

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2138003	(X3) Date Survey Completed 02/28/2022
Name of Provider or Supplier St Dominic Family Medicine - Dogwood	Street Address, City, State 205 Belle Meade Point, Flowood, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records since the last survey on 8/22/19 and confirmation by the laboratory director, the laboratory failed to retain all proficiency testing records for at least 2 years. Findings include: Review of proficiency testing (PT) records since the last survey on 8/22/19 revealed the Sysmex XP-300 hematology analyzer printouts of results for proficiency testing samples were not retained for at least 2 years for the following hematology PT Events: Events 2 and 3 of 2020 and Event 1 of 2021. The laboratory director confirmed the analyzer printouts for these proficiency testing results were not retained.</p>
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 laboratory refrigerator and room temperature logs since the last survey on 8/22/19, manufacturer's instructions for the Sysmex XP-300 hematology analyzer and Sysmex Eightcheck-3WP X-tra hematology controls, and confirmation by the laboratory director, the laboratory failed to ensure patient CBC (complete blood count) testing was performed following manufacturer's instructions for</p>

operating temperature of the Sysmex XP-300 hematology analyzer and for proper storage temperature of Sysmex Eightcheck-3WP X-tra hematology controls from January through December 2020, when there was no documentation of monitoring of refrigerator or room temperatures. Findings include: The manufacturer's instructions for the Sysmex XP-300 hematology analyzer state the environmental requirement is ambient temperature of 15 to 30 degrees Celsius. The manufacturer's instructions for the Sysmex Eightcheck-3WP X-tra hematology controls state the controls should be stored at 2 to 8 degrees Celsius. Review of laboratory refrigerator and room temperature logs since the last survey on 8/22/19 revealed no documentation of monitoring of laboratory refrigerator temperatures or laboratory room temperatures from January through December 2020. The laboratory director confirmed there was no documentation of laboratory refrigerator or room temperatures for 2020.

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 maintenance logs for the Sysmex XP-300 hematology analyzer since the last survey on 8/22/19 and confirmation by the Laboratory Director, the laboratory failed to document, as performed, the maintenance on the Sysmex XP-300 hematology analyzer, as defined by the manufacturer, from January through December of 2020. Findings include: Review of the maintenance logs for the Sysmex XP-300 hematology analyzer since the last survey on 8/22/19 revealed there was no documentation of the following maintenance procedures from January through December 2020: Daily Maintenance Perform Shutdown Verify Background Verify Vacuum/Pressure Check Trap Chamber Perform Quality Control Weekly Maintenance Clean SRV Tray Monthly Maintenance (or every 1,500 samples) Clean RBC and WBC Transducer Clean Waste Chamber Quarterly Maintenance (or every 4,500 samples) Clean Sample Rotor Valve The laboratory director confirmed there was no documentation available of Sysmex XP-300 hematology analyzer maintenance from January through December 2020.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of personnel records since the last survey on 8/22/19 and the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory

director failed to ensure Testing Personnel #2 had the appropriate education for performing moderate complexity testing prior to testing patients' specimens. Findings include: Review of the CMS 209 personnel form revealed Testing Personnel #2 is listed as performing moderate complexity testing. Review of personnel records since the last survey on 8/22/19 revealed the initial competency assessment for Testing Personnel #2 for performing complete blood count (CBC) testing was documented by the Laboratory Director/Technical Consultant on 8/29/20. There was no documentation of education for Testing Personnel #2 available on the day of the survey, 2/28/22.