

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2099823	<b>(X3) Date Survey Completed</b>  12/28/2021
<b>Name of Provider or Supplier</b>  Family Medical Associates West	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing (PT) records, CMS-209 (Laboratory Personnel Report) along with personnel records, and an interview with Testing Personnel #1 and #2, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on three out of five Testing Personnel listed on the CMS-209 (Laboratory Personnel Report) for the six events reviewed by the surveyor. The findings include: 1. A review of API attestation statements revealed Testing Personnel #1 and #3 performed 2020 Hematology 1st Event through 2021 Hematology 3rd Event. 2. A review of the CMS-209 and personnel records revealed Testing Personnel #2 and #4 were listed as Testing Personnel during the previous survey and Testing Personnel #5 started patient testing in June 2020. 2. During an interview on 12/28/2021 at 1:25 PM, Testing Personnel #1 and #2 confirmed the proficiency testing was not rotated to the other three testing personnel since the 1st Event 2020. .</p>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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>

This STANDARD is not met as evidenced by:  
Based on a review of Proficiency Testing records and an interview with Testing Personnel #1 and #2, the Laboratory Director failed to sign the attestation statement provided by American Proficiency Institute (API). This was noted on four out of six 2020 - 2021 Hematology Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed that Hematology Event #2 2020, Event #3 2020, Event #2 2021, and Event #3 2021 attestation statement were not signed by the Laboratory Director/delegate. 2. During an interview on 12/28/2021 at 1:25 PM, Testing Personnel #1 and #2 confirmed the above attestations were not signed by the Laboratory Director/delegate.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on a review of Proficiency Testing records and an interview with Testing Personnel #1 and #2, the laboratory failed to review and evaluate the results received from American Proficiency Institute (API). This was noted on one out of six 2020 - 2021 Hematology Proficiency Testing Events. The findings include: 1. A review of the Proficiency Testing records revealed 2021 1st Event was not reviewed and evaluated by the laboratory. The lymphocytes were scored as 80%, resulting in a score of 93% for the WBC (White Blood Cell) Differential; corrective action was not documented for the unacceptable results. 2. During an interview on 12/28/2021 at 1: 25 PM, Testing Personnel #1 and #2 confirmed the above event were not reviewed and evaluated.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

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, 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 a review of the Sysmex XP-300 calibration records and an interview with Testing Personnel #1 and #2, the laboratory failed to follow the manufacturer's frequency instructions to perform calibration verification at least every six months. This was noted on two of four 2020-2021 calibrations reviewed. The findings include: 1. A review of the Sysmex XP-300 calibration records revealed calibration was performed on 03/31/2020 and 03/16/2021 by a Sysmex service representative. The

Sysmex Service Maintenance Certificate for 3/31/2020 stated calibration verification expired 09/29/2020; however no calibration verification was performed until 03/16/2021. The Sysmex Service Maintenance Certificate for 3/16/2021 stated calibration verification expired 09/14/2021; however no calibration verification has been performed since 3/16/2021. 2. During an interview on 12/28/2021 at 1:40 PM, Testing Personnel #1 and #2 confirmed the only two Maintenance Certificates (Calibrations) from Sysmex that they had were 03/31/2020 and 03/16/2021.