

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2039517	<b>(X3) Date Survey Completed</b> 10/26/2023
<b>Name of Provider or Supplier</b> Laboratory Cooperation Of America	<b>Street Address, City, State</b> 263 Medical Park Boulevard, Petersburg, 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 (VCI Petersburg) on October 26, 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 and include two Conditions under 42 CFR part 493 CLIA Regulation: D2016 -42 CFR. 493.803 Successful Participation, D6076 -42 CFR. 493.1441 Laboratory Director.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and an interview, the laboratory failed to rotate Core Chemistry Module PT among testing personnel (TP) responsible for patient testing for five (5) of six (6) events reviewed (survey timeframe: January 2022 to October 26, 2023). Findings include: 1. Review of the CMS 209 form with the laboratory manager on 10/26/23 confirmed four (4) testing personnel (TP) were responsible for hematology and chemistry patient testing during the review timeframe of January 2022 to 10/26/23. 2. Review of the laboratory's scored American Proficiency Institute (API) Core Chemistry Module PT documentation, a total of 6 events (2022 Events 1-3, 2023 Events 1-3), revealed that TP A signed attestations/performed: API 2022 Events 1, 2, and 3; API 2023 Events 2 and 3. TP A signed attestations/performed 5 of 6 API Core Chemistry PT events reviewed. *See Personnel Code Sheet. 3. An exit interview with the lab supervisor on 10/26/23 at 1:30 PM confirmed the above findings.</p>

**D2015****TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on a pre-survey review of Centers for Medicare and Medicaid Services CASPER Report (CMS 0096D), proficiency testing (PT) records, procedures, lack of documentation, and interviews, the laboratory failed to retain hematology PT scored results and attestation statements signed by the laboratory director/testing personnel for one (1) of six (6) PT testing events during the twenty-two month review timeframe (January 2022 to October 26, 2023). \*REPEAT DEFICIENCY Findings include: 1. A pre-survey review of CMS 0096D report on 10/23/23 revealed the following unsatisfactory hematology analytes scored as zero (0%) reported for 2022 PT Event 2: 0760 Hematology Specialty, 0765 Cell ID White Blood Cell (WBC) Differential, 0775 Red Blood Cell (RBC Count), 0785 Hematocrit (HCT Non-Waived), 0795 Hemoglobin (HGB Non-Waived), 0805 White Blood Cell (WBC Count), 0815 Platelet (PLT Count). 2. Review of the laboratory's American Proficiency Institute (API) hematology PT records, a total of 6 events (2022 Events 1-3, 2023 Events 1-3), revealed no API scored report or signed attestation statements retained in the available PT binder logbooks for the event outlined above (2022 PT Event 2). 3. The inspector requested to review the API 2022 Event 2 Hematology PT scored result report and signed attestations. The lab manager could not locate the summary report and called API. API technical support provided the report on 10/26/23 at 12:30 PM. The printed API report revealed "0" scores for five (5) of 5 challenges on all hematology analytes due to "Failure to submit". The lab supervisor stated on 10/26/23 at 1 PM, "There was a problem submitting the results for that event and the former supervisor did a self grade after the fact, but I am not sure why the original API report and attestations are missing." 4. A review of procedures revealed a Quality Assurance Plan - which stated "The laboratory director has oversight responsibility for all activities of the laboratory including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure that the laboratory is enrolled and participates per an approved proficiency testing program for testing performed." 4. An exit interview with the lab supervisor on 10/26/23 at 1:30 PM confirmed the above findings.

**D2016****SUCCESSFUL PARTICIPATION**

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a

laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on a review of the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses in the American Proficiency Institute's Hem-5S Module for Basophil, Eosinophil, Lymphocyte, Monocyte, and Neutrophil counts in two out of three hematology PT testing events reviewed resulting in unsuccessful PT performance. See 2130

**D2127**

**HEMATOLOGY**  
CFR(s): 493.851(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:  
Based on a review of hematology proficiency testing (PT) documentation, procedures, and an interview, the laboratory failed to ensure Complete Blood Count (CBC) PT results were returned to American Proficiency Institute (API) for one (1) of six (6) events during the twenty-two month review timeframe (January 2022 to October 26, 2023). Cross Reference D2015. Findings include: 1. Review of the laboratory's API hematology PT documentation, a total of 6 events (2022 Events 1-3, 2023 Events 1-3), revealed that the laboratory failed to submit and received failure to participate scores for the following CBC module: 2022 Hematology Event 2 - 0% scores for Hematology Specialty, Cell Identification, Red Blood Cell, White Blood Cell, Platelet, Hemoglobin, and Hematocrit. 2. A review of procedures revealed a Quality Assurance Plan - which stated "The laboratory director has oversight responsibility for all activities of the laboratory including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure that the laboratory is enrolled and participates per an approved proficiency testing program for testing performed." 2. An exit interview with the lab supervisor on 10/26/23 at 1:30 PM confirmed the above findings.

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on an a review of proficiency testing (PT) records, procedure, and an interview, the laboratory failed to attain a score of at least eighty percent (80 %) of acceptable responses for Basophil, Eosinophil, Lymphocyte, Monocyte, and Neutrophil counts in two (2) out of three (3) consecutive Hematology Hem 5S Module PT events resulting in unsuccessful PT performance as reviewed on the date of the inspection, October 26, 2023. Findings include: 1. Review of American Proficiency Institute (API) Performance Summary Report provided by API technical support on 10/26/23 at 1 PM revealed the following unsatisfactory performance scores: Basophils (Hem 5S Module) - 2021 3rd Event 60 %, 2022 2nd Event 0 %; Eosinophils (Hem 5S Module) - 2021 3rd Event 60 %, 2022 2nd Event 0 %; Lymphocytes (Hem 5S Module) - 2021 3rd Event 60 %, 2022 2nd Event 0 %; Monocytes (Hem 5S Module) - 2021 3rd Event 60 %, 2022 2nd Event 0 %; Neutrophils (Hem 5S Module) - 2021 3rd Event 60 %, 2022 2nd Event 0 %; resulting in API summary report comment: "Unsuccessful Performance (Long Term)". 2. A review of procedures revealed a Quality Assurance Plan - which stated "The laboratory director has oversight responsibility for all activities of the laboratory including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure that the laboratory is enrolled and participates per approved proficiency testing program for testing performed." 3. An exit interview with the lab supervisor on 10/26 /23 at 1:30 PM confirmed the above findings.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:  
Based on a tour, review of maintenance logs, lack of documentation, procedures, and interviews, the laboratory failed to document 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 26, 2023). Findings include: 1. During a tour on 10/26/23 at 11:00 AM, the inspector noted one Nikon Model E-400 Serial #67552 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 10/26/23) revealed PM service records for the microscope outlined above by Southern Microscope vendor on the following dates: 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, "Microscope PM's are to be performed twice a year by outside service representative". The inspector requested to review additional microscope PM service for calendar year 2022. No additional PM documentation was available. The inspector noted in the general Procedures a Quality Assurance Plan - which stated "The laboratory director has oversight responsibility for all activities of the laboratory

including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure approved procedure manual is available and followed by personnel." 4. An exit interview with the lab supervisor on 10/26/23 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 interview, the laboratory failed to document a comparison evaluation of 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 26, 2023). Findings include: 1. Review of the 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; Peripheral Blood Smear Examination for Differential. The inspector also noted the following protocols: Method to Method Comparison - which stated "requirement is for semi-annual evaluation of data to verify comparability of patient results performed using different methodologies and applies to comparing automated differential to manual differential methodology." Quality Assurance Plan - which stated "The laboratory director has oversight responsibility for all activities of the laboratory including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure approved procedure manual is available and followed by personnel." 2. Review of the laboratory's QA documentation in calendar years 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 reviewed/evaluated by LD on 2/25/23; 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 inquired regarding the delay in evaluation of the comparison data performed on 10/14/22 and requested to review additional method comparison evaluations completed in calendar year 2022. No additional records were available for review. 3. An exit interview with the lab supervisor on 10/26/23 at 1:30 PM confirmed the above findings.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the Centers for Medicare and Medicaid Services Laboratory

Personnel Report form (CMS 209), CMS CASPER Report (0096D), proficiency testing (PT) records, maintenance logs, procedures, quality assessment (QA) records, lack of documentation, a tour, and interviews, the laboratory director failed to ensure QA policies were maintained during the twenty-two month survey timeframe: January 2022 to October 26, 2023. CROSS REFERENCE D6094.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, maintenance logs, quality assessment (QA) procedures, records, lack of documentation, a tour, and interviews, the laboratory director failed to ensure QA oversight policy was maintained during the twenty-two (22) month survey timeframe: January 2022 to October 26, 2023. 1. Review of the procedure manual revealed protocol "Quality Assurance Plan"- which stated "The laboratory director has oversight responsibility for all activities of the laboratory including but not limited to: oversee establishment and maintenance of QA and QC programs to ensure quality laboratory services and ensure approved procedure manual is available and followed by personnel." 2. Review of the Quality Assurance documentation revealed the laboratory director failed to ensure: - retention of documentation for one of six Hematology Module PT testing events during the 22 month review timeframe outlined above -Cross Reference D2015 ( a repeat deficiency); - timely result submission for one of six Hematology Module PT events in the 22 month review timeframe outlined above - Cross Reference D2127; - corrective action documentation for unsuccessful PT performance for Basophil, Eosinophil, Lymphocyte, Monocyte, and Neutrophil counts in two out of three consecutive Hematology Hem 5S Module PT testing events in 2022 - Cross Reference D2130; - twice annual microscope preventative maintenance (PM) was followed in calendar year 2022 - Cross Reference D5433; and - documentation of twice annual comparison evaluation of two methodologies utilized for white blood cell differential determinations in calendar year 2022 - Cross Reference D5775. 3. An exit interview with the lab supervisor on 10/26/23 at 1:30 PM confirmed the above findings.