

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0978581	(X3) Date Survey Completed 02/20/2025
Name of Provider or Supplier Afs, Pc	Street Address, City, State 356 St Luke'S Drive, Montgomery, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC), the laboratory failed to ensure the Testing Personnel signed the PT attestation statements. This was noted for two of the four events reviewed in 2023 through 2024. The findings include: 1. A review of the AAB-MLE records revealed no evidence of Testing Personnel signatures on attestation statements for the following events. A) Hematology S1 2023 Event B) Hematology S1 2024 Event 2. During the exit conference on 02-20-2025 at 12:55 PM, the TC confirmed the above findings.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC), the laboratory failed to retain the PT program forms and testing worksheets. The surveyor noted three of the four PT events reviewed were</p>

missing documentation from 2023-2024. The findings include: 1. A review of the AAB-MLE PT records revealed no documentation of program forms regarding receipt, storage, testing instructions of shipped PT specimens and testing worksheets were not retained for the following events. A) Hematology S1 2023 Event B) Hematology S1 2024 Event C) Hematology S2 2024 Event 2. The TC confirmed the above findings during the exit conference on 02-20-2025 at 12:55 PM.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of laboratory maintenance records and an interview with the Technical Consultant (TC), the laboratory failed to perform and document the annual pipette calibration indicated on the Monthly/Periodic Lab Maintenance Sheet. The surveyor noted one out of two calibrations was not performed from 2023-2024. The findings include: 1. A review of the Monthly/Periodic Lab Maintenance Sheet logs revealed the laboratory had not performed the 2024 pipette calibration requirement for the following pipettes. A) Pipette G8523040 B) Pipette P46523K 2. A further review of the Monthly/Periodic Lab Maintenance Sheet logs and an interview with the TC at approximately 10:50 AM revealed the following pipettes were calibrated in 2023. A) Pipette G8523040 B) Pipette P46523K C) Pipette 4343901 (discontinued use in 2024) 3. The TC confirmed the above findings on 02-20-2025 at 10:54 AM.