

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2008856	(X3) Date Survey Completed 04/15/2022
Name of Provider or Supplier Optum Medical Care Pc	Street Address, City, State 575 Underhill Blvd, Suite 100, Syosset, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's procedure manual, lack of written Quality Assessment (QA) procedure/ policy and confirmed in an interview with the testing person 4/15/2022 approximately 1:30pm, the laboratory failed to establish a written QA procedure/policy for monitoring technical and non-technical systems in the laboratory.</p>
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 room temperature, the laboratory failed to properly monitor, document, and take corrective action of room temperatures out of</p>

range. Findings: 1. The laboratory has established room temperature range as 59-86 F. The laboratory was recording min and max of room temperatures. The room temperature logs for the calendar years 2019, 2020, 2021 through survey date recorded a min. temperature below 59 F. 2. Confirmed in an interview with testing person on 4/14/2022 approximately 2pm.

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 a lack of the laboratory's QA policy, the laboratory director failed to establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D5291, D5413