| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>36D1033968 | (X3) Date Survey Completed<br>08/12/2019 |
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| Name of Provider or Supplier<br>Stark Family Health Center Inc | Street Address, City, State<br>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 |
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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>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 testing performed under the subspecialty of Routine Chemistry. All patients who had Routine Chemistry analytes tested in this laboratory from the 2nd PT event of 2018 to current had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to return 22 out of 22 Routine Chemistry PT results to the PT provider within the timeframe specified which resulted in an unsuccessful score of 0% (percent) for the 2nd testing event in 2019. (Refer to D2093) 2. The laboratory failed |

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| | to achieve satisfactory PT performance for the analytes, calcium, total (Ca), cholesterol, high density lipoprotein (CHOL, HDL), iron (Fe), magnesium (Mg) and sodium (Na), in two out of three consecutive PT testing events in 2018 and 2019 which resulted in unsuccessful analyte performance. All patients who had the above mentioned analytes tested from the 2nd PT event of 2018 to current had the potential to be affected by this deficient practice. (Refer to D2096) |
| **D2093** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(d)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of the American Proficiency Institute (API) proficiency testing (PT) documentation and interviews with a Testing Personnel (TP) and an API representative, the laboratory failed to return 22 out of 22 Routine Chemistry PT results to the PT provider within the timeframe specified which resulted in an unsuccessful score of 0% (percent) for the 2nd testing event in 2019. Findings Include: 1. Review of the 2019 API PT documentation found the laboratory received the following unsatisfactory PT scores: 2nd testing event of 2019: ALT 0% ALB 0% Alk Phos 0% AST 0% TBIL 0% CA, total 0% Cl 0% CHOL, total 0% CHOL, HDL 0% CK, total 0% Creat 0% Glu 0% Fe 0% MG 0% K 0% Na 0% Prot, total 0% TRIG 0% BUN 0% Uric Acid 0% Free Thyroxine 0% TSH 0% 2. The TP stated the 0% scores for the analytes listed above were due to a missed submission deadline. The TP further stated they contacted API, immediately purchased/conducted an off cycle PT testing event and performed acceptable self-evaluations for both testing events. The interviews occurred via electronic mail (email) on 08/01/2019 at 11:31 AM. 3. The API PT provider, on 08/12/2019 at 3:25 PM, verified the laboratory's lack of PT result submission by the due date which resulted in the unsuccessful 0% PT scores. |
| **D2096** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(f)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) documentation and an interview with a Testing Personnel (TP), the laboratory failed to achieve satisfactory PT performance for the analytes, calcium, total (Ca), cholesterol, high density lipoprotein (CHOL, HDL), iron (Fe), magnesium (Mg) and sodium (Na), in two out of three consecutive PT testing events in 2018 and 2019 which resulted in unsuccessful analyte performance. All patients who had the above mentioned analytes tested from the 2nd PT event of 2018 to current had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 2018 and 2019 API PT documentation, provided on 08/02 /2019 via electronic mail (email), revealed Ca, Fe and Mg analyte scores of 60% and a CHOL, HDL analyte score of 0% for the third testing event of 2018, a Na analyte |

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| | score of 60% for the first testing event of 2019 and Ca, Fe, Mg, CHOL, HDL and Na analyte scores of 0% for the 2nd testing event of 2019. 2. The TP confirmed, via an email on 08/02/2019 at 11:31 AM, that the laboratory did not achieve satisfactory PT performance for the analytes Ca, CHOL, HDL, Fe, Mg and Na in two out of three consecutive testing events in 2018 and 2019. |