Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0886445	02/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Goodlettsville Pediatrics	3103 Business Park Circle Suite 100, Goodlettsville, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS-209) and Clinical Laboratory Improvement Amendments Application for Certification (CMS-116), review of the laboratory's Quality Assessment Plan, review of the laboratory's Training and Competency of Lab Testing Personnel policy, lack of documentation, and staff interview, the laboratory failed to follow its policy for maintaining competency assessments records for one of two testing personnel performing complete blood count (CBC) patient testing in 2022. The findings include: 1. A review of the CMS-209 and CMS-116 provided by the laboratory on 02/02/2024 revealed two testing personnel performing CBC patient testing. 2. A review of the laboratory's "Quality Assessment Plan" revealed the following: - "This practice will assess the following goals of our Quality Assessment Program as follows: 4. Assure that laboratory personnel are adequately trained and their performance evaluated periodically" -"We will keep written records of our reviews, findings, and actions." 3. A review of the laboratory's Training and Competency of Lab Testing Personnel policy revealed the following: - "For moderately complex lab tests, competency will be performed at 6 months after inital training, then yearly therafter." - "The Testing Personnel Training/Competency Assessment form will be used to provide a guide for training and competency of employees performing lab testing." 4. The laboratory could not provide the 2022 Testing Personnel Training/Competency Assessment form for TP-1 on the survey date for review. 5. An interview with the Lead Testing Person and Site Administrator on 02

	/02/2024 at 1:30 p.m. confirmed the laboratory could not locate the form used to document the 2022 annual competency for TP-1.
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 a review of the laboratory's procedure manual and staff interview, the laboratory's procedure for complete blood count (CBC) testing failed to include reference intervals (normal values). The findings include: 1. A review of the laboratory's procedure manual revealed no reference intervals listed for CBC testing. 2. An interview with the Lead Testing Person and Site Administrator on 02/02/2024 at 1:30 p.m. confirmed no reference intervals were included in the procedure used by the laboratory for CBC testing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of hematology instrument printouts and final patient test reports, a review of the manufacturer operator's manual, lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for verifying three of six patient results with white blood cell (WBC) flags in 2022, 2023, and 2024. The findings include: 1. A random review of patient instrument printouts and final patient test reports revealed the following: - Patient 42509 performed on 10/01/22 at 10:49 a.m., the report indicated WBC Flag "G2" - Patient 1273357 performed on 07 /20/23 at 11:13 a.m., the report indicated WBC Flags "M2", "G1", "G2" - Patient 1288020 performed on 02/01/24 at 2:49 p.m., the report indicated WBC Flag "G1" 2.

	A review of the Horiba Micros 60 hematology analyzer operator's manual revealed the following: - "The "M2" flag indicates an excessive number of cells in the (130fl to 160fl zone). The Pathological elements which may be found in this area will include: Lymphoblasts, Myelocytes, Abnormal Lymphocytes, and Basophilia (too Many Basophils)." - "The "G1" flag indicates an excessive number of cells in the (160fl to 220fl zone). The pathological elements which may be found in this area will include: Eosinophilia (too many Eosinophils), Myelocytes, Neutorphile polynucleose." - "The "G2" flag indicates an excessive number of cells in the (220fl to 250fl zone). This flag makes it possible to follow an abnormal Granulocyte peak displacement. Some of the cell variances will include: Anomalies in the cell membrane of the Granulocytes, possible Lyse flow error, Fluidic errors, Old blood (after 6 to 8 hours) unrefrigerated, Granulocyte cell size less than 250fl." - 4.4 Sample Analysis: "8. If the sample has flags, repeat the sample. 9. If the repeated sample still has flags, perform a Concentrated Cleaning and re-run the sample." 3. There was no documentation of repeat testing or other corrective actions in response to the result flags for patients 42509, 1273357, and 1288020. 4. An interview with the Lead Testing Person and Site Administrator on 02/02/2024 at 1:30 p.m. confirmed the laboratory did not verify results that contained WBC Flags for patients 42509, 1273357, and 1288020.