

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2187808	<b>(X3) Date Survey Completed</b>  07/08/2022
<b>Name of Provider or Supplier</b>  Medstar Hem Onc And Infusion At Franklin Square Lo	<b>Street Address, City, State</b>  5601 Loch Raven Blvd Suite 103, Baltimore, MD	
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 procedure and interview with the clinical laboratory manager (CLM), the laboratory's procedure failed to reflect laboratory practice for hematology quality control (QC) review. Findings: 1. The procedure titled "Onc-Auto-201 Complete Blood Count of Whole Blood on the XS 1000i" was reviewed. 2. The procedure stated that the QC reports titled "Report (LP)" and "Report (GP)" were to be printed and reviewed by the lead technologist on a weekly basis. 3. The CLM stated at 10:40 am that the technologist no longer prints and reviews the QC reports</p>

weekly and instead downloads the QC reports to a flash drive and uploads them onto the manufacturer's (Sysmex) site where the reports are reviewed by the technical consultant. 4. During the survey on 07/08/2022 at 12:15 pm, the CLM confirmed that the current procedure does not reflect laboratory practice for weekly review of QC reports.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of the clinical laboratory improvement amendments (CLIA) certificate, manufacturer's service records, and patient chart printouts and interview with the clinical laboratory manager (CLM), the laboratory's records listed multiple different laboratory names. Findings: 1. The CLIA certificate of compliance listed "MedStar Franklin Square Cancer Center at Loch Raven" as the laboratory name. 2. The laboratory name listed on the hematology instrument manufacturer's (Sysmex) records was "Good Samaritan Hospital - Oncology Clinic." 3. The patient chart printout of the final results reported by the laboratory listed the laboratory name as "MedStar Hem Onc and Infusion at Franklin Square Loch Raven." 4. During the survey on 07/08/2022 at 12:15 pm, the CLM confirmed that the laboratory is referred to by multiple names that do not match the CLIA certificate of compliance. The CLM corrected the name in the Sysmex system during the survey.