

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1107141	(X3) Date Survey Completed 06/28/2022
Name of Provider or Supplier Bagwell Medical Clinic	Street Address, City, State 2670 Mcingvale Rd Suite H, Hernando, MS	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of Cell Dyn Emerald QC (quality control) records from instrument installation on 1/31/22 through 6/28/22 and confirmation with the laboratory director /technical consultant (LD/TC) at 4:00 p.m., the laboratory failed to retain the QC assay sheets for each lot used. QC assay sheets include acceptable ranges, storage requirements, lot numbers and standard deviations and should be kept for a minimum of 2 years. Findings include: 1. Review of the Cell Dyn Emerald records indicated that QC lot #2150 was in use on the day of the survey. The assay sheet for lot # 2150 was the only assay sheet available for review. 2. Review of the Cell Dyn Emerald QC records from the analyzer installation on 1/31/22 until 6/28/22 revealed the following hematology QC lots had been used: a. Cell Dyn QC lot # 1347 low, normal, high put in use on 1/31/22 b. Cell Dyn QC lot # 2038 low, normal, high put in use on 3/10/22 c. Cell Dyn QC lot # 2066 low, normal, high put in use on 4/4/22 3. Interview with the LD/TC at 4:00 p.m. on 6/28/22 confirmed the lab did not retain QC assay sheets for each lot number of QC material for the Cell Dyn Emerald hematology analyzer.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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</p>

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 review of laboratory records since the Abbott Cell Dyn Emerald installation on 1/31/21 and confirmation with the laboratory director/technical consultant (LD/TC) at 2:30 p.m. on 6/28/22, the laboratory failed to monitor and document the room temperature where hematology testing was performed. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Cell Dyn Emerald hematology analyzer. 2. Cell Dyn Emerald manufacturer's instructions require: a. The Cell Dyn Emerald reagent, lyse and detergent should be stored at a temperature range of 18-32 degrees Celsius (C) b. Operating specifications for the Cell Dyn Emerald hematology analyzer require a room temperature of 18- 32 degrees C. c. Quality control and calibration materials for the Cell Dyn Emerald must be allowed to come to room temperature before testing. 4. Interview with the LD/TC at 2:30 p.m. on 6/28/22 confirmed no room temperatures were being monitored and documented.