

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0704401	(X3) Date Survey Completed 02/07/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 2530 Empire Drive, Winston-Salem, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of laboratory procedure, review of quality control records, observation, and interview with the GS (general supervisor) 02/07/19, the laboratory failed to discard supplies that had exceeded their expiration dates and performed testing on patient specimens when control materials were expired. Findings: 1. The laboratory performs semen analysis on the SQA-V Gold analyzer and utilizes QwikCheck Beads for quality control of the SQA-V Gold analyzer each day of patient testing. Review of package insert for "QwikCheck Beads" revealed "The expiration date assumes that QwikCheck beads are stored at room temperature in their original containers and tightly capped to prevent evaporation. Open vial shelf-life is 90 days (tightly capped, stored in the original container at room temperature or refrigerated @ 5-15 degrees Centigrade)." Review of laboratory procedure "Semen Analysis" revealed "Quality Control...QwikCheck beads...Store at room temperature...The expiration date assumes that the beads are stored at room temperature in their original containers and tightly capped to prevent evaporation." The procedure failed to include an open vial shelf life of 90 days. Review of quality control records for the SQA-V Gold analyzer revealed the following: a. QwikCheck Beads, Lot #180617001, in use on 09/22/17, expiration date 12/22/17, was in use on the following 5 days when patients were tested: 12/26/17, 12/27/17, 12/29/17, 01/02/18, and 01/03/18. b. QwikCheck Beads, Lot #14117001, in use 04/01/18, expiration date 07/01/18, was in use on the following 7 days when patients were tested: 08/06/18, 08/07/18, 08/20/18, 08/21/18, 08/22/18, 08/24/18, and 09/04/18. c. QwikCheck Beads, Lot #260418001, in use 09/05/18, expiration date 12</p>

/04/18, was in use on the following 6 days when patients were tested: 12/05/18, 12/12/18, 12/17/18, 12/18/18, 12/21/18, and 12/26/18. 2. During a tour of the laboratory at approximately 5:30 p.m., surveyors observed the following expired supplies available for use: a. 1 open container of QwikCheck Reagent Strips for leukocytes and pH, lot #72003-120717 with expiration date 01/2019 on the laboratory counter; b. 1 open bottle of Roche AMM/ETOH/CO2 calibrator, lot #29732001 with expiration date 2019-01-31 in the chemistry undercounter refrigerator #3; c. 1 box of 5 tubes of Thermo Scientific Resolve Microscopic Immersion Oil Low Viscosity, lot #355504 with expiration date 11/2017 in the cabinet beneath the microscope and 1 open tube of immersion oil with the same lot number and expiration date on the counter beside the microscope. During interview at approximately 6:00 p.m., the GS confirmed the supplies were expired.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of operator's manual, review of maintenance records and interview with the GS (general supervisor) 02/07/19, the laboratory failed to perform required maintenance on the Medical Electronic Systems (MES) SQA-V Gold analyzer. The laboratory performs semen concentration and motility analysis on the MES SQA-V Gold analyzer. Review of SQA-V Gold operator's manual, page 1, revealed "SQA-V Gold Semiannual Validation/Proficiency/QC...In order to...confirm the correct operation of the SQA-V Gold Automated Sperm Quality Analyzer, MES had developed a series of recommendations to be performed on a semiannual basis. These recommendations include...1. Semiannual System Mini-Validation and Motility /Morphology QC...It is highly recommended that the facility confirm the precision and lower limit detection...by completing an abbreviated validation study on a semi-annual basis. It is also suggested that 5 samples be compared to the backup method on an annual or semi-annual basis...2. Semiannual Instrument Calibration Confirmation... It is recommended that twice per year, the SQA-V Gold calibration is checked against the original factory calibration parameters." Review of maintenance records for "Mini-Validation" revealed the laboratory performed a validation study in April of 2017 when the analyzer was moved to a new facility. The analyzer was replaced in August of 2018. A "Mini-Validation" was not performed from April of 2017 through August of 2018, a period of approximately 16 months. Review of maintenance records for a "comparison study with the backup method" revealed the laboratory performed a validation study in April of 2017 when the analyzer was moved to a new facility. The analyzer was replaced in August of 2018. A "comparison study with the backup method" was not performed from April of 2017 through August of 2018, a period of approximately 16 months. Review of maintenance records for the "SQA-V Gold calibration check" revealed the laboratory performed a calibration check in April of 2017 and April of 2018. The analyzer was replaced in August of 2018. Exit interview with the GS at approximately 6:00 p.m. confirmed the laboratory had not performed the maintenance as required on the SQA-V Gold analyzer. She stated the laboratory was unaware the "Mini-Validation" and comparison study were requirements for the analyzer. She also stated she was under the impression that the analyzer calibration checks were to be performed annually.