

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2154346	(X3) Date Survey Completed 09/20/2024
Name of Provider or Supplier Doctor's Reference Laboratory	Street Address, City, State Apt 261, Dr Pedro Blanco Torre Medica Ii, Manati, PR	
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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Doctor's Reference Laboratory on September 20, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on September 20, 2024. .
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Individualized Quality Control Plan (IQCP) implemented by the laboratory for the Mycoplasma pneumoniae IgM (M, pneumoniae) tests, M. pneumoniae test records sheet review and interview with the laboratory director on 9 /20/2024 at 11:55 am, it was determined that the laboratory did not follow the established procedure about the monitoring and documentation of the internal procedural control for M. pneumoniae tests. The findings include: 1. The laboratory implemented a Quality Control Plan (IQCP) for M. Pneunoniae test on October 26, 20222. The program established to monitor and document the internal procedural control of the test cartridge. Reviewed on September 2024 at 11:55 am. The internal control result must be documented in the M. pneumoniae test record sheet, column # 7. As per observed in the M. pneumoniae test records sheet. 3. Review of the M. pneumoniae test record sheet showed that he laboratory did not document the internal</p>

control reaction when they processed 667 out of 682 patients since March 2023 to September 18, 2024. 4. The laboratory director confirmed on September 20, 2024 at 1:45 PM, that the internal controls were not included as established in the QCP.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the Quality Assessment Plan (QAP) implemented for the M. pneumoniae test after the implementation of the IQCP and interview with the laboratory director on September 20, 2024, it was determined that the laboratory did not follow the established QAP. The findings include: 1. The QAP implemented by the laboratory on October 26, 2022, instructed the laboratory to, daily evaluate the M. pneumoniae quality control procedures and to take any needed corrective action. Review on September 20, 2024 at 1:00 pm. 2. The laboratory did not monitor not take any corrective action, when the laboratory did not document the internal control of the M. pneumoniae tests. 3. The laboratory director confirmed on September 20, 2024 at 1:25 PM corrective action was taken as established in the the QAP.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review and laboratory director interview on September 20, 2024 at 1:25 pm, it was determined that laboratory director failed to ensure compliance with IQCP quality assessment requirements for M. pneumoniae tests. Refer to D 5791.