

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0702573	(X3) Date Survey Completed 11/12/2021
Name of Provider or Supplier Family Medical Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	<p>SUCCESSFUL PARTICIPATION 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 CMS (Centers for Medicare and Medicaid Services) CASPER reports for Proficiency Testing (PT), a review of API (American Proficiency Institute) PT evaluations, and a telephone interview on 11/12/2021 with the testing personnel, the surveyor determined the laboratory failed glucose testing for three of four consecutive events in 2020 - 2021. These failures result in an non-initial unsuccessful PT participation for the laboratory. This affected Events #3, 2020, #2 and #3 of 2021. The findings include: 1. A review of the CASPER reports revealed the laboratory failed glucose testing for three of four consecutive testing events: a) Glucose score of zero percent (0 %) for Event #3, 2020. b) Glucose score of 20 % for</p>

	<p>Event #2, 2021. c) Glucose score of 0 % for Event #3, 2021. 2. A review of the API PT evaluations confirmed the above noted scores. 3. In a telephone interview on 11/12/2021 at 2:36 PM, the surveyor inquired of the testing personnel if she was aware of the last score of zero percent on Event #3, 2021 for glucose. The testing personnel reviewed the API evaluation, while on the telephone with the surveyor, and confirmed the zero percent score. The testing personnel stated she had switched reagents and performed a remedial PT event, which all were within acceptable limits. However, the third event of 2021 PT specimens were analyzed, using the "old" reagent, resulting in a failing score.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) Casper reports and API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed Glucose for three of four consecutive testing events (Event #3, 2020 and Event #2 and #3, 2021). These unsatisfactory performances of glucose testing resulted in a non-initial unsuccessful proficiency testing participation for the laboratory. The findings include: Refer to D2016.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS (Centers for Medicare and Medicaid Services) CASPER reports for Proficiency Testing (PT), a review of API (American Proficiency Institute) PT evaluations, and a telephone interview on 11/12/2021 with the testing personnel, the surveyor determined the Laboratory Director failed to ensure the laboratory staff performed remedial actions of glucose testing, after the initial unsuccessful PT participation to prevent further failures. A third failure within four consecutive testing events resulted in a non-initial unsuccessful PT participation. The findings include: Refer to D2016.</p>