

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2215498	(X3) Date Survey Completed 10/29/2021
Name of Provider or Supplier Reopen Diagnostics Llc (Db a Pandemic Response Lab)	Street Address, City, State 9605 Medical Center Dr Ste 220, Rockville, MD	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Directory of Service procedure and interview with the laboratory manager (LM) and quality control manager (QCM), the laboratory's instructions to clients failed to include acceptable specimen storage, transport, and stability information for all accepted specimen types and listed the incorrect address for the testing laboratory. Findings: 1. The procedure titled "PRL [Pandemic Response Lab] Directory Of Service for PRL-DC" included instructions for clients to collect, store and transport patient specimens to the laboratory. 2. The section titled "Collection Instructions" stated that, for patient swab specimens, the "Preferred" collection container was "LVL Technologies 1 mL tube with DNA/RNA Shield" and for the "Acceptable" collection container: "PRL accepts a majority of container types. Collection tube needs to be validated for use on PRL's automation platform." The section titled "Rejection Criteria" stated that collection "Kits that have not been validated for use on the PRL automation platform" will be rejected. The Directory of Service procedure does not include a list of validated and approved collection containers. 3. The laboratory also accepted patient swab specimens that were transported in viral transport medium and saline. Neither is listed as acceptable transport media in the Directory of Service procedure. 4. The section titled "Off-Site /Outpatient Transportation Instructions" stated to "Immediately refrigerate specimen</p>

after collection. Keep specimen at refrigerated temperature after collection to delivery" and "Cold packs/pouches should be used in a Styrofoam, or similar type cooler, to transport priority transport bags containing specimens." 5. The section titled "Specimen Stability" stated to keep specimens refrigerated after collection and that specimens should be transported refrigerated, but "ambient temperature transport is acceptable when immediately transported to lab." The section also stated that the "Preferred" stability was "Refrigerated: 72-hour stability" and "Acceptable" stability was "Frozen: undetermined stability. Please routinely send specimens refrigerated." 6. It was stated during the survey that patient swab specimens received in DNA/RNA Shield had a stability of 7 days at room temperature, patient saliva specimens received in the SDNA-1000 collection container had a stability of 30 days at room temperature, and the laboratory accepted samples that were shipped at non-refrigerated temperatures. The acceptable storage and transport stability for swab specimens collected in DNA/RNA Shield and saliva specimens collected in SDNA-1000 containers were not defined in the Directory of Service procedure. 7. The sections titled "Performing Department Laboratory Location" and "Disclaimer" stated that all testing would be performed at PRL located in New York City, but the Directory of Service procedure reviewed was for testing that was to be performed at PRL located in Rockville, MD. 8. During the survey on 10/29/2021 at 3:45 PM, the LM and QCM confirmed that the Directory of Service procedure did not include acceptable specimen storage, transport, and stability information for all accepted specimen types and listed the incorrect address for the testing laboratory.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of the test requisitions, Directory of Service procedure, final patient test reports and interview with the laboratory manager (LM), the laboratory failed to ensure that the final report included the source of the specimen when performing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) coronavirus disease 2019 (COVID-19) testing. Findings: 1. Review of the test requisition shows that the physician ordering the test is not required to document the source of the specimen. 2. Review of the Directory of Service procedure shows that the client can collect and submit a nasopharyngeal, anterior nasal, nasal mid-terminate (NMT), oropharyngeal, or saliva specimen. 3. Review of the final patient test report shows that the source of the specimen is not included. 4. During the survey on 10/29/2021 at 3:45 PM, the LM confirmed that the laboratory receives multiple types of specimens for testing SARS-CoV-2 (COVID-19) and the final patient test report failed to differentiate between the source of the potential specimens types.