

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2133403	(X3) Date Survey Completed 09/22/2020
Name of Provider or Supplier 4m Healthcare, Llc	Street Address, City, State 15110 Glenwood, Overland Park, KS	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on the review of Proficiency Testing (PT) attestation pages, CMS-209 personnel report and interview, the laboratory failed to include personnel who routinely perform the regular patient testing in the testing of proficiency samples. Findings: 1 Review of all 2019 and 2020 to date of survey PT attestation pages from CAP revealed all testing been performed by General Supervisor (GS)#1 and GS#2. 2. Review of the CMS 209 reveals both GS#1 and GS#2 are also testing personnel (TP) and are designated as TP#11 and TP#1 respectively. There are a total of 11 testing personnel on the CMS-209. Only 2 of 11 TP performed PT sample testing. 3. Interview with GS#1 September 22,2020 at 4:30 p.m. confirmed, the laboratory failed to include personnel who routinely perform the regular patient testing in the testing of proficiency samples.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must</p>

be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on an absence of thermometer function check records or certificates of accuracy and interview, the laboratory failed to perform a function check protocol for the thermometers. Findings include: 1. No documentation was available for function checks on 5 of 9 thermometers for a 17 month period. 2. No documentation was available for the certification of accuracy (NIST traceable) on 5 of 9 thermometers for a 17 month period. 2. Interview with GS#1 on September 22, 2020 at 4:00 p.m. confirmed, the laboratory failed to perform a function check protocol for the thermometers.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of competency assessment records, and interview, the laboratory failed to ensure that all six required elements for competency assessment are performed for Testing Personnel. Findings: 1. Competency assessments for TP #1, 2,3,4,5, 8 and 11 did not contain the following required elements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b. Monitoring the recording and reporting of test results; c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; d. Direct observation of performance of instrument maintenance and function checks; e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem solving skills. 2. Interview with GS#1 on September 22, 2020 at 1:00 p.m. confirmed, the laboratory failed to ensure that all six required elements for competency assessment are performed for Testing Personnel.