

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0904148	(X3) Date Survey Completed 10/10/2023
Name of Provider or Supplier Grundy County Primary Care Center	Street Address, City, State 10120 Sr 56, Coalmont, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of final patient test reports, review of test system records, and staff interview, the laboratory failed to verify the reference ranges that were in use at the time of the survey (10/10/23) for complete blood count (CBC) patient testing. The findings include: 1. Observation of the laboratory on 10/10/2023 at 8:05 am revealed a Horiba ABX Micros 60 instrument (SN# 206C591730) in use for CBC patient testing. 2. Review of three final patient test reports revealed the following CBC analyte reference ranges in use for patient evaluation: -White Blood Cell count (WBC): 4-10.5 -Red Blood Cell count (RBC): 4.1-5.6 -Hemoglobin (HGB): 12.5-17 -Hematocrit (HCT): 36-50 -Platelet count (PLT): 140-415 -Mean corpuscular volume (MCV): 80-98 -Mean corpuscular hemoglobin (MCH): 27-234 -Mean corpuscular hemoglobin concentration (MCHC): 32-36 -Red cell distribution width (RDW): 4.1-5.6 -Absolute granulocyte count (GRA#): 1.8-7.8 -Relative granulocyte count (GRA%): 40-74 -Absolute lymphocyte count (LYM#): 0.7 - 4.5 -Relative lymphocyte count (LYM%): 14-46 -Absolute monocyte count (MON#): 0.1-1 -Relative monocyte count (MON%): 4-13 3. Review of system records for CBC testing revealed no normal range validation of the reference intervals that were in use for evaluating the laboratory's patient test results. 4. Interview with the lab coordinator on 10/10/23 at 12:25 pm confirmed there was no documentation of validation of the</p>

reference ranges that were in use for patient evaluation with an annual testing volume of 6002 CBC test results.