

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1044735	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 448 Viking Drive Suite 100, Virginia Beach, VA	
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	An announced CLIA recertification survey was conducted at Laboratory Corporation of America Holdings on October 6, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification Form (CMS 116), procedures, calibration records, and interviews, the laboratory failed to document every six (6) month calibration procedures for one (1) automated semen analyzer according to manufacturer's protocol during the twenty-four (24) months reviewed. Findings include: 1. During a pre-survey review on 10/4/21, the inspector noted that the laboratory director indicated on the submitted CMS 116 form performance of high complexity automated semen analysis testing utilizing a SQA-V analyzer which includes patient result parameters: Sperm Concentration/Total Count, Total Motility Percentage (%), Progressive Motility %, Non-progressive Motility %, Immotility %, and</p>

Sperm Morphology, Leukocyte Concentration, and Motile Sperm Concentration. 2. Review of the laboratory's procedures revealed a Medical Electronic Systems (MES) SQA-V Gold Quality Semen Analyzer calibration protocol that outlined a manufacturer's calibration recommendation statement: "Perform SQA-V Gold calibration every 6 months. Send the calibration parameters to MES for calibration confirmation and retain subsequent comparison reports". 3. Review of the laboratory's SQA-V Gold analyzer (serial number 821) calibration records for the 24 month review timeframe (September 2019 through September 2021) revealed four calibration records dated 11/26/19, 8/19/20, 11/13/20, and 5/31/21. The lab inspector noted a nine month period between the 11/26/19 and 8/19/20 calibration documentation and inquired regarding an additional calibration performed in the timeframe of May 2020. The general supervisor (GS) stated at approximately 1:45 PM: "MES performed maintenance in February of 2020 that may have included a calibration". The inspector requested to review the February 2020 calibration records. The GS reached out to MES technical support at approximately 2:00 PM on 10/6/21. The telephone interview with the MES representative revealed no additional calibration records were documented or received by the manufacturer between November 2019 and August 2020. 4. In an exit interview with the general supervisor and primary testing personnel at approximately 2:30 PM on 10/06/21 the above findings were confirmed.