

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2221158	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Modmd, Pc	Street Address, City, State 6755-150 Peachtree Industrial Boulevard, Atlanta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 30, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2057	<p>VIROLOGY CFR(s): 493.831(b)</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 laboratory document review and staff interview, the laboratory failed to participate in Proficiency Testing with the College of American Pathologists for Covid PCR testing. The Findings include: 1. College of American Pathologist(CAP) Proficiency Testing document review revealed that the laboratory failed to participate in Proficiency Testing (PT) for Covid PCR testing Events A and B in 2021. 2. During an interview with the Technical Supervisor, and an interview over the phone with the Laboratory Director(CMS 209), on November 30, 2022, at 11:50 AM, in the breakroom, confirmed that the Proficiency Testing was not performed for Covid PCR testing Events A and B in 2021.</p>

<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory competency policy review and staff interview, the Laboratory Director (LD) failed to perform competency on Testing Personnel. The Findings include: 1. Competency document review revealed the Laboratory Director failed to perform competency on all Testing Personnel (TP) for 2021 as required by policy. 2. During an interview on November 30, 2022 with the Technical Supervisor (CMS-209), at 1:25 PM, in the breakroom, confirmed that the Laboratory Director failed to perform competency in 2021 for all Testing Personnel.</p>
<p>D5293</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist for 2021 (January 2021- December 2021) and 2022 (January-November). 2. During an interview with the Technical Supervisor (CMS 209), on November 30, 2022, at 2:25 PM, in the break room, confirmed the lack of a QA checklist for 2021 and 2022 thus far .</p>
<p>D5413</p>	<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: A review of maintenance logs and staff interview revealed the laboratory failed to monitor and document room temperature and humidity as required by the manufacturer. The Findings include: 1. Maintenance log review revealed the laboratory failed to monitor room temperature and humidity in the laboratory as</p>

required by the manufacturer of the QuantStudio Real-Time Covid PCR testing for 2021. 2. During an interview with the Technical Supervisor (CMS-209) on November 30, 2022 at 1:00 PM in the breakroom, confirmed there was no room temperature and humidity monitoring and documentation for 2021.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the Laboratory Director (LD) failed to ensure PT was performed for Covid PCR testing for 2021. The Findings include: 1. Review of PT records for 2021 revealed the laboratory director failed to ensure the performance of Proficiency Testing (PT) for 2021 for Events A and B for Covid PCR testing. 2. During an interview with the Technical Supervisor and an interview over the phone with the Laboratory Director (CMS-209), on November 30, 2022, at 11:40 AM, in the breakroom, confirmed that the Laboratory Directory failed to ensure the performance of Proficiency Testing (PT) for Covid testing in 2021 for Events A and B.

D6022

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, procedure manual (SOP), and staff interview, the laboratory director failed to ensure that the quality assessment(QA) programs are established and maintained to identify failures in the laboratory. Findings include: 1. Review of the SOP's revealed the Laboratory Director did not establish a written Quality Assessment (QA) program for the overall laboratory from 2021 to the date of the survey, November 30, 2022. 2. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for the overall laboratory. 3. During an interview with Technical Supervisor(CMS-209) on November 30, 2022 at approximately 1:25 PM, in the breakroom, confirmed that the laboratory did not have records for QA from 2021 to the date of the survey November 30, 2022.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and staff interview, the Laboratory Director(LD) failed to ensure Testing Personnel (TP) competency was performed. The Findings include: 1. Competency documents revealed that the Laboratory Director failed to perform all Testing Personnel (TP)competencies for 2021. 2. During an interview with the Technical Supervisor(CMS-209) on November 30, 2022 at 1:25PM, in the breakroom, confirmed that the Laboratory Director(LD) did not perform competency on the Testing Personnel(TP) for 2021.