

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2250646	<b>(X3) Date Survey Completed</b>  02/07/2024
<b>Name of Provider or Supplier</b>  Pioneer Healthcare, Llc	<b>Street Address, City, State</b>  6766 Hwy 98 W Ste 102, Hattiesburg, MS	
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 Sysmex XN-330 hematology analyzer Troubleshooting Manual, the Laboratory Policy and Procedure manual, and interview with Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to establish written procedures for the verification of results when patient complete blood count (CBC) results were flagged by the hematology analyzer for white blood cell (WBC), red blood cell (RBC), and platelet (PLT) abnormalities. Findings include: 1. Review of the Sysmex XN-330 hematology analyzer Troubleshooting Manual revealed the hematology analyzer</p>

produces Interpretive Program (IP) Suspect Messages for the following WBC, RBC, and PLT abnormalities: WBC IP Messages "IG Present" indicates increased immature granulocytes. "Left shift" indicates possibility of left shift. "Blasts/Abn Lymphs" indicates possibility that blasts are present/possibility of abnormal lymphocytes. "Atypical Lymphs" indicates possibility of atypical lymphocytes. "NRBC" indicates possibility of nucleated red blood cells. RBC IP Messages "RBC Agglutination" indicates possibility of RBC agglutination. "Turbidity/HGB Interference" indicates possibility of effect on hemoglobin by chylemia. "Iron Deficiency" indicates possibility of iron deficiency. "HGB Defect" indicates possibility of hemoglobin abnormality. "Fragments" indicates possibility of fragmented red blood cells. "iRBC" indicates possibility of erythrocyte inclusions. PLT IP Message "PLT Clumps" indicates possibility of PLT clumps. 2. Review of the Laboratory Policy and Procedure manual revealed no written procedures for the verification of results when patient CBC results were flagged by the Sysmex XN-330 hematology analyzer with WBC IP Messages, RBC IP Messages, and PLT IP Messages. 3. In an interview on 2/7/2024 at 11:45 a.m., Testing Personnel #2, listed on the CMS 209 personnel form, confirmed there were no procedures for verification of flagged CBC results. THIS IS A REPEAT DEFICIENCY.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on review of the Sysmex XN-330 hematology analyzer Troubleshooting Manual and interview with Testing Personnel #2, listed on the CMS 209 personnel form, the laboratory failed to document daily and weekly maintenance for seventeen, of seventeen, months since the last survey on 8/16/2022. Findings include: 1. Review of the Sysmex XN-330 hematology analyzer Troubleshooting Manual revealed the following maintenance tasks were required by the manufacturer: Daily Maintenance: "Shutdown" Weekly Maintenance: "Executing routine cleaning" 2. In an interview on 2/7/2024 at 11:45 a.m., Testing Personnel #2, listed on the CMS 209 personnel form, confirmed daily and weekly maintenance for the Sysmex XN-330 hematology analyzer was not documented as performed for the seventeen months since the last survey on 8/16/2022. Testing Personnel #2 confirmed the laboratory's annual volume for complete blood count (CBC) tests performed on the Sysmex XN-330 hematology analyzer was 2,580.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the Sysmex XN-330 hematology analyzer Troubleshooting Manual, the Laboratory Policy and Procedure manual, and interview with Testing Personnel #2, listed on the CMS 209 personnel form, the laboratory director failed to ensure an approved procedure manual was available to all testing personnel that included written procedures for the verification of results when patient complete blood count (CBC) results were flagged by the hematology analyzer for white blood cell (WBC), red blood cell (RBC), and platelet (PLT) abnormalities. Refer to D5403