Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0655181	08/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp Of America Holdings Stat Lab - Raleigh	8300 Health Park, Suite 223, Raleigh, NC	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2022, 2023, and 2024 coagulation records and interview with the quality manager (QM) 8/27/24, the laboratory failed to retain instrument printouts for all LED calibrations performed on the Sysmex CA-660 coagulation analyzer. Findings: Review of 2022, 2023, and 2024 "Sysmex CA-600 Operator's Maintenance Checklist" logs revealed "Perform LED Calibration" was a task listed on the log under "Quarterly Maintenance". Review of the logs revealed the laboratory documented the LED calibration date on the logs. Review of LED calibration instrument printouts revealed the laboratory had not retained instrument printouts for LED calibrations performed on the following dates documented on the maintenance logs: 4/4/22, 11/25 /22, 2/23/23, and 6/4/23. During interview 8/28/24 at approximately 2:25 p.m., the quality manager stated she was unsure how long the Sysmex CA-660 analyzer retained LED calibration records. She stated she was unable to print records of any LED calibrations performed before 6/29/23.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy and review of 2023 and 2024 American Proficiency Institute (API) proficiency testing (PT) records 8/27/24 and 8/28/24, the laboratory failed to evaluate "Not Graded" PT results to ensure the results were acceptable and no corrective action was required. Findings: Review of laboratory policy "Proficiency Testing Policy" revealed "12. All PT challenges that were intended to be graded but were not, PT must be assessed.". Review of PT results for API 2023 Hematology/Coagulation 3rd event revealed PT samples VA-03, DIF-03, ECI-11, ECI-12, ECI-13, ECI-14 and ECI-15 had "Not Graded" results. There was no documentation to indicate the "Not Graded" results were evaluated by the laboratory. Review of PT results for API 2024 Hematology/Coagulation - 1st event revealed PT samples DIF-01, ECI-01, ECI-02, ECI-03, ECI-04 and ECI-05 had "Not Graded" results. There was no documentation to indicate the "Not Graded" results were evaluated by the laboratory.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation 8/27/24 and record review 8/28/24, the laboratory failed to discard supplies that exceeded their expiration dates. Findings: 1. During a tour of the laboratory 8/27/24 at approximately 3:50 p.m., the surveyor observed the following items in drawers in the laboratory, available for use: a. 1 Cobas Integra Reference electrode, lot (10)31234447 with "Install before 2024-08-09" printed on the box. b. 1 Cobas Integra Chloride electrode, lot (10)31240947 with "Install before 2024-08-16" printed on the box. 2. Review of 2022, 2023, and 2024 wet prep/potassium hydroxide (KOH) logs on 8/28/24 revealed the laboratory used KOH (lot #512662) with an expiration date of 5/26/23 to test 1 patient (150-936-0002-0) on 5/30/23. The laboratory had noted in a "Memo to file" that expired KOH was used to perform patient testing, but there was no documentation to indicate that a review was conducted to determine whether the patient's results were affected by the use of expired KOH.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2023 and 2024 hematology maintenance logs 8/27/24, the laboratory failed to perform and document the monthly maintenance for the Sysmex XS-1000iC for 6 of 12 months in 2023 and 1 of 8 months in 2024. Findings: Review of the "Sysmex XS-1000iC Maintenance" procedure revealed "... Monthly Maintenance 1. Monthly Rinse Sequence: To be performed monthly or every 1200 cycles. This procedure cleans the

	optical detector block. ..." Review of the 2023 and 2024 maintenance logs revealed the monthly rinse was not performed during the following months: 1. 2023 - January, March, May, June, July, November 2. 2024 - April The laboratory had not documented the number of cycles during 2023 and 2024.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2023 chemistry quality control (QC) and corrective action records and interview with quality manager (QM) 8/27/24-8/28/24, testing personnel (TP) failed to follow the laboratory's corrective action policy when QC failed to meet established ranges on the Integra 400 chemistry analyzer. Findings: Review of laboratory procedure "Integra 400 Quality Control Procedure" revealed the following "CORRECTIVE (TROUBLESHOOTING) ACTION: If controls do not meet established ranges and rules, follow the recommended steps below. Document all work on the Corrective Action Log. 1. Repeat control that failed. 2. If repeat fails, determine if the control was at fault (i.e. age, storage). Prepare a fresh control and repeat. 3. If second repeat fails, determine if the reagent was at fault (i.e. age, storage). Try another reagent pack, if available and repeat controls. 4. Before recalibrating, see approval from lab supervisor. If yes, then recalibrate with fresh calibrator and run controls. 5. If control fail after calibration, prepare Roche Diagnostic assayed controls (Precinorm and Precipath Universal controls) and run. * If the BioRad controls are out of range and the Roche PreciControls are within the stated range, patients may be reported. * If both BioRad and Roche PreciControls are out of the established ranges, patients cannot be reported out....". Review of March 2023 thru November 2023 Integra 400 QC and corrective action logs revealed TP failed to follow the laboratory's corrective action procedure when BioRad QC failed to meet established ranges on the following months and days. 1. March 2023, 21 days; 3/1-3/3, 3/6-3/9, 3/14-3/17, 3/20-3/24, and 3/27-3/31. For example: a. March 1, 2023 - BioRad QC failed for Alkaline phosphatase (ALP) level 2, Aspartate aminotransferase (AST) level 2, and Glucose (GLU) Levels 1 and 2. Corrective action log and QC records failed to indicate the use of fresh controls and a new reagent pack prior to calibrating and releasing patient test results based on Roche PreciControls. b. March 29, 2023 - BioRad QC failed for ALP levels 1 and 2. Corrective action log and QC records failed to indicate use of fresh control, new reagent pack or calibration prior to releasing patient test results based on Roche PreciControls. 2. April 2023, 7 days; 4/2, 4/4-4/6, 4/13, 4/24, and 4/28. For example: a. April 2, 2023 - BioRad QC failed for Total Bilirubin (TBIL) level 2, ALP level 2, AST level 2 and Gamma-glutamyltransferase (GGT) level 2. Corrective action log and QC records failed to indicate the use of fresh control, new reagent packs or calibration prior to releasing patient test results based on Roche PreciControls. 3. May 2023, 5 days; 5/1-5/3, 5/5 and 5/8. For example: a. May 2, 2023 - BioRad QC failed for Potassium (K) level 1 and 2, and GGT level 1. Corrective action log and QC records failed to indicate use of fresh controls, new reagent packs or calibration prior to releasing patient test results based on Roche PreciControls. 4. June 2023, 6 days; 6 /1, 6/12-6/15 and 6/26. For example: a. June 12, 2023 - BioRad QC failed for AST level 2 and ALP level 1. Corrective action log and QC records failed to indicate use of

	fresh controls or reagent prior to calibration and release of patient test results based on Roche PreciControls. 5. July 2023, 5 days; 7/3, 7/5, 7/14, 7/19, and 7/24. For example: a. July 3 and July 5, 2023 - Corrective action log revealed "Chemistry QC expired", QC records revealed all patient testing was resulted based on Roche PreciControls. 6. August 2023, 10 days; 8/1-8/4, 8/7, 8/10-8/11, 8/17 and 8/29-8/30. For example: a. August 1 thru August 3, 2023 - BioRad QC failed for Chloride (CL) levels 1 and 2. Corrective action log and QC records failed to indicate use of fresh controls, reagent or calibration prior to the release of patient test results based on Roche PreciControls. 7. September 2023, 9 days; 9/14-9/15, 9/18-9/19, 9/21-9/22 and 9/26-9/28. For example: a. September 15, 2023 - BioRad QC failed for CL level 1, AMY level 1 and CREA level 2. Corrective action log and QC records failed to indicate use of fresh controls, reagent or calibration prior to the release of patient test results based on Roche PreciControls. b. September 18, 2023 - BioRad QC failed for Creatinine (CREA) level 2 and AST level 2. Corrective action log failed to indicate use of fresh reagent and calibration prior to the release of patient test results based on Roche PreciControls. 8. October 2023, 10 days; 10/4, 10/6, 10/9-10/10, 10/12, 10/16-10/18, 10/20 and 10/26. For example: a. October 6, 2023 - BioRad QC failed for Calcium (CA) level 1, Carbon Dioxide (CO2) levels 1 and 2, CREA levels 1 and 2, GGT level 2, Lactate dehydrogenase (LDH) level 2, Total Protein (TP) level 2 and Uric Acid (UA) level 2. Corrective action log and QC records failed to indicate repeat testing using BioRad QC, use of fresh controls and reagents, and calibration prior to the release of patient test results based on Roche PreciControls. 9. November 2023, 4 days; 11/15-11/16, 11/20 and 11/24. For example: a. November 16, 2023 - BioRad QC failed for Alanine transaminase (ALT) levels 1 and 2, and CL levels 1 and 2. Corrective action log and QC records failed to indicate reagent change or calibration prior to the release of patient test results based on Roche PreciControls. Interview with GM 8/27/24 at approximately 2:00 p.m. confirmed TP had not followed the laboratories corrective action policy for failed QC. She stated the laboratory experienced a large turn over in employees during this time period.