| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D0895280 | 04/25/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Waldorf Pediatrics Llc | 4255 Attamont Pl Suite 301, White Plains, MD | |

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 |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on record review and interview with the technical consultant, the laboratory did not ensure that the reference ranges provided in the written procedure agreed with the ranges printed on patient final reports. 1. The written procedures normal reference range for a white blood cell count (WBC) for the Group 3 age group is 5.4-16 mm 3. 2. On March 25, 2024 The laboratory performed a complete blood count (CBC) for Patient A who was in the Group 3 age group. The normal white blood cell count (WBC) printed on the patient test report was 3.5 - 16 mm 3, but the normal range for group 3 individuals stated in the written procedure was 5.4 - 16 mm 3. 3. During |

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| | interview on April 25 at 12:30 pm, The technical consultant (TC) stated that the discrepancy between the WBC normal range in the written procedure and the range reported on the final report was corrected during the survey, Note the ranges for all the age groups need to be reviewed to ensure they agree with the ranges on the patient reports. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory did not have a corrective action log to document problems encountered with quality control testing for hematology or problems with the analyzer operation. Findings: 1. The corrective action log is a record of problems and corrective actions concerning acceptability of hematology quality control results or operation of the hematology analyzer, including troubleshooting and other actions taken to correct the problem. It is also a record for the laboratory director or technical consultant to review and determine if further action or monitoring is needed. 2. The laboratory in 2024 did not maintain a corrective action log to document hematology quality control problems. 3. This was confirmed during interview on April 25, 2023 with the technical consultant at 12:30 PM. |