

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1033968	(X3) Date Survey Completed 04/08/2020
Name of Provider or Supplier Stark Family Health Center Inc	Street Address, City, State 4465 Fulton Drive Nw #100, Canton, OH	
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 record review and interviews with Testing Personnel (TP) and an American Proficiency Institute (API) proficiency testing (PT) representative, the laboratory failed to successfully participate in a PT program for the non-waived calcium (Ca) testing performed under the subspecialty of Routine Chemistry. All patients who had Ca tested in this laboratory from the third API PT event of 2019 to current had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to achieve satisfactory PT performance for the analyte calcium, total (Ca) in two out of three consecutive PT testing events in 2019 and 2020 which resulted in a subsequent unsuccessful analyte performance. All patient Ca specimens tested from</p>

the third API PT event of 2019 to current had the potential to be affected by this deficient practice. (Refer to D2096)

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 record review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and interviews with Testing Personnel (TP) and an American Proficiency Institute (API) proficiency testing (PT) representative, the laboratory failed to achieve satisfactory PT performance for the analyte calcium, total (Ca) in two out of three consecutive PT testing events in 2019 and 2020 which resulted in a subsequent unsuccessful analyte performance. All patient Ca specimens tested from the third API PT event of 2019 to current had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2019 and 2020 API PT documentation revealed a Ca analyte score of 0% for the second PT event of 2019 and Ca analyte score of 40% for the first testing event of 2020. %; percent 2. A prior unsuccessful PT review, on 08/12/2019, of the laboratory's 2018 and 2019 API PT documentation, provided on 08/02/2019 via electronic mail (email), revealed a Ca analyte score of 60% for the third testing event of 2018 and a Ca analyte score of 0% for the 2nd testing event of 2019. A CMS-2567 was issued for this initial unsuccessful PT performance with an acceptable Plan of Correction and Allegation of Compliance resulting in a Ca PT analyte score of 100% for the third PT event of 2019. 3. The TP confirmed, via an email on 04/01/2020 at 4:41 PM, that the laboratory did not achieve successful PT performance for the analyte Ca in two out of three consecutive testing events in 2019 and 2020. Along with the prior unsuccessful PT performance, this unsuccessful PT performance resulted in a subsequent PT issue. 4. The API PT representative confirmed the laboratory's Ca PT analyte score to be 0% and 40% for the second event of 2019 and the first event of 2020 respectively. The telephone interview occurred on 04/02/2020 at 10:00 AM.