

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0948889	(X3) Date Survey Completed 01/25/2022
Name of Provider or Supplier Mayer J Saad Md Pc	Street Address, City, State 2950 Hempstead Turnpike, Levittown, NY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's thermometer calibration procedure, observation of storage room thermometer, lack of 2021 thermometer calibration record for refrigerator #2 an interview with the technical consultant and testing person, the laboratory failed to maintained the laboratory's written calibration procedure. FINDINGS: 1. The laboratory's calibration procedure requires calibration of thermometers used for room, refrigerators and freezers annually. 2. The laboratory failed to maintain the procedure and perform a calibration on refrigerator #2 thermometer in 2021, no calibration records were available for review. 3. It was observed on 21/25/22 at 12:30 PM that the storage room thermometer was not a certified. 4. The technical consultant and testing person confirmed on 21/25/22 at approximately 12:00 PM, the laboratory failed to maintained the laboratory's written calibration procedure and implemented a certified thermometer for room temperature.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and</p>

specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's thermometer calibration procedure, lack of 2021 thermometer calibration record for refrigerator #2 an interview with the technical consultant and testing person, the laboratory failed to perform and document the calibration for refrigerator #2 used to store reagents, controls and calibration material in the calendar year in 2021. Refer 5413

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of thermometer calibration expiration date, the laboratory lacked 2021 calibration log for thermometer used in refrigerator numbered 2 and last date of thermometer calibration was performed on September 6, 2022. The storage room thermometer was not a certified calibrated thermometer. It was determined that the laboratory director failed to implement and maintain the laboratory's quality assessment program. It was confirmed on an interview with testing person and technical consultant on January 25, 2022 about 12pm. Refer 5413