

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0702573	<b>(X3) Date Survey Completed</b>  12/01/2022
<b>Name of Provider or Supplier</b>  Family Medical Associates	<b>Street Address, City, State</b>  42320 Hwy 195, Haleyville, 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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER Report 0153D, the American Proficiency Institute (API) 2022 Chemistry Performance Summary, and an interview with the Technical Consultant, the laboratory failed to achieve satisfactory performance for Sodium, (a regulated Chemistry analyte) on two consecutive proficiency testing (PT) surveys, Events #2 and #3 in 2022. These failures resulted in an initial unsuccessful PT participation in Sodium. The findings include: 1. A review of the CASPER Report 0153D and the API 2022 Chemistry Performance Summary revealed the following scores: A) Event #2, 2022: Sodium: 60 % B) Event #3, 2022: Sodium: 40 % 2. During an interview on 10/24/2022 at 1:20 PM, the</p>

Technical Consultant confirmed the above noted finding, and stated the Testing Personnel failed to follow the API's specimen handling instructions. .

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services CASPER 0153D Report, the American Proficiency Institute (API) 2022 Chemistry Performance Summary, and an interview with the Technical Consultant, the laboratory failed to achieve satisfactory performance in Sodium testing (a regulated Chemistry analyte) on two consecutive proficiency testing (PT) surveys, Events #2 and #3 in 2022. These failures resulted in initial unsuccessful PT participation for Sodium. The findings include: 1. A review of the CASPER 0153D Report and the API 2022 Chemistry Performance Summary revealed the following scores: A) 2022-Event #2: Sodium 60 % B) 2022-Event #3: Sodium 40 % 2. During a telephone interview on 10/24/2022 at 1:20 PM, the Technical Consultant confirmed the above findings, and stated the testing personnel failed to follow API's specimen handling instructions. SURVEYOR ID #32558 Licensure and certification Surveyor