

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2138003	(X3) Date Survey Completed 04/03/2018
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Centers of Medicare and Medicaid Services database proficiency testing report and confirmation by laboratory staff at 2:00 PM on 4/3/18, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Sysmex XP 300 hematology analyzer. The laboratory must enroll and participate in an approved program for each specialty performed.</p>
D5403	<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</p>

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.

This STANDARD is not met as evidenced by:

1. Based on review of the laboratory procedure manual and confirmation with staff at 3:00 on the day of survey, 4/3/18, the laboratory did not have available a written approved procedure that included imminent life threatening test results (panic/alert /critical values). Findings include: There was a procedure on how to handle critical results, but no ranges set at which results were considered critical.
2. Based on the review of the Sysmex XP 300 Operator's manual, the laboratory failed to use the reference intervals which were recommended by the manufacturer and listed in the Operator's manual until they could establish their own reference (normal) intervals. Findings include: The laboratory was using a reference range entered in the instrument by the service representative for the installation process in November 2017. This range was not intended as a reference interval (normal range) for patients.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

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.

This STANDARD is not met as evidenced by:

Based on review of Sysmex XP 300 installation records, six patient CBC results printed from the clinic progress notes, Sysmex analyzer patient printouts, Operator's manual and interview with the technical consultant, the laboratory failed to follow the Sysmex Operator's manual instructions to establish its own reference intervals (normal ranges) based upon the laboratory's population. Findings include: On the day of survey, the surveyors observed a set of reference ranges entered in the Sysmex XP 300 by the service representative (Range 1), a set of reference ranges which printed on the clinic progress notes (Range 2), and a set of reference ranges available on the pre-printed report form for the Hematology analyzer (Range 3). After confirmation with technical consultant, it was confirmed the laboratory did not follow the manufacturer's instructions to establish its own reference intervals based upon the laboratory's patient population.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of temperature records from 12/1/17 through 4/3/18 and confirmation with staff at 2:30 pm on the day of survey 4/3/18, the laboratory failed to monitor and document the temperature and humidity of the room where the Sysmex XP 300 was stored and operated. Findings include: Maintaining appropriate conditions according to the instructions of the manufacturer is essential for optimal test performance. The Sysmex manufacturer's instructions state: 1. Use the instrument in places where ambient temperature ranges between 15-30 degrees Celsius (C). Optimal room temperature is 23 degrees C. 2. Allow quality control (QC) material to come to room temperature at 18-25 degrees C for 15 minutes. 3. Store Cell Pack, Stromatolyser-WH, reagents and bleach at room temperature of 15-30 degrees C. 4. Use the instrument in places where relative humidity ranges between 30% and 85%

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on lack of performance verification documentation available for review and confirmation by staff at 4:00 pm on 4/3/18, the laboratory failed to verify or establish reference intervals (normal ranges) appropriate for its population for the Sysmex XP 300 hematology analyzer. The Sysmex was installed in November 2017; the laboratory has tested approximately 400 Complete Blood Counts (CBC) since then. Findings include: On the day of survey, the reference (normal) ranges observed in the Sysmex XP 300 analyzer were ranges entered by service personnel for the installation process.

D5807

TEST REPORT
CFR(s): 493.1291(d)

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

This STANDARD is not met as evidenced by:
Based on review of six patient CBC (Complete Blood Count) reports from the laboratory's EMR (electronic medical records) system and interview with staff on day

of survey at 2:30 pm, the laboratory failed to have pertinent reference intervals (normal ranges) available with the reporting of patient CBC results. Findings include: On the day of survey, it was observed that the normal values in the Sysmex XP 300 hematology analyzer had been turned off --this was due to a provider request who did not want ranges on the analyzer printout. With this range system turned off, the testing personnel were not alerted to abnormal or critical values when testing patient samples. When trying to determine if reference intervals were available to the authorized person or individual using the test results, the surveyors found three different sets of reference intervals in use for the CBC testing performed. 1. The temporary range entered in the Sysmex by the service representative. 2. A second reference range that printed on patient "in-house" progress notes. 3. A third reference range (reference laboratory ranges) pre-printed on the paper used to print the report from the CBC analyzer. None of these ranges had been established or verified for the patient population of the facility.