

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2175258	(X3) Date Survey Completed 12/08/2023
Name of Provider or Supplier Smg Pediatric Clinic Seymour	Street Address, City, State 11021 Chapman Hwy, Seymour, TN	
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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's Complete Blood Count (CBC) procedure for the Sysmex XP-300 hematology analyzer, document request, patient test record review, and staff interview, it was revealed that the laboratory failed to establish criteria for reporting abnormal results to physicians in 2022 thru the survey date of 12.08.2023. The findings include: 1. Observation of the laboratory on 12.08.2023 at 1:15 p.m. revealed a Sysmex XP-300 (serial number B5909) hematology analyzer in use for Complete Blood Count (CBC) patient testing. 2. Review of the Sysmex XP-300 hematology analyzer Operator's manual (March</p>

2017 Revision) stated the following: "Flag; Probable sample cause; Correction: WL; Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase in large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc; Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, Check smear, etc. RL; Presence of fragmented red blood cells, increase in large platelets, platelet aggregation or agglutination, etc; Manual red blood cell count of sample, Check smear, etc. PL; Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells, etc; Warm sample at 37C for 30 minutes and repeat analysis, Check smear, etc. WU; Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc; Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, Check smear, etc. RU; Effects of cold agglutinin, inclusion of white blood cells, etc.; Warm sample to 37C for 30 minutes and repeat analysis, Check smear, etc. PU; Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, etc.; Manual platelet count of sample, Check smear, etc. DW (RBC); Significant anisocytosis; Check smear, etc. DW (PLT); Inclusion of fragmented red blood cells, nonuniformity in size of platelets, effects of cryoglobulins; Check smear, etc., Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc. MP (RBC); Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes; Check smear, etc. MP (PLT); Platelet aggregation, sample with low values for platelets; Check Smear, etc. T1; Presence of CML or other immature granulocytes; incomplete lysing of red blood cells, etc; Check smear, etc., Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc. T2; Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc.; Check smear, Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc. F1, F2, F3; Presence of CML or other immature granulocytes, sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. Check smear, Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc. AG; Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc.; Check smear, etc. 3. Request for the laboratory to provide a policy for flagged CBC results revealed none. 4. Random review of patient test reports from the Sysmex XP-300 hematology analyzer revealed the following 2 of 3 patient CBC test results with a flag: -Date 09.09.2022: Patient 1073811; AG Flag: No documentation of repeat testing and No documentation of a smear check. -Date 12.08.2023: Patient 1157421: AG Flag: No documentation of repeat testing and No documentation of a smear check. 5. In an interview at 3:00 p.m. on 12.08.2023, the laboratory lead was asked to describe how flagged CBC results were addressed. She stated that results were reviewed on the LIS by laboratory personnel and released to the patient's EMR for provider review. The flagged results were showing on the printout from the Sysmex XP-300 analyzer, but NOT showing in the LIS and EMR. Results are reviewed by the provider in the EMR only, where the flags were NOT showing. She also stated, "We are working on adding a procedure for what to do if there is a 'flag' or error on the instrument printout but there is not a procedure for rerunning samples that have error codes." This confirmed the above findings. Word Key: WBC = White Blood Count RBC = Red Blood Count PLT = Platelet CML= Chronic Myeloid Leukemia LIS = Laboratory Information System EMR=Electronic Medical Record C= degrees Celsius