

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2297657	<b>(X3) Date Survey Completed</b> 08/09/2024
<b>Name of Provider or Supplier</b> Discover Diagnostic Laboratory, Llc	<b>Street Address, City, State</b> 110 Cypress Station Dr, Suite 117, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced survey of the laboratory was conducted on 08/09/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D3003</b>	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to define protocols for handling specimens to minimize cross contamination between samples for its 4 of 4 molecular polymerase chain reaction (PCR) test panels, Respiratory, Urinary Tract Infection, Wound and Vaginitis. Findings included: 1. Surveyor's observations on 08/09/2024 at 1320 hours in the laboratory revealed the testing person number 1 (as indicated on submitted Form CMS 209) did not change gloves and/or follow any disinfection mechanism to minimize cross contamination between each patient sample, while specimen handling, transfer and /or test panel inoculation. 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for disinfection of surfaces and /or change/disinfection of gloves between patient samples to minimize sample cross contamination. 3. In an interview on 08/09/2024 at 1330 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS 209) confirmed the findings.</p>
<b>D5211</b>	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory's proficiency testing (PT) records, policies/procedures and staff interview, the laboratory failed to document evaluation of laboratory's PT result (concordance %, acceptability) for 2 of 4 PT blind studies performed by the laboratory in 2023, the PT blind studies for the wound and vaginitis panels. Findings included: 1. Review of laboratory's PT records revealed the laboratory performed PT by blind studies. PT blind studies were performed as follows: Wound panel - blind study PT performed March 2024 Vaginitis panel - blind study PT performed March 2024 2. Further review of the above blind study PT records revealed the laboratory failed to document evaluation of blind study PT results for concordance % and/or results' acceptability. 3. Review of laboratory's policies/procedures revealed there were no protocols in place for performing/evaluating PT by blind studies. 4. In an interview on 08/09/2024 at 1130 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS 209) confirmed the findings.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

Based on surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to define and follow protocols for patient sample secondary container (aliquot) labeling to ensure prevention of sample's misidentification for 7 of 12 sample aliquots observed. Findings included: 1. Surveyor's observations on 08/09/2024 at 1015 hours in the laboratory revealed 7 of 12 aliquoted samples stored in the refrigerator did not have a unique identifier. The aliquoted samples were labeled with patient's first name initial and the last name. 2. Review of laboratory/s policies/procedures revealed the laboratory did not have protocols in place for labeling of aliquoted samples to ensure sample's identity was preserved and to avoid mix-up of samples from patients with similar names. 3. In an interview on 08/09/2024 at 1015 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS 209) confirmed the findings.

**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:

A. Based on review of laboratory's final test reports and staff interview, the laboratory failed to include in test's final report specimen source for 2 of 4 reviewed reports, the Respiratory and Vaginitis polymerase chain reaction (PCR) test panels' reports. Findings included: 1. Review of laboratory's final test reports for the Respiratory PCR panel revealed there was no specimen source description that would indicate which part of the respiratory tract the sample came from. The report stated: Patient's DOB: 11/24/1974 Specimen collected: 06/25/2024 Specimen reported: 6/28/2024 Lab order: Discover RPP PLUS Specimen type: Swab (no indication of sample's source) 2. Review of laboratory's final test reports for the Vaginitis panel revealed there was no specimen source description. The report stated: Patient's DOB: 03/28/1995 Specimen collected: 6/26/2024 Specimen reported: 6/26/2024 Lab order: Vaginitis + STI Specimen type: change (no indication of sample's source) 3. In an interview on 08/09/2024 at 1400 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS 209) confirmed the findings. B. Based on review of laboratory's final test reports and staff interview, the laboratory failed to include in test's final report the information necessary for interpretation of results, or normal ranges for 4 of 4 tests performed by the laboratory, the Respiratory, Urinary Tract Infection, Wound and Vaginitis polymerase chain reaction (PCR) test panels. Findings included: 1. Review of laboratory's final patient test reports for its Respiratory, Urinary Tract Infection, Wound and Vaginitis polymerase chain reaction (PCR) test panels, revealed the reports did not have information necessary for interpretation of results (interpretative criteria) for the reported values, or normal ranges. 2. In an interview on 08/09/2024 at 1400 hours in the laboratory, the technical supervisor (as indicated on submitted Form CMS 209) confirmed the findings.