Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226814	04/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lab Corp Of America Holdings	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 conducted at Laboratory Corporation of America, Holdings on April 28-29, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures, lack of documentation, and interviews, the laboratory failed to evaluate twelve microbiology non-graded analyte challenges resulted on six of six events reviewed for the survey timeframe of May 31, 2024 to April 29, 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2024 Events 2-3, 2025 Events 1-3, 2026 Event 1), a total of six events, revealed that API released non-graded analyte responses for: Urine Culture MIC/Zone Values by Vitek 2 on the following: API 2024 Event 2 - challenge UR-06 and UR-07; API 2024 Event 3 - challenges UR-11; API 2025 Event 1 - challenges UR-01, UR-02; API 2025 Event 2 - challenges UR-06 and UR-07; API 2025 Event 3 - challenges UR-11 and UR-12; API 2026 Event 1 - challenges UR-01, UR-02; Urine Culture Susceptibility on the following event: API 2025 Event 1 - Urine Culture B, Susceptibility Interpretation -UR-02; Eleven Urine Culture MIC/Zone and one Urine Culture Susceptibility challenge samples were reported by API as "Not Graded, See Data Summary". 2. Review of the laboratory's PT evaluation records revealed no evaluation/verification of accuracy for the non-graded challenge results outlined above. The inspector requested to review documentation of an evaluation for the non-graded challenges. The documentation was not available. 3. The inspector noted, on each API Evaluation Review/Corrective

	Action forms (page 1), a protocol instruction, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or "not graded" analytes. Laboratories are responsible for documenting and performing corrective action and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 4. Review of the laboratory's procedures revealed a policy (title: Proficiency Testing Guideline) that stated, "The Laboratory Director or designee (documented) must review and sign PT survey evaluations including: graded, ungraded, regulated, non regulated, educational, and challenges not graded due to lack of consensus." 5. An exit interview with the Laboratory Director, Laboratory Manager, Stat Lab Supervisor, and Microbiology Lead Tech on 4/29/26 at 4:30 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on tours, a review of coagulation instrument maintenance logs, lack of documentation, quality assessment (QA) records, manufacturer's guidelines, and interviews, the laboratory failed to document required Siemens Sysmex quarterly instrument maintenance for six of seven quarters within the survey timeframe of May 31, 2024 to April 29, 2026. Findings include: 1. During a tour of the laboratory on 4 /28/26 at 3 PM, the inspector noted a Siemens Sysmex CA-660 (Serial Number 24747) in use for patient coagulation testing. 2. Review of the laboratory's CA-660 instrument maintenance checklists revealed the following required maintenance to be completed quarterly: Clean/Inspect Filters. 3. Review of the CA-660 maintenance checklists for the survey timeframe, 5/31/24 - 4/29/26, revealed that the maintenance task outlined above was documented once on 11/12/24. The inspector requested to review documentation that the filter cleaning maintenance was completed after 11/12 /24 during the additional six of the seven quarters reviewed. No records were available. 4. Review of the laboratory's QA records revealed no documentation of corrective action notations for the lack of the quarterly maintenance outlined above. 5. Review of Siemens Sysmex CA-660 online user guide revealed maintenance instruction that stated, "Quarterly- perform a deep clean of the air filters/check ventilation." 6. The inspector returned to tour the coagulation bench in the Stat Laboratory on 4/29/26 at 1 PM and requested to inspect the condition of the CA-660 air filters. The inspector noted that two of two air filters were clogged with approximately half inch thick layer of dust. The inspector inquired regarding the laboratory's protocol for cleaning the instrument's air filters. The testing personnel stated on 4/29/26 at 1:10 PM, "We have obviously overlooked the filter maintenance for awhile. I will get everyone together for a huddle to review this now." 7. An exit interview with the Laboratory Director, Laboratory Manager, Stat Lab Supervisor, and Microbiology Lead Tech on 4/29/26 at 4:30 PM confirmed the above findings B. Based on a review of microbiology instrument maintenance logs, lack of documentation, manufacturer's guidelines, quality assessment (QA) records, and interviews, the laboratory failed to document two of two Biomerieux Vitek 2 instruments' required weekly maintenance in 9 of 99 weeks and required monthly maintenance in 3 of 23 months reviewed (timeframe of May 31, 2024 to April 29, 2026). Findings include: 1. Review of the microbiology laboratory's two instruments utilized for microbial identification/antibiotic susceptibility revealed logs (Vitek 2,

	Serial Number SN5797 and SN5799 Preventative Maintenance Checklists) with the following required maintenance to be documented: Weekly: Optics Cleaning and Saline Sterility Check; Monthly: DensiChek Performance Verification, Clean Components- Boats/Carousels/Cassettes/Waste Tray/Base Pan/Vacuum Seal/Vacuum Chamber/Drip Pan. 2. During a review of the Vitek 2 instruments' maintenance logs, on 4/29/26 at 11 AM, the inspector noted that the weekly and monthly maintenance tasks outlined above were not documented during the following weeks/months: Weekly Clean Optics Vitek SN5797 - 12/15-12/19/25, 12/22-12/26/25; Vitek SN5799 - 2/24-2/28/25, 8/11-8/15/25, 12/15-12/19/25, 12/22-12/26/25; Weekly Saline Sterility Check Vitek SN5797 - 3/24-3/28/25, 6/16-6/20/25; Vitek SN5799 - 2/24-2/28/25; Monthly DensiChek Performance Verification Vitek SN5797 - September 2025; Vitek SN5799 - June 2025; Monthly Cleaning- Boats/Carousels/Cassettes/Waste Tray /Base Pan/Vacuum Seal/Vacuum Chamber/Drip Pan Vitek SN5797 - September 2025; The Vitek SN5797 lacked weekly "clean optics' documentation for two of four weeks in December 2025, "saline sterility check" for one of four weeks in March 2025 and one of four weeks in June 2025, monthly "cleaning component" tasks and "DensiChek Performance Verification" in September 2025. The Vitek SN5799 lacked weekly "clean optics' recorded for one of four weeks in February and one of four weeks August of 2025, two of four weeks in December 2025, "saline sterility check" for one of four weeks in February 2025, and monthly "DensiChek Performance Verification" in June 2025. The inspector requested to review the maintenance documentation for the weeks/months outlined above for SN5797 and SN5799. No additional records were available. 3. Review of Biomerieux Vitek 2 online user manual revealed maintenance guideline that stated: "Weekly maintenance for the Vitek 2 system focuses on ensuring optical accuracy and prevention of contamination. Key tasks to be completed weekly are cleaning the transmittance optics and performing saline sterility checks and cleaning the pipette station. "Monthly maintenance and performance verification for the Vitek 2 systems are critical for ensuring accurate microbial identification and susceptibility results. Verify the DensiChek with calibration standards monthly and document components on preventative maintenance checklist are cleaned". 4. Review of the laboratory's QA records revealed no documentation of corrective action noted for the lack of the weekly and monthly maintenance outlined above. 5. An exit interview with the Laboratory Director, Laboratory Manager, Stat Lab Supervisor, and Microbiology Lead Tech on 4/29/26 at 4:30 PM confirmed the above findings
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based a review of instrument maintenance logs, lack of quality assessment (QA) documentation, and interviews, the laboratory failed to document QA corrective actions when required Siemens Sysmex CA-660 and Biomerieux Vitek 2 instruments' maintenance tasks were not documented by the Stat Lab and Microbiology personnel per protocol during the review timeframe of May 31, 2024 to April 29, 2026. Findings include: 1. Review of the laboratory's Stat Lab and Microbiology instruments'

	maintenance checklists during timeframe 5/31/24 - 4/29/26 revealed that personnel failed to document the following required preventative maintenance: CA-660 (Serial Number 24746) quarterly maintenance - the inspector noted the quarterly maintenance cleaning filters task was documented once during the 23 months of review - Refer to D5429A; Vitek 2 (SN 5797, SN 5799) weekly maintenance was not documented in 9 of 99 weeks and monthly maintenance tasks were not documented in 3 of 23 months reviewed - Refer to D5429B. 2. Review of the laboratory's QA records for the timeframe outlined above revealed no documentation that discussion with staff or corrective actions were noted for the missing weekly, monthly, and quarterly maintenance protocols. 3. An exit interview with the Laboratory Director, Laboratory Manager, Stat Lab Supervisor, and Microbiology Lead Tech on 4/29/26 at 4:30 PM confirmed the above findings