

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2246783	<b>(X3) Date Survey Completed</b>  04/17/2023
<b>Name of Provider or Supplier</b>  Nura Diagnostic Inc	<b>Street Address, City, State</b>  900 Valley View Ave Ste 9, Pasadena, CA	
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>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patients test records, and interview with the laboratory technical consultant and testing person on April 17, 2023, at 12:15 pm, the laboratory failed to follow test manufacturer's procedure for specimen integrity after collection and before completion of the testing. The findings include: 1. The laboratory received 4 patient's specimens (# 1146, 1147, 1153, 1156) for the hepatitis antigen and antibody testing that was collected on March 6, 2023. It stored the sample in the refrigerator till the testing was performed on March 15, 2023. So, the laboratory performed the test after storing the specimens in the refrigerator for 9 days. However, the test manufacturer's procedure instructs to store the sample in the refrigerator no longer than 7 days before testing due to sample integrity issue. Hence, the laboratory performed the test on a compromised sample. Therefore, the accuracy of the reported test results to the patients cannot be assured and may have harmed patients. 2. The laboratory technical consultant and testing person on April 17, 2023, at 12:15 pm, affirmed that the laboratory stored the sample in the refrigerator for more than 7 days before testing. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/17/2023 stated that the laboratory performs approximately 14,000 tests, annually.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</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.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, patients test records, and interview with the laboratory technical consultant and testing person on April 17, 2023, at 12:15 pm, the laboratory failed to follow its procedure for specimen storage. The findings include: 1. The laboratory stored hepatitis testing specimens in the refrigerator for too long that exceeded the manufacturer's instructed time limit, see D5203. Therefore, the validity of the patients' hepatitis test results rendered by the laboratory cannot be assured. 2. The laboratory technical consultant and testing person on April 17, 2023, at 12:15 pm, affirmed that the laboratory did not follow the manufacturer's instruction in storing the specimens. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/17/2023 stated that the laboratory performs approximately 14,000 tests, annually.

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, patient testing records and interview with the laboratory technical supervisor and testing person April 17, 2023, at 12:15 pm, it was determined that the laboratory director failed to assure the quality of laboratory services provided. The findings include: See D5203 and D5311.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, patient testing records

and interview with the laboratory technical supervisor and testing person April 17, 2023, at 12:15 pm, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: See D5203 and D6070.

**D6070**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, patient testing records and interview with the laboratory technical supervisor and testing person April 17, 2023, at 12:15 pm, the laboratory testing person #1 failed to follow the laboratory's procedures for specimen handling and processing. The findings include: See D5203.