

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0910367	<b>(X3) Date Survey Completed</b> 04/09/2018
<b>Name of Provider or Supplier</b> Mercy Hematology & Oncology	<b>Street Address, City, State</b> 1320 Mercy Drive Nw, Canton, OH	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #1, the laboratory failed to establish, have available and follow written policies and procedures for the newly implemented Sysmex XP300 Hematology test system. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, found a "Test System QC and Remedial Action" policy and procedure with reference to "A. ABX Hematology Analyzer". 2. Review of the Sysmex XP300 installation and validation records provided on the date of the inspection, revealed the transition of all patient Hematology testing from the previous ABX Hematology analyzer to the Sysmex XP300 occurred on June 29, 2017. 3. The Surveyor requested the laboratory's approved policy and procedure for the Sysmex XP300 from the OM and TC#1. TC#1 confirmed the laboratory did not establish and have available a policy and procedure for the Sysmex XP300 Hematology analyzer newly implemented on June 29, 2017 and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/09/2018 at 11:33 AM.</p>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests</p>

and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Office Manager (OM) and Technical Consultant (TC) #1, the laboratory failed to report correct "reference intervals" or "normal" values for female red blood cell (RBC) counts, as determined by the laboratory and approved by the Laboratory Director. Findings Include: 1. Review of the laboratory's Sysmex XP300 validation documentation, provided on the date of the inspection, revealed the following RBC reference range, approved by the Laboratory Director on 07/28/2017: 4.20 - 6.20 "1) Combined M & F. 'Laboratory Director's initials' 7/28/2017" M & F; male and female 2. Review of two out of two of the laboratory's female patient test reports, dated 07/28/2017 and 03/14/2018 and provided on the date of the inspection, revealed the following reported RBC reference range: 4.2 - 5.4 3. The OM and TC#1 confirmed the laboratory did not report the correct RBC "reference interval" or "normal" values, as determined by the laboratory and approved by the Laboratory Director. The interviews occurred on 04/09/2018 at 11:55 AM.