

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0681749	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Kansas Pathology Services, Llc	Street Address, City, State 1212 E 27th Street Unit B, Hays, 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 laboratory's lack of documentation and interview, the laboratory failed show documents with reference ranges (normal values) for fifteen Complete Blood Count (CBC) analytes and calculations in the "Sysmex Xs 1000i" or "Critical Alert & Reportable Range" policies at time of survey. Findings: 1. Patient test reports for both male and female with reference ranges had no corresponding reference ranges for the following fifteen analytes and calculations: Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell Distribution Width (RDW), Mean</p>

Platelet Volume (MPV), Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, Neutrophil Absolute (#), Lymphocyte #, Monocyte #, Eosinophil #, and Basophil #. 2. Lack of documentation in the "Sysmex Xs 1000i" policy failed to present both male/female reference ranges of the CBC analytes and calculations: MCV, MCH, MCHC, RDW, MPV, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, Neutrophil Absolute (#), Lymphocyte #, Monocyte #, Eosinophil #, and Basophil #. 3. Lack of documentation in the "Critical Alert & Reportable Range" policy failed to present both male/female reference ranges of the CBC analytes and calculations: MCV, MCH, MCHC, RDW, MPV, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, Neutrophil Absolute (#), Lymphocyte #, Monocyte #, Eosinophil #, and Basophil #. 4. Interview with the general supervisor #1 and laboratory director on November 15, 2023 at 10:10 a.m. confirmed, the laboratory failed to contain fifteen CBC reference range values (normal values) documented in the "Sysmex Xs 1000i" and/or "Critical Alert & Reportable Range" policies while reporting patient test results at time of survey.