

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0956168	<b>(X3) Date Survey Completed</b> 04/24/2024
<b>Name of Provider or Supplier</b> 21st Century Diagnostic Laboratory	<b>Street Address, City, State</b> 121 N Victory Blvd, Burbank, 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>D2020</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) records and interview with the laboratory technical supervisor on April 24, 2024, at 1:30 pm, the laboratory failed to attain at least 80% score at the M3 event in 2023 in the specialty of bacteriology resulted an unsatisfactory performance for the event. The findings include: 1. The laboratory failed to correctly identify the bacteria in the urine sample provided by the AAB-MLE PT organization at the M3 event in the year 2023. It correctly identified only 1 sample out of 5 samples provided. Hence the laboratory received 20% score from the AAB-MLE PT organization which was unsatisfactory performance. Therefore, the accuracy of the laboratory test results cannot be assured and may have potential to harm patients. 2. The laboratory technical supervisor on April 24, 2024, at 1:30 pm, affirmed that the laboratory received a 20% score in bacteriology from the AAB-MLE PT organization at M3 event in 2023. 3. The laboratory's testing declaration form signed by the laboratory director on 4/20/2024, stated that the laboratory performed approximately 4,321 tests in bacteriology, annually.</p>
<b>D5205</b>	<p><b>COMPLAINT INVESTIGATIONS</b> CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p>

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's records and interview with the laboratory technical supervisor on April 24, 2024, at 2 pm, the laboratory failed to document all complaints that was reported to the laboratory. The findings include: 1. The laboratory could not show any records that it documented and investigated any complaints it received. The laboratory informed that it documents all complaints on the laboratory test requisition form, however, was unable to show any records. Therefore, it cannot be assured that the laboratory indeed documenting and investigating complaints it received. 2. The laboratory technical supervisor on April 24, 2024, at 2 pm, confirmed that the laboratory's system is not appropriate to find any complaint and cannot assure that the complaints were documented and investigated to resolve. 3. The laboratory's testing declaration form signed by the laboratory director on 4/20/2024, stated that the laboratory performed approximately 510,769 tests, annually.

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's proficiency testing (PT) records and interview with the laboratory technical supervisor on April 24, 2024, at 1:30 pm, the laboratory director failed to ensure that the laboratory maintained an acceptable levels of analytical performance for bacteriology tests. The findings include: The laboratory received an unsatisfactory performance score from the proficiency testing organization in the year 2023. See D2020.

**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 Surveyor review of laboratory's personnel records and interview with the laboratory technical supervisor on April 24, 2024, at 2 pm, the laboratory director failed to assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The findings include: The laboratory reported 3 general supervisors and testing persons on the CMS-209 form. At the interview, general supervisor #1 represented as technical supervisor. The laboratory did not have any document showing that the director had assigned the duties to each person.