Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2155134	04/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	380 W County Road D, New Brighton, MN	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the actual reportable range values obtained during the performance verification of a new Chemistry analyzer were included in the procedure manual (6). Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a. m. on 04/30/19. 2. A Roche Cobas e411 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and began testing patient specimens using

	this analyzer on 11/05/18 as indicated in laboratory records. 3. The reportable ranges found in the Cobas e411 SOP's manual for 5 of 6 analytes reviewed on date of survey did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated below. Analyte PV Procedure FSH* 0.11-170.60 2-200 Estradiol 97.03-2429.0 5.0-4300.0 hCG* 11.60-9469.0 1-10,000 LH* 0.10-69.57 0.1-200.0 Prolactin 0.30-24.15 0.047-470.0 4. In an interview at 2:20 p.m. on 04/30/19, the GS confirmed the above finding.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities as required for a Microbiology test system. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 04/30/19. 2. A BD Veritor system was observed as present and available for use during the tour. The GS indicated the laboratory performed Respiratory Syncytial Virus (RSV) and Influenza A and B (Flu A/B) testing with this system. The laboratory began RSV and Flu A/B testing in November 2018 as indicated in laboratory records. 3. Quality control (QC) performance was required monthly and with each new lot and shipment of RSV and Flu A/B test devices as established in the BD Veritor System for Rapid Detection of RSV and the Veritor System for Rapid Detection of Flu A and B procedures located in the Flu A/B and RSV manual. 4. Laboratory records indicated RSV and Flu A/B QC was performed monthly and with new lots and/or shipments of test devices in the timeframe reviewed, January through April 2019. 5. The laboratory did not establish an Individualized Quality Control Plan (IQCP) to reduce the frequency of RSV and Flu A/B QC required each day of patient testing. 6. In an interview at 2:40 p.m. on 04/30/19, the GS confirmed the above finding. In an email received at 9:43 a.m. on 05/03/19, the GS indicated 2 RSV and 3 FLU A/B patient specimens had been tested by the laboratory since November 2018.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the

	laboratory failed to ensure reference intervals were consistent between Chemistry procedures and a patient test report. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 04/30/19. 2. A Roche Integra 400 chemistry analyzer was observed as present and available for use during the tour. The laboratory began testing patient specimens using this analyzer on 11/05/18 as indicated in laboratory records. 3. Reference intervals included in the Integra 400 SOP's manual for 6 of 7 analytes reviewed on date of survey were not consistent with those included on the patient test report reviewed as indicated below. Patient #27910 - adult female tested on 02/11/19 Analyte Procedure Report Sodium 135-148 134-144 Potassium 3.5-5.5 3.5-5.2 Chloride 96-109 96-106 Calcium 8.6-10.2 8.7-10.3 CO2* 19-28 20-29 BUN* 5-26 8-27 4. In an interview at 2:25 p.m. on 04/30/19, the GS confirmed the reference interval discrepancies between the Integra 400 standard operating procedures and the patient test report. *Note CO2 Bicarbonate BUN Blood Urea Nitrogen