

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2151696	(X3) Date Survey Completed 03/17/2022
Name of Provider or Supplier Omni Laboratory Services	Street Address, City, State 5862 N Lincoln Ave, Chicago, 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
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of manuals, lack of documentaion, and interview, the laboratory director (LD) failed to provide overall management to ensure the establishment of quality assessment (QA) policies and procedures (D6094) and failed to ensure an approved and complete standard operating procedure manual was available to all personnel (See D6106).</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to establish and implement quality assurance (QA) procedures which monitor, assess, and when indicated, correct identified problems in the laboratory. Findings include: 1. The laboratory's standard operating procedures manual was reviewed. 2. The LD failed to establish written procedures that provide an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions for the following phases of the testing process: *Preanalytic -</p>

assessing practices/issues related to test requests, specimen submission, handling, specimen acceptance and rejection, and referral. *Analytic - assessing: practices /issues related to test procedures; accurate and reliable test systems; equipment, instruments; reagents; materials; and supplies; specimen and reagent storage condition; equipment/instrument/test/system maintenance and function checks; control procedures; comparison of test results. Corrective actions; and test records. See D5400, D5405, and D5441. *Post-analytic -assessing practices/issues related to test reports. See D5805. 3. On a Desk follow-up survey conducted on 03/17/22 at 10:00AM, the laboratory director and the general supervisor confirmed the above findings.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure six out of six testing personnel (TP) had an approved procedure manual available for any aspect of the testing process. Findings: 1. The laboratory's standard operating procedures manual, the OPTI SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) Emergency Use Authorization (EUA), and manufacturers' package inserts were reviewed. 2. The LD failed to establish and make available the following procedures for 6 out of 6 TP: *Complete written procedures for their laboratory developed tests (LDT) and when manufacturer's instructions /package inserts, EUA, or operator's manuals are used as the test system's procedure. See D5405. *Control procedures for all analytic systems. See D5441. *Quality assurance procedures for preanalytic, analytic, and postanalytic phases of the tests. See D5791 and D6094. 3. On a Desk follow-up survey conducted on 03/17/22 at 10:00 AM, the laboratory director and the general supervisor confirmed the above findings.