

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2026623	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Express Medical Labs, Llc	Street Address, City, State 9830 S Ridgeland Ave - Ste 115, Chicago Ridge, IL	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with the technical supervisor, the procedure manual failed to include all required information applicable to their COVID- 19 tests. Findings: 1. Review of the laboratory's procedures revealed that the procedures failed to include the following: a. 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. b. The laboratory's system for entering results in the patient record and reporting patient results including, when</p>

appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values. c. Description of the course of action to take if a test system becomes inoperable. 2. On March 16, 2021 at 1:30 PM, the technical supervisor confirmed the surveyor's findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures manual; personnel records; and interview with the technical supervisor, the laboratory director failed to specify in writing, the responsibilities and duties of each consultant and each supervisor in the laboratory. Findings: 1. Review the laboratory's procedure manual revealed that there was no documentation to show that the laboratory director assigned personnel to the following positions: a. Clinical Consultant b. General Supervisor 2. Review of personnel records revealed that the laboratory director did not assign, in writing, anyone to the positions of Clinical Consultant and General Supervisor of the laboratory. 3. On March 16, 2021 at 10:30 AM, the technical supervisor confirmed the surveyor's findings.