Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0678339	05/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
East Tn Children's Hospital Primary Care	352 Fountain View Circle, Alcoa, 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 review of the operator's manual for the Sysmex XP-300 hematology analyzer, random review of patient test records from 05.10.2022 through 05.12.2022, and staff interview, it was revealed that the laboratory failed to ensure that 3 of 10 Complete Blood Count (CBC) results with flags were verified prior to reporting these results to the provider. Findings included: 1. 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 withg 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, etc; Check smear, Centrufuge 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 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 lusing 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. 2. A random review of patient test reports from the Sysmex XP-300 hematology analyzer from 05.10.2022 through 05.12.2022 revealed the following 3 of 10 results with a CBC flag: Date 05.10.2022; Patient 73954; F2 and F3 Flags; NO documentation of repeat testing and NO documentation of a smear check. Date 05.11.2022; Patient 332662; T2 Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 05.11.2022; Patient 57297; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. 3. The laboratory was asked to provide a policy for flagged CBC results. No policy was provided. 4. In an interview on 05.12.2022 at 1:10pm in the library room, the laboratory supervisor was asked to describe how flagged CBC results were addressed. She stated that the results were reviewed on the LIS, which did not show CBC flags on patient results. The flagged results were showing on the printout from the Sysmex XP-300 instrument. These results are then given to the provider. She also stated the laboratory did NOT have a policy for flagged CBC specimens. 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 ==========
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 Sysmex XP-300 operator's manual (March 2017 revision), laboratory environmental records (01.2022 and 02.2022), and confirmed in interview, the laboratory failed to ensure humidity levels were within operating specifications for the Sysmex XP-300 for two of two months reviewed. Findings included: 1. Review of the Sysmex XP-300 operator's manual stated the following in the section titled "Operating Environment": "Relative Humidity: 30% to 85%" 2. Review of the laboratory environmental logs (01.2022 and 02.2022) titled "Quality Control Log; Room Temperture/Humidity" revealed the laboratory utilized a humidity range of 15-75% humidity for the Maryville Pediatric Group lab. (Note: The Maryville Pediatric Group Lab is the location of the Sysmex XP-300 instrument.) The humidity range used by the laboratory did not correspond to manufacturer's specified acceptable humidity range of 30-85%. 3. Review of laboratory environmental records (01.2022 and 02.2022) revealed an acceptable humidity range of greater than 15% and less than 75% for the Maryville Pediatric Group Lab and the following days when the humidity levels were NOT within manufacturer's operating specifications of 30-85%: 01.11.2022: 28% 01.17.2022: 29% 01.22.2022: 28% 01.24.2022: 27% 01.26.2022: 29% 01.27.2022: 26% 01.28.2022: 29% 01.29.2022: 28% 01.31.2022: 26% 02.01.2022: 29% 02.02.2022: 29% 02.07.2022: 28% 02.08.2022: 29% 02.09.2022: 29% 02.10.2022: 29% 02.11.2022: 27% 02.15.2022: 27% 02.16.2022: 28% 02.21.2022: 29% The laboratory failed to ensure acceptable humidity levels were within operating specifications for the Sysmex XP-300. 4. In an interview on 05.12.2022 at 1:10pm in the library room, after review of the environmental records, the laboratory supervisor confirmed the above findings.
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