

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0314820	(X3) Date Survey Completed 02/11/2026
Name of Provider or Supplier Southeast Urology Network DbA A Michael Alabaster,	Street Address, City, State 995 S Yates Suite 1, Memphis, TN	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the SCITECK AUA-450 operator's manual, a review of the laboratory's environmental records, review of patient test records, and staff interview, the laboratory failed to define acceptable humidity ranges that were consistent with the manufacturer's requirements for operation of the SCITECK AUA-450 instrument since patient testing began on 11/14/25. The findings include: 1. Laboratory observation on 02/11/26 at 8:30 a.m. revealed the SCITECK AUA-450 used for performing patient testing for quantitative urinalysis analytes. 2. A review of the manufacturer's operator's manual revealed an environmental indoor humidity range of 45 - 85%. 3. A review of the laboratory's environmental records revealed the following: The laboratory used an acceptable humidity range of 20 - 80%. Recorded humidities were outside the manufacturer's acceptable range for 14 of 16 days in November 2025, 31 of 31 days in December 2025, 31 of 31 days in January 2026, and 10 of 10 days in February 2026. 4. A review of patient test records revealed the first patient was reported on 11/14/25 for patient 68745D. 5. The technical consultant confirmed the survey findings in an electronic mail communication received on 02/19/26 at 3:56 p.m.</p>

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 laboratory observations, a review of the manufacturer's package insert, a review of the laboratory's procedure manual, a lack of documentation, and staff interview, the laboratory failed to perform centrifuge function checks (Revolutions Per Minute (RPMs) and timer checks) for the two centrifuges used to process cloudy urines in preparation for patient testing on the SCITECK AUA-450 instrument. The findings include: 1. Laboratory observation on 02/11/26 at 8:30 a.m. revealed the SCITECK AUA-450 used for performing patient testing for quantitative urinalysis analytes. 2. The manufacturer's package insert stated that cloudy or turbid samples are to be centrifuged before analysis. 3. The laboratory procedure titled "URINALYSIS - AutoUA AUA-450" stated that urine samples suspected of containing gross blood should be centrifuged at a speed of 2500-3500 RPM for five minutes. 4. Laboratory observation on 02/11/26 at 12:05 p.m. revealed two Horizon mini E centrifuges that were used to process cloudy, turbid, or bloody urines in preparation for testing. 5. The laboratory failed to provide documentation of RPM or timer checks for the two centrifuges. 6. The technical consultant confirmed the survey findings during an interview on 02/11/26 at 2:00 p.m. and stated that the laboratory had performed 904 patient quantitative urinalysis samples since testing began on 11/14/25.

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.

This STANDARD is not met as evidenced by:

CITATION ONE: Based on laboratory observation, a review of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), a review of patient test records, a review of laboratory records, and staff interview, the laboratory failed to perform corrective action for documentation of temperature, humidity, and maintenance on dates when the laboratory was not operating since testing began on 11/14/25. The findings include: 1. Laboratory observation on 02/11/26 at 8:30 a.m. revealed the SCITECK AUA-450 used for performing patient testing for quantitative urinalysis analytes. 2. A review of the laboratory's Form CMS-116 revealed that the laboratory's hours of operation were Monday through Friday, 8-4:30 p.m. 3. A review of patient test records revealed that the first patient was reported on 11/14/25 for patient identification number 68745D for the quantitative urinalysis analytes. 4. A review of the laboratory's temperature, humidity, and maintenance records for the SCITECK AUA-450 instrument revealed documentation of maintenance, temperatures, and humidity readings on dates that the

laboratory was not open. SCITECK instrument maintenance was documented 29 of 31 days in November 2025, 31 of 31 days in December 2025, and 31 of 31 days in January 2026. Refrigerator temperatures used for storage of reagents and specimens were documented 26 of 30 days in November 2025, 31 of 31 days in December 2025, and 31 of 31 days in January 2026. Humidity was documented 26 of 30 days in November 2025, 31 of 31 days in December 2025, and 31 of 31 days in January 2026. All documents had been reviewed by either the technical consultant or laboratory director, with no documented corrective action. 5. The technical consultant confirmed the survey findings during an interview on 02/11/26 at 2:00 p.m. CITATION TWO: Based on laboratory observation, a review of the laboratory's quality assessment documentation, and staff interview, the laboratory failed to have a process in place for the review of calibration data, with approximately 904 patients reported since testing began on 11/14/25. 1. Laboratory observation on 02/11/26 at 8:30 a.m. revealed the SCITECK AUA-450 used for performing patient testing for quantitative urinalysis analytes. 2. A review of the laboratory's quality assessment documentation revealed no documented review of calibration records for the quantitative urinalysis analytes. 3. The technical consultant confirmed the survey findings during an interview on 02/11/26 at 2:00 p.m. and stated that the laboratory had tested approximately 904 patients since testing began on 11/14/25.