

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0681749	<b>(X3) Date Survey Completed</b>  05/04/2022
<b>Name of Provider or Supplier</b>  Kansas Pathology Services, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<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 hematology policy, Sysmex Xs 1000i validation and interview, the laboratory failed to document reference ranges (normal values) for twenty Complete Blood Count (CBC) analytes and calculations in the "Sysmex Xs 1000i" policy. A male and female CBC laboratory patient test report displayed patients' male/female normal values with no correlating values listed in the "Sysmex Xs 1000i" policy at time of survey. Findings: 1. No documentation in the "Sysmex Xs 1000i" policy demonstrating the present of female reference ranges of the CBC analytes: White Blood Cell Count (WBC), Red Blood Cell Count (RBC), hematocrit</p>

(HCT) hemoglobin (HGB), platelets (PLT) Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil % and Basophil %. 2. No documentation in the "Sysmex Xs 1000i" policy demonstrating the present of both male/female reference ranges of the CBC analytes and calculations: PLT, Mean Corpuscula Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red cell Distribution Width (RDW), Mean Platelet Volume (MPV), Neutrophil Absolute (#), Lymphocyte #, Monocyte #, Eosinophil #, and Basophil #. 3. Based on a review of a Male and Female CBC patient reports with reference ranges for WBC, RBC, HCT, HGB, PLT, MCV, MCH, MCHC, RDW, MPV, Neutrophil %, Lymphocyte %, Monocyte %, Eosinophil %, Basophil %, Neutrophil #, Lymphocyte #, Monocyte #, Eosinophil # and Basophil #, the reference range documentation could not be presented from the Sysmex XS 1000i policy. 4. Interview with the laboratory director on May 4, 2022 at 10:30 a.m. confirmed, the laboratory failed to verify the reference ranges (normal values) were documented in the "Sysmex Xs 1000i" policy while reporting patient CBC test results at time of survey.