

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0229024	<b>(X3) Date Survey Completed</b> 10/18/2022
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 840 Greenbrier Circle Suite 100, Chesapeake, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Laboratory Corporation of America Holdings-Chesapeake on October 17-18, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of proficiency testing records, lack of documentation, and interviews, the laboratory failed to perform test accuracy verification twice annually for hematology semen analysis sperm viability/vitality procedure in calendar year 2021 during the twenty-two months reviewed (January 2021 to October 17-18, 2022). Findings include: 1. During a laboratory tour at approximately 1:30 PM on 10/17/22, the inspector observed the laboratory utilizing a Medical Electronic Systems Sperm Quality Analyzer (SQA) for automated semen analysis testing. The inspector inquired regarding how accuracy assessments are determined for the semen analysis parameters. The technical consultant (TC) stated on 10/17/22 at approximately 2:00 PM, "We are enrolled in proficiency testing for semen analysis and receive two events each year." 2. Review of the laboratory's hematology semen analysis proficiency testing records from January 2021 to 10/17/22, a total of three events, revealed the following documentation for the semen analysis sperm viability/vitality parameter: 2021 College of American Pathology (CAP) Semen Analysis Module A - SEM 03, SEM 04 viability/vitality challenges were not graded. CAP noted "Laboratory response submitted as sample unsatisfactory"; 2021 American Proficiency Institute (API) Semen Analysis Event 3 - viability/vitality challenge responses were evaluated and graded 100%; 2022 API Semen Analysis Event 1 - viability/vitality challenge</p>

responses were evaluated and graded 100 %. 3. The inspector requested to review additional PT or accuracy verification records for semen analysis viability/vitality testing documented in calendar year 2021. No documentation was available for review. The TC stated on 10/17/22 at approximately 4:00 PM, "In 2021, we switched to a different proficiency testing company because the CAP samples were not satisfactory. We enrolled with API in the summer of 2021 and received one event. We did not have any other PT events in 2021. We have finished one with API this year and expect another PT shipment later this month." 4. An exit interview with the laboratory supervisor on 10/18/22, at approximately 12 PM, confirmed the above findings.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Center for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), personnel files, lack of documentation, and an interview, the laboratory director (LD) failed to document competency assessment for one of two technical consultants (TC) in calendar year 2021. Findings: 1. Review of the laboratory's CMS 209 form revealed that the LD identified two TC's as also responsible for non-waived immunology, chemistry, and hematology testing during the twenty-two months reviewed (January 2021 to the date of the inspection on October 17-18, 2022). 2. Review of the available laboratory personnel files revealed no competency assessment documentation for "TC 1" for the duties of technical consultant. (See Personnel Code Sheet.) The inspector requested to review TC 1's competency assessment documentation encompassing the duties for the role of technical consultant. The lab supervisor stated on 10/17/22 at approximately 3:00 PM: "I do not have it for you to review but we can get that completed." 3. An exit interview with the laboratory supervisor on 10/18/22, at approximately 12 PM, confirmed the above findings.