (PPMP) testing.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2025 AU680 quality control (QC) records, lack of documentation and interview with technical consultant (TC) 11/13/25, the technical consultant (TC) failed to ensure patient test results were not reported when quality control results were not within acceptable ranges for the testing performed on the AU680. Findings: See D5481.