

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0327121	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Family Medical Center Of Hart County	Street Address, City, State 117 West South St, Munfordville, KY	
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
D0000	A recertification survey was conducted on 04/13/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review the laboratory's procedure manual, Uricult CLIA Compliance Reference Guide and interview, the laboratory failed to verify the accuracy of 1 of 1 urine colony count procedure performed (Uricult test procedure). Findings included: Review of the laboratory procedure manual revealed there was no test procedure for the Uricult test. Review of the test distributor's "Uricult CLIA Compliance Reference Guide", undated, revealed, "No standard proficiency survey required but must participate in a bi-annual assessment program." During an interview on 04/13/2023 at 11:05 PM, the Laboratory Manager (LM) stated she was unaware the Uricult test was not a moderate complexity test, therefore PT was not done.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible,</p>

traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the Cell-Dyn 1700 Complete Blood Counts procedure, calibration report and interview, the laboratory failed to calibrate the Cell-DYN hematology analyzer at the frequency indicated for 2 of 2 years reviewed (2021 and 2022).

Findings included: A review of the laboratory procedure titled "Complete Blood Counts Cell-DYN 1700" revised on 04/27/2016, revealed "7. Calibration: a.

Calibration is required whenever the quality control is out of range or once every six (6) months whichever comes first." A review of the calibration report for the Cell-DYN hematology analyzer revealed the analyzer was calibrated on 12/30/2021 and 10/18/2022. Another calibration was due 06/2022 but was not performed. During an interview on 04/13/2023 at 1:20 PM, the Laboratory Manager (LM) stated calibrations were only completed annually for the Cell-DYN hematology analyzer.