

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>49D2023996</p>	<p>(X3) Date Survey Completed</p> <p>10/25/2023</p>
<p>Name of Provider or Supplier</p> <p>Laboratory Corporation Of America</p>	<p>Street Address, City, State</p> <p>4730 Puddledock Road - Suite 100, Prince George, VA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An announced CLIA recertification survey was conducted at Laboratory Corporation of America (VCI Puddledock) on October 25, 2023 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:</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of maintenance logs, procedures, lack of documentation, and interview, the laboratory failed to document performance of twice annual preventative maintenance (PM) per their established protocol for the hematology microscope in calendar year 2022 (survey review timeframe: January 2022 to the day of the inspection October 25, 2023). Findings include: 1. During a tour on 10/25/23 at 11:00 AM, the inspector noted one Nikon Model E-200, Serial #751737, microscope in the hematology laboratory utilized for patient peripheral blood smear examinations. 2. Review of the laboratory's equipment maintenance logs (timeframe: January 2022 to 10/25/23) revealed the following records of PM service completed by Southern Microscope vendor: 6/30/22, 3/16/23, 10/9/23. 3. Review of the laboratory's Preventative Maintenance and Quality Control Manual revealed a protocol (titled: LabCorp Microscope Maintenance) which outlined a duty chart and statement,</p>

"Microscope PM's are to be performed twice a year by outside service representative". The inspector requested to review additional microscope PM service recorded in calendar year 2022. No additional PM documentation was available. 4. An exit interview with the lab supervisor on 10/25/23 at 1:30 PM confirmed the above findings.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of procedures, quality assurance (QA) records, lack of documentation, and interviews, the laboratory failed to document a comparison evaluation of the two (2) methodologies utilized for patient white blood cell (WBC) differential determinations twice annually in calendar year 2022 (survey review timeframe: January 2022 to date of the survey October 25, 2023). Findings include: 1. Review of the laboratory's procedure manual revealed the following 2 procedures for determination of WBC differential counts: Sysmex XS-1000ic Complete Blood Count with automated White Blood Cell Differential, and Peripheral Blood Smear Examination for Differential. The inspector requested to review a policy for a comparison of the 2 blood cell differential count methods. The laboratory supervisor stated on 10/25/23 at 12:00 PM, "Our policy is to perform the method comparisons twice annually." 2. Review of the laboratory's QA documentation in calendar year 2022 and year to date 2023 revealed the following blood cell differential test result comparison studies for the 2 methods outlined above: Calendar year 2022 - 10/14/22 with no Lab Director (LD) review/evaluation documented; Calendar year 2023 - 4/25/23 reviewed/evaluated by LD on 5/18/23, and 10/3/23 reviewed/evaluated by LD on 10/9/23. The inspector requested to review an evaluation for the comparison evaluation recorded on 10/14/22 and to review additional WBC differential count methods' comparison evaluations completed in calendar year 2022. No additional records were available for review. 3. An exit interview with the lab supervisor on 10/25/23 at 1:30 PM confirmed the above findings.