

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0901100	(X3) Date Survey Completed 03/15/2019
Name of Provider or Supplier Ph Enterprises Inc DbA 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical supervisor #1, the laboratory failed to include reference intervals (normal values) for WBC manual differentials. Findings: 1. Review of the procedure manual revealed a lack of normal values for WBC manual differentials. 2. Interview with the technical supervisor #1 on 15 March 2019 at 1:00 PM confirmed the laboratory failed to include normal values for WBC manual differentials.</p>
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the hematology staining area and interview with the technical supervisor #1, the laboratory failed to identify the contents and document the preparation and expiration dates of the reagents used in staining white blood cell (WBC) differentials. Findings: 1. Observation of the WBC differential staining area showed unlabeled containers with no preparation or expiration dates. 2. Interview with the technical supervisor #1 on 15 March 2019 at 1:00 PM confirmed the laboratory failed to identify the WBC staining material and include the preparation and expiration dates.