Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0681006	03/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Urology Specialists	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
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 procedure, record review and general supervisor (GS) interview on 3/20/19 at 1:00 p.m., the laboratory failed to perform and maintain documentation of comparison testing of the two Dirui H500 Urine Analysis Analyzers at least twice a year. Findings: 1. The General Policies and Procedures, section of the facilities Standard Operating Procedures, has the subsection of Laboratory Quality Assessment Plan, CMP-001 Revision: 001, that reads on page 19, under '...Comparison of Test Results Laboratories with multiple instruments testing locations that perform same test (s) are required to have test result compared every six months. Results are evaluated by the General Supervisor for any variance produced by each method that are not a reflection of differences in the reference ranges...". 2. The review of the records revealed that the comparison of test results was performed on: a. 1/24/2019 b. 6/27 /2017 3. The GS confirmed during interview at 1:00 p.m. that the laboratory was not performing the every six months comparison of test results as required.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on deficiencies cited, review of Quality Assurance (QA) policy, and quality improvement monthly records review on 3/20/19, the laboratory's quality assessment plan was not effective in identifying and correcting problems. Findings: The General Policies and Procedures, section of the facilities Standard Operating Procedures, has the subsection .3.2.5 Quality Assessment Review, CMP-001 Revision: 001, that reads on page 19, "...All quality assessment activities are documented and reviewed per specifications on monthly basis. Reviews should be retained electronically or placed in appropriate binders and signed off by he laboratory Director/Designee and Compliance Team...Identified problems should be thoroughly investigated by the General Supervisor and all contributing factors...".
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of procedures and reports, and staff interview on 3/20/19, the laboratory failed ensure the accuracy of data transmission from the laboratory information system (LIS) the electronic medial record. Findings: The General Policies and Procedures, section of the facilities Standard Operating Procedures, has the subsection 4.5 Laboratory Information System (LIS), CMP-001 Revision: 001, that reads on page 26, "...The LIS is a software system that records, manages, and stores data for clinical laboratories. Upon installation of an LIS system, functional integrity must be checked. Verification of system functionality will be performed and reviewed by the laboratory Director or Designed prior to the release of patient reports...Reports are checked against requisitions for correctness of all patient demographic data and account information. The final computer report must have the Lab Director's name, CLIA Number, ASR statement, and the correct units and reference ranges for each test..". During the records review, a laboratory report, entitled, "Verification of Lab Information System" representing two separate events were obtained. These reports outline, document and demonstrate the LIS Verification process. It reads, "...Patient final computer reports are checked for the following information and compared to the patient requisition and the instruments print off of patient results for the following: a. Correctness of all patient demographic data, b. Account information, c. Lab Director's name, d. Test results, e. Reference ranges, f. Unit of measure for test ordered, g. Test ordered and completed, h. CLIA number, i. Ten requisitions and their reports are to be verified to include each area of the lab. If a result has to be entered manually this

	information must also be reviewed...". All area reviewed were checked and the tech who performed the audit and director signed off the activity. The forms are dated 6/1 /17; and, 07/05/17 (7/13/17).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Base on review of the facility's electronic medical record (EMR) Urochart test reports and general supervisor (GS) interview on 3/20/19 at 1:30 p.m., the test report was incomplete and did not contain all required information. The reports that were printed and reviewed by the surveyor on 3/20/19 did not include the following: 1. the testing laboratory's name was present, but the address was missing; 2. the units of measures were missing; and, 3. the reference range or normality where not provided for all analytes tested and reported. During GS interview at 1:30 p.m., it was confirmed that the EMR had not been tested to confirm the presence of required results data points on the report.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on patient report review and staff interview on 3/20/19 at 9:15 a.m.; and, again at 10:30 a.m., staff failed to ensure that the laboratory's policy and procedure were followed when a patient's test report required correcting. Findings: The General Policies and Procedures, section of the facilities Standard Operating Procedures, has the subsection 5.3.1.3. Corrected or Addendum Reports, CMP-001 Revision: 001, that reads on page 41, "...When errors in the reported patient test results are detected, the laboratory will notify the authorized person ordering the test, issue a corrected report, and document the occurrence on the incident report form....The corrected report will be submitted through the LIS; the report will contain the original result along with the corrected result. Copies of both the original report and the corrected report will be filed with the completed incident report form...". During staff interview at 10:30 a.m, the staff demonstrated the laboratory's policy and procedure for correcting a patient's test report by modifying a current patient's data in the laboratory information system

	LIS. The erroneous result was visible in the Select Information System (SLS), the LIS, but it did not transmit across to the Urochart Electronic Medical Record (EMR). Upon further review, both systems failed to retain a copy of the incorrect results, to be displayed with the corrected report.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory director delegation, review of personnel records and interview with staff 3/20/19, the laboratory director failed to ensure technical consultant duties were delegated to personnel meeting the qualification requirements for technical consultant. Findings: Review of laboratory director delegation revealed the laboratory director delegated responsibility for evaluating the competency of testing personnel to 3 of the laboratory's 7 testing personnel (TP #1, TP #2, and TP #3) and to an off-site consultant. Review of personnel records revealed 3 of the 4 designated personnel had evaluated the competency of other testing personnel during 2017 and 2018. Examples: a. TP #1 evaluated the competency of TP #6 in April and September 2018; b. TP #3 evaluated the competency of TP #5 in September 2018; c. The outside consultant evaluated the competency of TP #1 in December 2017 and June 2018. Review of personnel records revealed only 1 of the 4 (TP #2) met the qualifications to serve as technical consultant: a. TP #1 had an associate degree in medical laboratory technology. b. TP #2 had a bachelor of science degree in medical technology. c. TP #3 had an associate of science degree and documentation of completion of a hospital-based medical laboratory technology training program. d. The off-site consultant had an associate degree in medical laboratory technology. During interview at approximately 1:15 p.m., the off-site consultant stated he was unaware he did not meet the requirements to serve as technical consultant for the laboratory.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's CMS (Centers for Medicare and Medicaid Services)-116 application and test menu, review of personnel records, and interview with the off-site consultant 3/20/19, the laboratory director failed to ensure testing personnel competency was evaluated for all tests performed by the laboratory. Review of the CMS-116 application and test menu for the 3/20/19 CLIA (Clinical Laboratory Improvement Amendments) initial certification survey revealed the laboratory performs post vasectomy semen analysis for the presence/absence of sperm with an estimated annual test volume of 540. Review of personnel records revealed there was no documentation that competency was evaluated for post vasectomy sperm presence /absence for 7 of 7 testing personnel during 2017 or 2018. During interview at approximately 1:00 p.m., the off-site consultant confirmed that post vasectomy sperm presence/absence had not been included in testing personnel competency evaluations during 2017 and 2018.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records 3/20/19 and the deficiency cited at D6065, the laboratory failed to verify that 2 of 7 testing personnel (TP #1, TP #2) met the minimum education requirements for performing moderate complexity testing.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with off-site management representatives 3/20/19, the laboratory failed to verify that 2 of 7 testing personnel (TP #1, TP #2) met the minimum education requirements for performing moderate complexity testing. Findings: 1. Review of personnel records for TP #1 revealed an Associate in Science degree and a certificate for completion of a hospital-based laboratory training program. The records did not include a transcript for the associate degree. 2. Review of personnel records for TP #2 revealed a Bachlor of Science degree. The bachelor's degree did not indicate a major, and the records did not include a transcript. During interview at approximately 1:00 p.m., the laboratory's off-site

	consultant and a representative from the off-site management team stated they thought the required documentation was in the personnel files. They stated additional education documentation might be available in their off-site office.