

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1022336	(X3) Date Survey Completed 11/29/2022
Name of Provider or Supplier St Dominic's Gynecologic Oncology	Street Address, City, State 971 Lakeland Dr Ste 750, Jackson, 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
D5401	<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 review of installation procedures for the Sysmex XP-300, interview with testing personnel (TP) #1 on 11/29/2022 at 3:30 p.m., and lack of a written procedure manual, the laboratory failed to establish a written procedure manual for performing CBC (Complete Blood Count) testing with the Sysmex XP-300 Hematology analyzer, in use for patient testing from 08/12/2021 through 11/29/2022. Findings include: 1. The laboratory has an annual volume of 944 patient samples for CBC. 2. There was no procedure manual available for review on 11/29/2022 for performing patient CBC's on the Sysmex XP-300 Hematology analyzer. 3. The LD/TC confirmed in an interview on 11/29/2022 at 3:30 p.m. that there was no written procedure for performing CBC's, approved and signed by the laboratory director.</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:

Based on review of the laboratory's procedure manual and lack of an approved manufacturer's operator's manual for the Sysmex XP-300 hematology analyzer, the laboratory failed to provide a procedure manual for the step-by-step performance of complete blood count (CBC) testing with the Sysmex XP-300 hematology analyzer. Findings include: 1) A manufacturer's operator's manual for the Sysmex XP-300 was available in the laboratory, but had not been reviewed and approved by the laboratory director. 2) The operator's manual did not include elements unique to the laboratory, as required. a) Control procedures. b) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. c) Reference intervals (normal values) for the facility's population. d) Imminently life-threatening (panic, alert) values and steps to take when identified. e) The laboratory's system for entering results in the patient record. 3) TP #1 confirmed in an interview at 3:30 p.m. on 11/29/2022 that no step-by-step procedure for the performance of CBC's with the Sysmex XP-300 had not been developed and reviewed by the laboratory director. 4) The laboratory performs 944 patient CBC's annually.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records for the Sysmex XP-300 hematology analyzer from 08-12-2021 (date instrument placed in service) through 11/29/2022 and confirmation by Testing Personnel #1 listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, the technical consultant failed to document, as performed, review of QC records for the hematology analyzer since the instrument was installed. Findings include: 1) Quality control (QC) was performed each day of patient testing and daily records placed in a binder along with patient results. 2) There was no documentation to indicate that the technical consultant had reviewed the QC reports. 3) Testing Personnel #1 confirmed in an interview at 3:30 p.m. on 11/29/2022 that the technical consultant had not reviewed the QC for the Sysmex XP-300 since the instrument was placed in service in August of 2021. 4) The laboratory has an annual volume of 944 patient CBC's.