

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0956168	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier 21st Century Diagnostic Laboratory	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2077	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records for the second event of 2020 (Q2-2020), five (5) randomly selected patients, and interview with the technical supervisor (TS); it was determined that the laboratory failed to participate a testing event for General Immunology which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained an overall score of 0% for General Immunology testing during Q2-2020 as follow: Anti-HIV = 0.0 % H BsAg = 0.0% Anti-HBc = 0.0% 2. The TS affirmed on May 11, 2022, at approximately 11:30 a.m. the unsatisfactory score of 0% obtained by the laboratory on General Immunology testing for Q2-2020. 3. Based on the annual test volume reported for 2021, the laboratory performed and reported approximately 12,191 tests for the specialty of General Immunology.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory written test procedures reflecting the current laboratory practice, review of five (5) randomly chosen patients results, and interview with the laboratory's technical supervisor (TS); it was determined that the laboratory failed to have current written procedures for all tests performed in the laboratory reflecting the current practice. The findings included: 1. On the day of the survey on May 11, 2022, at approximately 2:00 p.m. the laboratory failed to provide current written procedures for all test procedures performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed covering period from 9/29/2020 to 2/16/2022 the patients had various test ordered, analyzed, and reported for which the laboratory had no current written tests procedures available reflecting the current practice. 3. The TS confirmed on May 11, 2022, at approximately 2:30 p.m. that the laboratory did not have current written procedures available for all test performed in the laboratory.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, proficiency testing reports, five (5) randomly chosen patients, and interview with the technical supervisor; it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by delegating responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. See D2077 and D5401.