

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1007731	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Winston Medical Clinic Llc	Street Address, City, State 17540 E Main St, Louisville, MS	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for Sysmex Eightcheck-3WP X-TRA hematology controls and the laboratory's annual test volumes, lack of documentation of laboratory refrigerator temperatures from 4/7/2022 through 1/10/2024, and interview with Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 1/10/2024 at 11:20 a.m., the laboratory failed to follow manufacturer's instructions for twenty of twenty months for refrigerator storage of hematology controls, used for complete blood count (CBC) testing on the Sysmex XP-300 hematology analyzer. Findings include: 1. Manufacturer's instructions for Sysmex Eightcheck-3WP X-TRA hematology controls state, "Eightcheck-3WP X-TRA is to be stored closed at 2 to 8 degrees Celsius. Avoid freezing this material. When stored properly, the unopened product can be used until the expiration date stated on the label on the vial. Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for control or calibration verification." 2. On 1/10/2024 there was no documentation of laboratory refrigerator temperatures for twenty of twenty months from 4/7/2022 through 1/10/2024. 3. Testing Personnel #2 confirmed on 1/10/2024 at 11:20 a.m. that there was no documentation of laboratory refrigerator temperatures since the last survey on 4/6/2022. 4. Review of the laboratory's annual test volumes revealed the laboratory's annual CBC test volume was 17,592.</p>
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Policy and Procedure Manual and manufacturer's instructions for Sysmex Eightcheck-3WP X-TRA hematology controls, interview with Testing Personnel #2, listed on the CMS 209 personnel form, on 1/10/2024 at 11:20 a. m., and lack of documentation of laboratory refrigerator temperatures from 4/7/2022 through 1/10/2024, the laboratory failed to follow its written Quality Assurance Program for recording daily refrigerator temperatures for twenty of twenty months from 4/7/2022 through 1/10/2024. Findings include: 1. Review of the Laboratory Policy and Procedure Manual revealed the Quality Assurance Program stated, "Lab temperatures and humidity as well as refrigerator and freezer temperatures are recorded daily to ensure proper conditions for instruments and proper temperatures for what is housed in the refrigerators/freezers. Package inserts are reviewed to determine acceptable operating temperatures." 2. Manufacturer's instructions for Sysmex Eightcheck-3WP X-TRA hematology controls, used for quality control of complete blood count (CBC) testing on the Sysmex XP-300 hematology analyzer, state, "Eightcheck-3WP X-TRA is to be stored closed at 2 to 8 degrees Celsius. Avoid freezing this material. When stored properly, the unopened product can be used until the expiration date stated on the label on the vial. Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for control or calibration verification." 3. On the day of the survey, 1/10/2024, there was no documentation of laboratory refrigerator temperatures for twenty of twenty months from 4/7/2022 through 1/10/2024. 4. Testing Personnel #2 confirmed on 1/10/2024 at 11:20 a.m. that there was no documentation of laboratory refrigerator temperatures since the last survey on 4/6/2022.