Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0226814	**(X3) Date Survey Completed** 07/10/2020
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 unannounced, off-site CLIA complaint survey was conducted at LabCorp of America Holdings on June 29, 2020 to July 10, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, laboratory missed /delayed specimen documents, patient records and interviews, the laboratory failed to establish and follow a written policy to ensure the reporting of missed or delayed specimen test results for four (4) of twenty-seven (27) patients collected on April 30, 2020. Findings include: 1. Review of the laboratory's list of specimens sent by the doctor's office (client) revealed 27 patients had specimens collected on April 30, 2020. 2. Review of the laboratory's "Missed/Delayed Specimen Pick-up Form-Reported Missed Pick-up" form revealed the following information: "Date notification received: 5/1/2020 Time received: 11:44 AM Client Account Number 45805080 Additional Client Information Location where specimens were found: Inside the Lab-Counter Touch Lavender Tubes Left Out of Lab Ready. Technical Missed specimen types? 4 lavenders Specimens accepted for tested? Yes Accessioning /Testing @RV Stat Lab per IOP[In Office Personnel]." 3. Review of the laboratory's "Richmond Missed Pick Up-Stat Lab and Customer Services Documentation' form revealed the following information: "Stat Lab Account Number: 45805080 Number of Specimens: 4 Number of Patients: 4 Date of Collection: 04/30/2020 Date Samples Received 05/01/2020 Specimen Types: 4 lavenders Reason for Missed Pickup: Touch

	Lavenders left out of Lab Ready. How were samples stored? Inside Lab on Counter Is Integrity of samples compromised? No What testing can be saved? All CBC's ran in RV Lab per IOP Request) What testing will be rejected? None Is the Client aware of the problem? Yes Customer Services KAE notified? Yes Client notified? Yes Name of Client notified N/a office closed Date/Time Client Notified Office closed Response of Client N/A Specimens commented out by Burlington N/A Specimens commented out by Branch N/A" 3. Review of the "Missed Pick-up Accessioned 305780-LabCorp Upload Manifest Log" and patient test requisitions for April 30, 2020 revealed the following client's regional specimen numbers with tests requested listed: 121-496-4529-0 tests requested-Complete Blood Cell count with differential (CBC/diff), Hemoglobin A1C, Thyroid Stimulating Hormone (TSH), Free Thyroxine (Free T4), Complete Metabolic Panel (CMP), Lipid Profile (LP), Hepatitis B Surface Antigen (HBsAg), Hepatitis C Virus Antibody (HCV), 121-496-9878-0 tests requested-CBC /diff, Hgb A1C, TSH, Free T4, CMP, LP, HBsAg, HCV; 121-646-0339-0 tests requested CBC/diff, Hgb A1C, TSH, Free T4, CMP, LP, HBsAg, HCV and; 121-646-0774-0 tests requested-CBC/diff, TSH, Free T4. Total=4 patients 4. In an interview on July 7, 2020 at approximately 1:00 PM with the client's Medical Assistant (MA), the MA stated the office was not notified by the laboratory of any missed specimens or delayed results from April 30, 2020. The MA stated they became aware of an issue with results on June 12, 2020 when a patient called the office for their test results collected on April 30, 2020. The MA was unable to give the patient their results because the CMP, TSH, Free T4, LP, HBsAg and HCV were reported as "deleted" in the laboratory information system. 5. In an interview on July 7, 2020 at approximately 3:00 PM with the branch Laboratory Manager (LM), the LM stated, "On May 1, 2020, the laboratory received a telephone call from the client's In Office Phlebotomist (IOP) informing the branch laboratory four patient's lavender top tubes were left at the client's office on the counter on April 30, 2020. The four lavender top tubes (regional laboratory specimen numbers 121-496-4529-0, 121-496-9878-0, 121-646-0339-0 and 121-646-0774-0) were not sent for analysis at the regional laboratory. The 4 patient's other specimens for the CMP, TSH, Free T4, LP, HBsAg and HCV were picked up on April 30, 2020, sent to the regional laboratory, analyzed and results were reported on May 1, 2020. On May 1, 2020, the laboratory courier picked up the four missed lavender top specimens and brought the specimens to the branch laboratory for analysis. The branch laboratory accessioned the four lavender tops with the branch laboratory's specimen numbers. The branch laboratory analyzed and resulted the four-missed specimen at approximately 3:00 PM on May 1, 2020. Between 3:40 and 5:00 PM on May 1, 2020, a technologist from the branch laboratory deleted the regional laboratory specimen numbers along with the corresponding test (CMP, TSH, Free T4, LP, HBsAg and HCV) results." The LM stated the laboratory was not aware of the "deleted" results until the surveyor notified them. 6. Review of the laboratory's policies and procedures revealed the laboratory failed to establish a policy to ensure the reporting of missed or delayed specimen test results. The surveyor requested a policy from the laboratory. The laboratory provided no policy for ensuring the reporting of missed or delayed specimen test results. 7. In an interview on July 7, 2020 at approximately 3:30 PM, the LM confirmed the findings