Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229024	09/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	840 Greenbrier Circle Suite 100, Chesapeake, 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 Labcorp of America Holdings-Chesapeake on September 19-20, 2018 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:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, temperature logs, and an interviews, the laboratory failed to document monitoring of laboratory refrigerators, freezers, heat block warmer, room, and humidity temperatures according to their written policy for twelve (12) of twenty-one (21) months reviewed. Findings include: 1. Review of the Policy and Procedure Manual revealed a general laboratory policy (Temperature Monitoring, Policy #: LC-MV-CL-DOC-164) that stated: "temperatures are recorded on a daily basis on appropriate logs". 2. The inspector requested to review the laboratory temperature logs for January 2017 up to the date of survey on 9/19/18. The review of the available temperature records revealed documentation of refrigerators, freezers, heat block warmer, room temperatures, and room humidity for January 2018 to the date of the inspection on 9/19/18. The inspector requested to review temperature documentation in calendar year 2017 for the Danny Refrigerator 1 and 2, Danny Freezer 1, Danny Black Freezer, Danny White Freezer, Walk In Refrigerator,

	and the Fisher Scientific IsoTemp Heat Block. The technical consultant (TC) stated on 9/19/18 at approximately 2:30 PM: "We moved all of 2017 records to a storage facility. I have requested for them to be delivered for your review". During the second day of the survey, 9/20/18, at approximately 11:30 AM, the TC stated: "I apologize but the storage facility has outsourced the delivery of the records you requested and they are stating that they cannot deliver today." 3. In an interview with the TC, laboratory manager, and quality manager (via telephone conference call) at approximately 11:45 AM on 9/21/18, it was confirmed that the laboratory records failed to include documented monitoring of the laboratory refrigerators, freezers, heat block warmer, room temperatures, and room humidity according to their written policy for twelve (12) of twenty-one (21) months reviewed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of instrument performance validation records, patient test logs, and an interview, the laboratory director (LD) failed to evaluate and verify the reportable range for Lipase and Hemoglobin A1c testing after moving the COBAS Integra 400 Plus analyzer into a new laboratory room on September 2, 2018. Findings include: 1. Review of the COBAS Integra 400 Plus analyzer performance verification documentation revealed no evaluation or verification by the LD of Hemoglobin A1c and Lipase reportable range for the Integra 400 Plus Serial Number 397971 after its move on September 2, 2018. The inspector requested to review documentation that the laboratory director verified the reportable ranges prior to patient testing. No documentation was available for review. 2. Review of the patient accessioning test log from the laboratory's information system revealed that the lab had reported fifty-three (53) Hemoglobin A1c and eight (8) lipase patient test results from 9/3/18 to the date of the survey on 9/20/18. 3. In an exit interview with the technical consultant, laboratory manager, and quality manager (attending via conference call) at approximately 11:45 AM on 9/20/18, it was confirmed that the laboratory director failed to evaluate and verify the reportable range for Lipase and Hemoglobin A1c, after relocating the COBAS Integra analyzer, prior to reporting sixty-one (61) patient results as outlined above.
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 a review of instrument maintenance logs and interviews, the laboratory failed to document performance of required chemistry and hematology instrument daily, weekly, monthly, quarterly, semi-annual, and periodic maintenance for twelve (12) of twenty-one (21) months reviewed. Findings include: 1. Review of the laboratory's two (2) Roche Integra 400 Plus instrument maintenance logs revealed the following required duties for Instrument 1 (Serial Number 401468) and Instrument 2 (Serial Number 397971): Daily Activities- verify solutions, water supply, analyzer temperature, cassette temperature, cleaner temperature, removal of expired reagents; Daily Maintenance- change activator, prime fluid system, deproteinize probes, initialize ISE module, Prime ISE calibrators, activate electrodes, clean probes, electrode service; Weekly Maintenance- clean probes and splash guard, clean ISE tower, back up database, clean wash station, clean instrument; Monthly Maintenance- clean waste box fitting, clean ISE tower (manually); Electrode Replacement- Chloride (every 90 days), Lithium (every 120 days), Sodium (every 180 days), Potassium (every 180 days), Reference (every 720 days); Quarterly Maintenance- replace ventilation filters, replace external water reservoir filter; Semi-Annual Maintenance- Clean external water reservoir, clean waste reservoir, clean internal water reservoir, clean wash station, replace ISE tubing; Replacement of Probes- Probe B, Probe C, plunger pipette B and C, dosage pipette B and C, replacement of halogen lamp (every 800 hours). Review of the laboratory's COBAS e411 instrument maintenance logs revealed the following required duties: Daily- clean S/R probe, check reagent and system reagent rotor condensation; Weekly- clean incubator and aspiration station, clean sipper probe; Every Two Weeks- clean rinse stations, perform liquid flow cleaning. Review of the laboratory's Sysmex XS-1000i C hematology instrument maintenance logs revealed the following required duties: Daily- verify background, verify pressure vacuum; Weekly- power down IPU; Monthly- monthly rinse; Periodic- replace air pump, replace piercer. 2. Review of the available laboratory maintenance documentation, outlined above, revealed maintenance records for the nine (9) months of January 2018 to the date of the survey on September 20, 2018. The inspector requested to also review chemistry and hematology maintenance logs for calendar year 2017. The technical consultant (TC) stated on 9/19/18 at approximately 2:30 PM: "We moved all of 2017 maintenance records to a storage facility. I have requested for them to be delivered for your review". During the second day of the survey, 9/20/18 at approximately 11:30 AM, the TC stated: "I apologize but the storage facility has outsourced the delivery of the records you requested and they are stating that they cannot deliver today." 3. In an exit interview with the TC, laboratory manager, and quality manager (joined on conference call) at approximately 11:45 on 9 /20/18, it was confirmed that the laboratory failed to provide documentation of the performance of chemistry and hematology required instrument maintenance, outlined above, for twelve (12) of the twenty-one (21) months reviewed.