

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2099823	(X3) Date Survey Completed 02/25/2026
Name of Provider or Supplier Family Medical Associates West	Street Address, City, State 26279 Hwy 195, Double Springs, 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC), the Laboratory Director (or designee) failed to document review and evaluation of PT performance. The surveyor noted six out of six 2024-2025 PT events were not reviewed. The findings include: 1. A review of the API PT records revealed no documentation of review on the returned evaluations by the Laboratory Director, or designee, for the following events: a) 2024 Hematology, 1st, 2nd and 3rd Events b) 2025 Hematology, 1st, 2nd and 3rd Events 2. The TC confirmed the above findings during the exit conference on 02-25-2026 at 2:30 PM.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the API (American Proficiency Institute) Proficiency Testing (PT) records and an interview with the technical Consultant (TC), the laboratory</p>

failed to ensure PT results were submitted before the due date specified by API. This was noted for one of the three Hematology PT events in 2024. The findings include: 1. A review of the API PT records revealed a score of 0 percent due to "Failure to participate" in 2024 Hematology 3rd Event. 2. TC confirmed the above findings during the exit conference on 02-25-2026 at 2:30 PM.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) 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 applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 and lack of environmental records, the Sysmex XP-300 Instructions for Use (IFU) manual and an interview with the Technical Consultant, the laboratory failed to ensure and record humidity in the room where the Sysmex XP 300 Hematology analyzer was operated. The surveyor noted humidity was outside the manufacturer's acceptable limits for 4 of the 31 days in January 2026 and no documentation of humidity for 14 out of the 24 months reviewed in 2024-2025. The findings include: 1. A review of the 2026 laboratory's environmental records revealed the following humidity. A) January 26, 2026, was 23 percent B) January 27, 2026, was 16 percent C) January 29, 2026, was 23 percent D) January 30, 2026, was 28 percent 2. A lack of the 2024-2025 environmental records revealed the following. A) No evidence of laboratory humidity documentation from January - December 2024. B) No evidence of laboratory humidity documentation from January - February 2025. 3. A review of the Sysmex XP-300 IFU manual revealed on page 14-1, under Technical Information, 14.1 Specifications, Operating Environment, Relative Humidity: 30-85 percent. 4. TC confirmed the above findings during the exit conference on 02-25-2026 at 2:30 PM.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of personnel evaluation records and an interview with Technical Consultant (TC), the TC failed to assess and document the semi-annual competency for one of the four Testing Personnel (TP) responsible for moderate complexity testing. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TC failed to perform and

document the semi-annual competency assessment for TP4 during the first year of testing in 2025. 2. During the exit conference on 02-25-2026 at 2:30 PM, TC confirmed the above findings.