Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2175253	12/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Smg Pediatric Clinic West	125 Huxley Rd, Knoxville, 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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the operator's manual for the Sysmex XP-300 hematology analyzer, random review of patient test records from 12.04.2023, and staff interview, it was revealed that the laboratory failed to ensure that 4 of 10 Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Findings included: 1. Observation of the laboratory on 12.04.2023 at 9:30 a.m. revealed a Sysmex XP-300 (serial number B5128) hematology analyzer in use for Complete Blood Count (CBC) patient testing. 2. Review of the Sysmex XP-300 hematology analyzer Operator's manual (March

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. A random review of patient test reports from the Sysmex XP-300 hematology analyzer from 12.04.2023 revealed the following 4 of 10 patient CBC test results with a flag: - Date 12.04.2023; Patient 682365; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. - Date 12.04.2023; Patient 886563; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. - Date 12.04.2023; Patient 997965; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. - Date 12.04.2023; Patient 1308202; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. 4. The laboratory was asked to provide a policy for flagged CBC results. No policy was provided. 5. In an interview on 12.04.2023 at 12:30 p.m., the laboratory lead was asked to describe how flagged CBC results were addressed. She stated that patient CBC 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 the laboratory did NOT have a policy for flagged CBC results. 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
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 observation of the laboratory, review of the operator's manual for the Sysmex XP-300 hematology analyzer, laboratory environmental records (01.2023 and 02.2023), and confirmed in interview, the laboratory failed to ensure humidity was within operating specifications for the Sysmex XP-300 hematology analyzer for two of two months reviewed. Findings included: 1. Observation of the laboratory on 12.04.2023 at 9:30 a.m. revealed a Sysmex XP-300 (serial number B5128) hematology analyzer in use for Complete Blood Count (CBC) patient testing. 2. Review of the Sysmex XP-300 operator's manual stated the following in the section titled "Operating Environment": "Relative humidity: 30% - 85%" 3. Review of the laboratory environmental records (01.2023 and 02.2023) titled "Pediatric Clinic Temp Check Off Sheet" revealed the laboratory utilized a humidity range of 20%-75%. The humidity range used by the laboratory did not correspond to manufacturer's specified acceptable humidity range of 30%-85%. 4. Review of laboratory environmental records (01.2023 and 02.2023) revealed the following days when the humidity was NOT within manufacturer's operating specifications of 30%-85%: 01.07.2023: 29% 01.16.2023: 28% 01.27.2023: 26% 01.28.2023: 29% 02.04.2023: 24% 02.06.2023: 27% 02.07.2023: 27% 02.13.2023: 29% 02.14.2023: 29% The laboratory failed to ensure acceptable humidity was within operating specifications for the Sysmex XP-300. 5. An interview on 12.04.2023 at 12:30 p.m. with the laboratory lead confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on observation of the laboratory, quality control (QC) record review, and staff interview, the laboratory failed to have a procedure in place to monitor the accuracy and precision of QC for the Sysmex XP-300 hematology analyzer used for Complete Blood Count (CBC) patient testing in 2022 and 2023. The findings include: 1. Observation of the laboratory on 12.04.2023 at 9:30 a.m. revealed the Sysmex XP-300 (Serial Number B5218) hematology analyzer in use for CBC patient testing. 2. Review of the laboratory QC records from January 2022 through the date of the survey (12.04.2023) revealed the laboratory did not print/review Levy-Jennings (L-J) charts to monitor accuracy and precision over time. 3. Interview on 12.04.2023 at 12: 30 p.m. with the laboratory lead confirmed the laboratory did not monitor the accuracy and precision of QC data for the Sysmex XP-300 over time from January 2022 through the date of the survey (12.04.2023).