Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2133403	06/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
4m Healthcare, Llc	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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the CMS 116 form test lists, procedure manual, lack of approved IQCP, quality control (QC) records, patient test reports and interview, the laboratory failed to perform a positive and negative control material each day of patient testing on the BioFire Respiratory Panel 2.0. Findings: 1. Review of the CMS116 CLIA non-waived testing list revealed the BioFire Respiratory Panel 2.0 is performed on the BioFire Torch instrument. This panel is FDA approved and classified as moderate complexity. 2. Review of the procedure "MOL-28 Biofire Respiratory Panel 2.0 and 2.1," approved for use by the laboratory director on 9/3/21, page 9, item 9.4.1 contained "External QC will be evaluated once per month, or for each new kit lot received." 3. No IQCP had been authorized by the laboratory director on the BioFire Respiratory Panel 2.0 for the reduced QC frequency. 4. Review of QC records revealed QC was performed on 3 of 91 patient testing dates. 5. Review of patient test reports revealed 355 of 371 patient results were reported from 2/4/22 -6/14 /22 without daily QC testing. 6. Interview with the Technical Supervisor on 6/14/22 at 3 p.m. confirmed, the laboratory failed to perform a positive and negative control material each day of patient testing on the BioFire Respiratory Panel 2.0.