

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0681006	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Alliance Urology Specialists	Street Address, City, State 509 North Elam Avenue, 2nd Floor, Greensboro, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 AAB (American Association of Bioanalysts) proficiency testing records 2/8 /23, the laboratory failed to evaluate the results of all ungraded proficiency testing responses for 4 of 13 test events to ensure corrective action was taken and documented as needed. Findings: Review of the laboratory's quality assessment plan revealed "... SECTION 3 - QUALITY SYSTEMS ... 3.2.1 General Laboratory Phase ... Proficiency Testing ... Graded results are reviewed and documented as satisfactory or unsatisfactory. Results not scored or ungraded is to be evaluated as a self-grade and documented on approved corrective action form. ..." Review of 2020, 2021, and 2022 AAB proficiency testing records revealed the results were signed by the laboratory director to indicate review. Review of 2020, 2021, and 2022 AAB proficiency testing records revealed ungraded and unacceptable urine sediment examination results were included on the following events with no corrective action documented: 1. 2020 Q2 - incorrect result for the ungraded educational urine sediment sample; 2. 2020 Q3 - incorrect result for 1 of 2 urine sediment samples; 3. 2021 Q3 - incorrect result for the ungraded educational urine sediment sample; 4. 2022 Q2 - incorrect result for 1 of 2 urine sediment samples.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of 2020, 2021, and 2022 i-STAT records and interview with technical consultant (TC) #2 on 2/8/23, the laboratory failed to test two levels of quality control material each day of patient testing or establish an IQCP (Individualized Quality Control Plan). Review of 2020, 2021, and 2022 i-STAT records revealed the instrument validation was performed 9/23-9/24/20. Review of 2020, 2021, and 2022 i-STAT records revealed the laboratory had performed an electronic simulator check each day of testing and had tested two levels of control on each new lot number of incoming cartridges, but the laboratory had not tested two levels of control material each day that patients were tested on the i-STAT. During interview at approximately 2:15 p.m., TC #1 confirmed the laboratory had not established an IQCP for the i-STAT analyzer and had not tested two levels of quality control material each day that patients were tested.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 Dirui urinalysis records 2/8/23, the laboratory failed to perform and document comparison testing for their Dirui urine analyzers at least twice a year for 2 of 3 years reviewed. Findings: Review of the laboratory's quality assessment policy revealed "... 3.2.4 Post-Analytical System ... Comparison of Test Results Laboratories with multiple instruments or multiple testing locations that perform the same test(s) are required to have test results compared every six months. Results are evaluated by the General Supervisor for any variance produced by each method..." Review of 2020, 2021, and 2022 Diuri urinalysis records revealed comparison testing was performed in June 2021, June 2022, and December 2022. There was no documentation of comparison testing twice during 2020, and no documentation of comparison testing in December 2021. This deficiency was cited on the previous survey 3/20/19.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel

records, and interview with TC (technical consultant) #2 on 2/8/23, the technical consultant failed to perform and document annual competency evaluations as required for 2 of 4 testing personnel (TP #1 and TP #4) during 2020. Review of the laboratory's quality assessment procedure revealed "... 3.2.1 General Laboratory Phase ... Personnel training and evaluation ... Employee competency assessments are completed as follows: initial, 6 months, 12 months, and annually thereafter. ..."

Review of personnel records for TP #1 and TP #4 revealed there were no records available to indicate that their competency was evaluated in 2020. During interview at approximately 10:25 a.m., TC #2 stated they were unable to locate 2020 competency evaluations for TP #1 and TP #4.