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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0702573 | (X3) Date Survey Completed 05/18/2020 |
| 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 CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to successfully participate in Alkaline Phosphate testing for two of three consecutive testing events (Event #2, 2019 and Event #1 of 2020). The laboratory scored zero percent (0 %) for the Alkaline Phosphate for both events, resulting in an initial unsuccessful proficiency testing participation. The findings include: 1. A review of the CASPER reports revealed the laboratory scored zero percent for Alkaline Phosphate for Event #2, 2019 and Event #1, 2020. The failure of two of three consecutive testing events for the</p> |

same analyte resulted in an initial unsuccessful proficiency participation. 2. A review of the API proficiency testing evaluations confirmed the above noted findings.

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 CMS (Centers for Medicare and Medicaid) CASPER reports (#153 / #155), and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to perform satisfactorily for Alkaline Phosphate (Chemistry testing) for two of three consecutive testing events (Event #2, 2019 and Event #1 of 2020). The laboratory scored zero percent (0 %) for the Alkaline Phosphate for both events, resulting in an initial unsuccessful proficiency testing participation. The findings include: Refer to D2016.