Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0975215	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Blackmon Pediatrics	7714 Conner Road, Suite 101, Powell, 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 11.10.2023 through 11.15.2023, and staff interview, it was revealed that the laboratory failed to ensure that 8 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 11.15.2023 at 8:45 a.m. revealed a Sysmex XP-300 (serial number B9725) hematology analyzer in use for Complete Blood Count (CBC) patient testing. 2. Review of the Sysmex XP-300 hematology analyzer Operator's

manual (October 2015 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 11.10.2023 through 11.15.2023 revealed the following 8 of 10 results with a CBC flag: Date 11.10.2023; Patient 792569; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.10.2023; Patient 804019; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.10.2023; Patient 792308; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.13.2023; Patient 792662; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.13.2023; Patient 797740; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.14.2023; Patient 791937; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.14.2023; Patient 793979; AG Flag; NO documentation of repeat testing and NO documentation of a smear check. Date 11.15.2023; Patient 803516; WL and AG Flags; 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 11.15.2023 at 11:45 a.m., the laboratory lead was asked to describe how

	flagged CBC results were addressed. She stated that "the patient results were reviewed on the LIS by laboratory personnel and released to the patient's EMR". The flagged results were showing on the printout from the Sysmex XP-300 analyzer and the LIS, but NOT showing in the 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 manufacturer's operator's manual, lack of documentation and interview with the laboratory lead, the laboratory failed to monitor the humidity in the area where the complete blood count (CBC) analyzer was in operation in 2022 and 2023. The findings include: 1. Observation of the laboratory on 11.15.2023 at 9:35 a.m. revealed the Sysmex XP-300 analyzer (serial #B9725) in use for patient testing for CBC. 2. Review of the manufacturer's operating manual revealed a humidity range of 30% to 85% for operation of the analyzer. 3. Review of environmental records from 2022 and 2023 revealed no documentation that the humidity was being monitored. 4. Interview with the laboratory lead on 11.15.2023 at 11:30 a.m. confirmed the laboratory did not monitor the humidity in the area were the Sysmex XP-300 CBC analyzer was located in 2022 and 2023.