Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0866459	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	10200 Pioneer Blvd, Ste 500, Santa Fe Springs, CA	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interviews it was determined the laboratory failed to establish written policies and procedures to ensure positive patient identification during gynecologic specimen processing and staining. The laboratory failed to label four of four specimen slides with a unique identifier during gynecologic specimen processing and staining on November 16, 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure positive patient identification during gynecologic specimen processing and staining. 2. During observation of gynecologic specimen processing and staining on November 16, 2021 at 9:15 AM, Laboratory Assistant B failed to label four of four gynecologic specimen slides with the complete patient identifier accession number. Specimens include: Accession #: # Written on Specimen Slide: -C21-33163 33163 -C21-33164 33164 -C21-33165 33165 -C21-33171 33171 3. During further observation of gynecologic specimen processing and interview with Laboratory Assistant B and the Cytology Supervisor on November 16, 2021 at 9:30 AM, it was confirmed it was the laboratory's practice to not write the complete patient identifier accession number on gynecologic specimen slides during processing. The Cytology Supervisor stated that a label with the complete patient identifier accession number was not applied to the specimen slides until after staining of the specimen slides. 4. During an interview on November 16, 2021 at 3:30 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor confirmed these findings.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined the laboratory failed to establish written policies and procedures to assess the competency of Technical Supervisors. The laboratory failed to assess the competency of two of two Technical Supervisors in 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two Technical Supervisors in 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on November 15, 2021 at 1:50 PM, the Laboratory Director /Technical Supervisor A confirmed these findings.
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 review of 26 laboratory policies and procedures, observation and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process of removing the gynecologic specimen collection device from the HOLOGIC THINPREP vial prior to processing. a. During an observation of HOLOGIC THINPREP Pap Test processing on November 16, 2021 at 9:35 AM, Laboratory Assistant B demonstrated and stated the following: -"If a collection device

	is in the vial, the device is removed with forceps. The forceps are placed in bleach, 95% alcohol and then water. Then we process the specimen and document on the vial and on the form that the specimen came with a device." 2. During an interview on November 16, 2021 at 3:30 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor confirmed these findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, lack of training records and interview it was determined the laboratory failed to ensure two of two Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test in accordance with the manufacturer's instructions. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The Survey Team requested and the laboratory failed to provide training records for two of two Technical Supervisors who performed diagnostic interpretations on HOLOGIC THINPREP 2000 SYSTEM Tests in 2020 and to the date of the survey in 2021. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on November 15, 2021 at 1:50 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor confirmed these findings.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined the laboratory failed to establish written policies and procedures to ensure that the search for prior negative gynecologic specimens received within the previous five years for each patient with a current high grade squamous intraepithelial lesion (HSIL) or malignancy was performed. The laboratory failed to document the search for prior negatives for 58 of 61 patients with a current

	HSIL or malignancy reported by the laboratory in January through November 17, 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for documenting the search for all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. 2. The Survey Team requested and the laboratory failed to provide records of a search for prior negative gynecologic specimens received within the previous five years, for 58 of 61 patients with a current HSIL or malignancy reported by the laboratory January through November 17, 2021. a. The Cytology Supervisor provided on November 21, 2021 at 10:15 AM a computer-printed document titled CYTOLOGY SEARCH, which detailed the case numbers of patients with a current HSIL or malignancy reported by the laboratory January through November 17, 2021. Cases include: -C21-00217 -C21-01010 -C21-01389 -C21-03231 -C21-04153 -C21-04829 -C21-05062 -C21-04979 -C21-05114 -C21-05163 -C21-05278 -C21-05736 -C21-05720 -C21-07490 -C21-07866 -C21-07973 -C21-08159 -C21-08427 -C21-08379 -C21-08540 -C21-08719 -C21-09506 -C21-09800 -C21-10421 -C21-10495 -C21-10667 -C21-10695 -C21-10985 -C21-12132 -C21-12259 -C21-12527 -C21-12984 -C21-13549 -C21-13515 -C21-13760 -C21-14005 -C21-15712 -C21-15846 -C21-15881 -C21-16955 -C21-17258 -C21-17759 -C21-19295 -C21-20180 -C21-21657 -C21-25844 -C21-26740 -C21-27479 -C21-28487 -C21-28590 -C21-29544 -C21-30155 -C21-30445 -C21-30498 -C21-30532 -C21-31235 -C21-31359 -C21-32717 3. During an interview on November 17, 2021 at 9:50 AM, the Cytology Supervisor stated, "the Pathologist will look up the history on the HSIL case, but there is no documentation of the search". 4. During an interview on November 17, 2021 at 12:00 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to include criteria to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on November 17, 2021 at 9:50 AM, these findings were confirmed with the Cytology Supervisor.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview, it was determined the Laboratory Director failed to ensure that two of two Technical Supervisors who performed HOLOGIC THINPREP Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2020 and to the date of the survey in 2021. Cross refer to D5411 Findings include: 1. The Laboratory Director failed to ensure that two of two Technical Supervisors had received the appropriate morphology training prior to reporting patient specimens in 2020 and to the date of the survey in 2021. a. The Survey Team reviewed laboratory records titled CYTOLOGY LABORATORY ANNUAL STATISTICS and PATHOLOGIST SIX-MONTH STATISTICS. The records detailed the following numbers of cases were evaluated and reported by Laboratory Director/Technical Supervisor A and Technical Supervisor B: -2020 COMBINED TOTAL OF PAP TESTS EXAMINED AND REPORTED: 6359 cases -January through June 2021 COMBINED TOTAL OF PAP TESTS EXAMINED AND REPORTED: 2643 cases 2. During an interview on November 15, 2021 at 1:50 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor confirmed these findings.
D9999	