

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226814	(X3) Date Survey Completed 07/14/2022
Name of Provider or Supplier Lab Corp Of America Holdings	Street Address, City, State 8040 Villa Park Drive Suite 200, Richmond, 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 completed at Labcorp of America Holdings on July 13-14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: A. Based on a laboratory tour, review of policies and procedures, Quality Assurance (QA) records, lack of documentation, patient test logs, and an interview, the laboratory failed to establish and follow a policy to perform and evaluate a comparison of manual differentials with automated blood cell differentials performed on the Sysmex XS-1000ic hematology instrument for twenty-seven (27) of 27 months reviewed (review timeframe: April 2020 to date of the survey July 13-14, 2022). Findings include: 1. During a laboratory tour on 7/13/22 at approximately 10 AM, the inspector noted patient Complete Blood Count (CBC) samples were being assayed on a Sysmex XS-1000ic (Serial Number A10553) hematology instrument in the Stat Laboratory. The inspector also noted a manual differential counter and Hematek slide stainer. 2. Review of the laboratory's policies and procedures revealed a procedure for Manual Differential Protocol. The inspector noted there was no documentation of a policy/procedure to evaluate a comparison of their manual differential method with the automated blood cell differential method reported on the Sysmex instrument. 3. Review of the laboratory's QA documentation from April 2020 through the end date</p>

of the survey on 7/14/22 revealed no documentation of blood cell differential test result comparison studies for the two (2) methods outlined above during the 27 months of review. 4. The inspector requested to review a policy for a comparison of the 2 blood cell differential count methods. The technical supervisor (TS) stated on 7/14/22 at approximately 12:00 PM, "We do not have a policy. I will consult with our Director of QA to see if we have a corporate policy that we can use site specific." 5. The inspector inquired of the number of manual differentials reported during the 27 months from 4/1/20-7/14/22. The TS consulted the patient test logs and stated at approximately 2 PM, "We have reported two thousand four hundred thirty (2,430) manual differentials in that time" 6. An exit interview with the TS on 7/14/22 at approximately 3 PM confirmed the above findings. B. Based on a laboratory tour, review of policies and procedures, Quality Assurance (QA) records, lack of documentation, and an interview, the laboratory failed to follow their policy for a method comparison of twenty-five (25) of 25 chemistry analytes assayed on two (2) Roche C501 instruments in calendar year 2021. Findings include: 1. During a laboratory tour on 7/13/22 at approximately 10 AM, the inspector noted patient chemistry analyte testing on 2 Roche C501 instruments in the Stat laboratory (Serial Numbers SN - 16Z309, 16Z315). 2. Review of the laboratory's policies and procedures revealed a policy ("Multiple Instrument Comparison") that stated: "This procedure is designed to compare instruments of same type and applies to all disciplines. Any assay performed on multiple instruments must have a correlation performed semiannually between all instruments performing the assays." 3. Review of the laboratory's QA documentation for calendar year 2021 revealed one (1) "Multiple Instrument Comparison Worksheet" record dated as performed on 7/30/21 for the following 25 analytes: Amylase, Chloride, Direct Bilirubin, Creatine Kinase, Creatinine, Triglycerides, Potassium, Sodium, Lipase, Alanine Transaminase (ALT /SGPT), Magnesium, Carbon Dioxide, Gamma-Glutamyl Transferase (GGT), Aspartate Aminotransferase (AST), Total Protein, Albumin, Total Bilirubin, Alkaline Phosphatase, Lactate Dehydrogenase (LDH), Glucose, Blood Urea Nitrogen (BUN), Uric Acid, Cholesterol, Calcium, Phosphorus. The inspector requested to review additional Roche analyzer comparison studies conducted in 2021 for the 25 analytes outlined above assayed on Roche C501 SN 16Z309 and 16Z315. No additional records were available for review. 4. An exit interview with the TS on 7/14/22 at approximately 3 PM confirmed the above findings.