

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2113162	(X3) Date Survey Completed 07/25/2023
Name of Provider or Supplier Medcenter Fayette	Street Address, City, State 122 17th Court Ne, Fayette, AL	
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
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 reviews of personnel and proficiency testing (PT) records, and an interview with Testing Personnel #1, the laboratory failed to implement policies and procedures to ensure competency in Urine Sediment Examination after two PT failures in 2022. The findings include: 1. A review of MLE (Medical Laboratory Evaluation) PT records revealed the laboratory failed two out of three surveys in 2022 in the sub-specialty of Urine Sediment Examination. There was no documentation of remedial actions for the failures. (Refer to D5221.) The surveys were performed by two different testing personnel. 2. A review of personnel records revealed no indication of how the competency assessments was performed for microscopic examinations. 3. During an interview on 7/25/2023 at 1:40 PM, Testing Personnel #1 confirming the above findings. .</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of MLE (Medical Laboratory Evaluation) Proficiency Testing (PT) records, and an interview with Testing Personnel #1, the laboratory failed to perform and document remedial actions for failing scores on two out of three 2022 surveys in</p>

the sub-specialty of Urine Sediment Examination. The findings include: 1. A review of the MLE PT records revealed the following failing scores in the sub-specialty of Urine Sediment Examination: a) 2022-Event M1: 0% b) 2022-Event M3: 50% 2. The Review sheets for these surveys revealed the laboratory had documented no corrective action for the failing scores. 3. During an interview on 7/25/2023 at 1:40 PM, Testing Personnel #1 confirming the above findings. .

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of the Beckman Coulter DxH500 Hematology analyzer records and an interview with Testing Personnel #1, the laboratory failed to ensure maintenance procedures were performed with the frequency prescribed by the manufacturer. The laboratory had no documentation of monthly maintenance from October 2022 to the date of the survey on 7/25/2023. The findings include: 1. A review of the Beckman Coulter DxH500 Hematology analyzer records revealed the instrument was installed in September 2022, however there was no documentation of monthly maintenance from October 2022 to the date of the survey on 7/25/2023. 2. A review of the instrument manual on page 12-1, under "Cleaning Procedures" revealed the following table, "...Matrix of Frequency for Cleaning Procedures ... Procedure: Performing a Bleach Cycle ... Purpose: To remove clogs ... Frequency: Every 1,000 cycles or monthly, whichever comes first ...". 3. During an interview on 7/25/2023 at 4:15 PM, the surveyor asked if the laboratory had performed the monthly bleach cleaning procedure on the Beckman Coulter DxH500. Testing Personnel #1 answered, "No, because we are nowhere near to 1000 cycles". The surveyor reviewed the manufacturer's instructions with Testing Personnel #1, who realized she had misread the directions of 1000 cycles or monthly, "whichever comes first". The surveyor also noted the laboratory had not updated their maintenance procedures when they discontinued use of the Beckman Coulter AcT diff Hematology instrument in September 2022. SURVEYOR ID#32558 Licensure and Certification Surveyor