

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2187282	<b>(X3) Date Survey Completed</b>  07/07/2021
<b>Name of Provider or Supplier</b>  Medbio Reference Laboratories, Inc	<b>Street Address, City, State</b>  11002 Veirs Mills Road Ste 404, Wheaton, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 record review, the laboratory did not ensure that temperature records were unique and specific to the laboratory surveyed, did not maintain humidity records and did not state the acceptable temperature ranges on worksheets. Findings: 1. The upstairs room temperature and freezer temperature records maintained by MedBio Reference Laboratories to store test reagents were identified as "Institute for Asthma and Allergy" records and not MedBio Reference Laboratories; 2. The workspace room temperature records (where analyzers were located) and the refrigerator and freezers (1 and 2) in the same work area did not include the acceptable temperature limits for each; and 2. The laboratory did not maintain humidity records for the area that the test analyzers were located.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p>

	<p>This STANDARD is not met as evidenced by: Based on record review, the laboratory did not document the lot number and expiration date of the SARS-Cov-2 antibody test kits used for immunoassay testing and the laboratory did not document the expiration date of the SARS -Cov-2 molecular testing kits to ensure they were not used past expiration.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review, the laboratory director did not provide overall management in accordance with 493.1445 of this subpart and failed to ensure credentialing documentation of testing staff was available for review. See D6102 for findings; and failed to perform six month competency checks for testing staff. See D6103 for findings.</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of staff credentials, the laboratory director did not ensure that he evaluated credentials in a reliable manner and ensure staff met CLIA personnel requirements for high complexity testing. Findings: 1. "Testing Person #1" obtained a foreign degree, the surveyor requested the evaluation of that degree by a CLIA approved credentialing agency. The laboratory director presented an english translation of the foreign degree as that evaluation; and 2. "Testing Person #2" obtained a doctorate and the director presented this to the surveyor, but the degree did not state the discipline or major field of study conferred to "Testing Person #2" or a transcript to ensure an acceptable number of credit hours were achieved in chemistry and biology.</p>
<p><b>D6103</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must 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.</p>

This STANDARD is not met as evidenced by:

Based on review of written procedures and competency check records the laboratory director did not ensure that there were written procedures and records showing that competency assessments were performed for the six month evaluation of testing staff.