

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0901100	(X3) Date Survey Completed 03/31/2021
Name of Provider or Supplier Ph Enterprises Inc Db a Mag-Lab	Street Address, City, State 200 E Centennial Drive, Suite 10a, Pittsburg, 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
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 be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on an absence of thermometer function check protocols, function check records or current certificates of accuracy and interview, the laboratory failed to define and perform a function check protocol for the thermometers. Findings: 1. No documentation of a function check protocol for the thermometers was available at the time of survey. 1. No documentation was available for performance of function checks on 7 of 7 thermometers for a 2 year period. 2. No documentation was available for current certification of accuracy on 7 of 7 thermometers for a 2 year period. 2. Interview with Technical Consultant #1 on 3/31/2021 at 10 a.m. confirmed, the laboratory failed to define and perform a function check protocol for the thermometers.</p>