

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1010720	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Rice And Lake Urology Llp	Street Address, City, State 2000 10th Avenue, Suite 150, Columbus, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 26, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Policy and Procedure manual, and staff interview, the laboratory did not have a procedure for the Roche Chemstrip 10 Urinalysis Dipstick, nor a copy of the package insert saved for a reference for performing the test. Findings: 1. Based on review of the Policy and Procedure manual the laboratory did not have a procedure for the performance of the Roche Chemstrip 10 Urinalysis Dipstick. Review of a copy of the package insert from a new, unopened box of strips, stated that the strip should be read 1 min after dipping the strip in the specimen. Any color change after the one minute time interval was to be considered irrelevant. 2. Interview with staff # 2, and the office manager, on July 26, 2018, at approximately 2pm, in the front office, confirmed that the laboratory did not have a written procedure for performing the Roche Chemstrip 10 Urinalysis Dipstick. When ask about a package insert in a notebook in place of a procedure, the two staff member stated that they were unaware that they were to keep a copy of the package insert. They were however able to pull a package insert out of a new box, to use as a reference.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of the Quality Control(QC) material, during a tour of the laboratory, and staff interview, the laboratory was performing QC on the Roche Chemstrip10 strips using expired QC. One box expired in 2015, and one box expired in 2017. Findings: 1. During a tour of the laboratory, it was noted that the QC for the urinalysis Chemstrips had expired. One box had expired in 2015, and one box in 2017. They were immediately discarded. 2. Interview with staff #3, on July 26, 2018, at approximately 2:45 pm, in the lab, confirmed that the QC had expired in 2015 and 2017. The office manager was notified of the expired QC material on July 26, 2018 at approximately 2:50pm in the front office.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 the Quality Control(QC) documents, the laboratory was not meeting the laboratory's, nor the manufacturer's test system criteria for acceptability before reporting patient test results. Findings: 1. Review of the QC documents for the Broche Chemstrip 10 Urinalysis testing, confirmed that the laboratory was in fact performing QC once a day of patient testing. However there were no ranges posted to verify if the results were acceptable by the manufacturer of the QC material. When ask to contact the manufacturer for ranges associated with the most current lot number, it was determined that even though they were using Chemstrip10 manufactured by Roche , they were using Urine Controls manufactured by McKesson for McKesson Chemstrips. There were no ranges available for the McKesson QC and the Roche Chemstrip10. 2. Interview with staff#2 and the office manager, on July 26, 2018 at approximately 2:30pm, in the front office area, confirmed that they were using Roche Chemstrip 10 Urinalysis test strips and McKesson QC, and was not verifying the results before patient testing because there were no accepapble ranges available for the McKesson QC when used on the Roche Chemstrip10 strips. 3. The Laboratory Director (LD) was notified and chose to stop testing until they could evaluate a different strip and QC from a different manufacturer that provided both, strip and QC. A signed letter was provided stating the above.