

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0898790	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Laurelwood Pediatrics	Street Address, City, State 5050 Sanderlin Avenue, Memphis, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, testing personnel failed to sign two of five attestation statements from 2022 and 2023. The findings include: 1. Review of the laboratory's 2022 and 2023 API PT records revealed attestation statements were not signed by testing personnel for 2022 event two (sample 09) and 2022 event three (sample 13). 2. The laboratory director confirmed the survey finding during interview on 2/7/24 at 4:00 PM.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessment policy, review of testing personnel records and staff interview, the laboratory failed to follow its' own policy for annual competency assessments for three of six established testing personnel who performed patient testing for Complete Blood Count (CBC) in 2022, 2023 and 2024. The findings include: 1. Review of the laboratory's testing personnel</p>

competency assessment policy revealed "Annual competency assessment will be performed for all established personnel." 2. Review of the laboratory's testing personnel competency assessment records revealed annual competency assessments were not performed for testing person three in 2022, 2023 or 2024, testing person five in 2022 or testing person six in 2022. 3. During an interview on 2/7/24 at 4:00 PM, the laboratory director confirmed the laboratory did not follow its own testing personnel policy when annual competencies were not performed for established personnel in 2022, 2023 or 2024 for three of six established testing personnel.

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:

CITATION NUMBER ONE: Based on review of patient CBC results, the laboratory procedure manual and staff interview, the laboratory procedure manual failed to include the normal ranges used by the laboratory. The findings include: 1. Review of CBC results for patient number 123982 performed on 1/31/24 revealed reference ranges on the instrument printout that were different from the ranges in the EMR. 2. Review of the laboratory procedure manual revealed the revised reference/normal ranges were not included as part of the procedure manual. 3. During an interview on 02/07/24 at 4 PM, the lab director stated the practice had recently implemented new reference ranges for their patient population, and confirmed the ranges were not included in the laboratory procedure manual. CITATION NUMBER TWO: Based on review of patient CBC instrument printouts, CBC results in the patients' electronic medical record (EMR), the CELL DYN manufacturers operator's manual, lack of procedure, and interview with the laboratory director, the laboratory failed to have a procedure to follow when patient results are flagged by the CBC instrument. The findings include: 1. Review of patient CBC instrument printouts for 07/31/23 revealed four patients with flagged results. There was no documentation that the results were verified before reporting. All four patient results had white blood cell differentials that were flagged with 's' and instrument flags of either L2 and L3 or L3 (Sample ID 00002, Sample ID 00003, sample ID 00006, Sample ID 00007). 2. Review of CBC results for patient ID number 123982, performed on 1/31/24, revealed differential results flagged with 's' on the instrument print out from the CELL-DYN Emerald. The

instrument flag was "L2." There was no documentation that the CBC was repeated to verify the flagged results. The instrument flags from the instrument did not cross into the patient electronic medical record. 3. Review of the manufacturer's operator manual revealed the following regarding results that are flagged by the instrument: "The CELL-DYN Emerald displays a measure and flagging message when a sample exhibits any reportable abnormalities as detected by the analyzer. The messages are created when one of the following sample abnormalities is present: Dispersional data alerts (H, h, L, l, +, +, +, +, D, ---); Suspect Measurand Flags (s); Count Invalidation Flags (*)." WBC Flags: L1-Platelet aggregates, nucleated red blood cells, giant platelets, cryoglobulins, incomplete lysis of red blood cells, small lymphocytes, fibrin clots, and shift in white blood cell distribution due to EDTA anticoagulant equilibration. L2-Myelocytes, Lymphoblasts, Basophils L3-Eosinophils, Myelocytes L5-Large size cells present Actions to take for the flagged WBC results included checking the specimen for clots or agglutination, following the laboratory review criteria, review a stained smear to confirm the results, redraw and retest the specimen as required. PLT flags: P1-Abnormal quantity of debris, contaminated reagent, electronic noise, microbubbles, or small cells. P2-Shistocytes P3-Microcytic RBCs, shistocytes, giant platelets, sickle cells, platelet clumps. Actions to take for flagged platelet results included checking a background count, repeating on the same specimen, reviewing a stained smear, and verifying the platelet count by a different method. 4. There was no procedure for actions to take when CBC results are flagged by the instrument. 5. During interview on 02/07/24 at 4PM, the laboratory director confirmed the laboratory failed to have a procedure to follow when CBC results from the CELL-DYN Emerald instrument are flagged. She further confirmed that flags associated with the CBC results do not cross to the EMR and are not seen by the provider responsible for using the results. Word key: White Blood Cell=WBC EDTA=Ethylenediaminetetraacetic acid Platelet=PLT

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 manufacturer's operator's manual, lack of documentation and interview with the laboratory director, the laboratory failed to monitor room temperature and humidity in the area where the CELL-DYN Emerald complete blood count (CBC) instrument was used in 2022, 2023 and 2024. The findings include: 1. Observation of the laboratory on 02/07/24 at 10:45 AM revealed the CELL-DYN Emerald used for patient testing for CBC with automated White Blood Cell differential (CBC w/Diff). 2. Review of the manufacturer's operator manual revealed environmental requirements for both room temperature and humidity. The room temperature range was 64 to 90F or 18 to 32C; the humidity range was up to 80%. 3. There was no documentation that room temperature or humidity was monitored in 2022, 2023, or 2024. 4. During an interview conducted on 2/7/24 at 4:00 PM the laboratory director confirmed the

laboratory failed to monitor room temperature and humidity in the area where the CELL-DYN Emerald CBC instrument was used in 2022, 2023 and 2024.