Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D1033968	**(X3) Date Survey Completed** 02/18/2025
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**
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to test the proficiency test samples with the regular patient workload. This deficient practice had the potential to affect 544 out of 544 patients tested under the subspecialty of Routine Chemistry from 09/24/2023 through 02/01/2024. Findings Include: 1. Review of the laboratory's policy and procedure titled "5.1 Proficiency Testing Compliance" approved via signature and date by the Laboratory Director on 06/03/2024, and provided on the date of inspection, revealed the following statement: "Test PT samples with the regular patient workload using routine methods and rotating testing among all testing personnel as staffing allows." 2. Review of the American Proficiency Institute's 2024 Chemistry Core 1st event "Performance Review and Corrective Action" sheet signed and dated by the Laboratory Director on 02/22 /2024 revealed the following statement: "when PT was run, no patient samples were run." 3. The TP confirmed no patients samples were ran with 2024 Chemistry Core 1st event proficiency test samples. The interview occurred on 02/18/2025 at 11:00 AM.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: REPEAT DEFICIENCY Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to successfully participate in one out of five American Proficiency Institute (API) PT events for Folate and Vitamin B12 in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 544 out of 544 Folate and Vitamin B12 tests performed between 09/24/2023 through 02/01/2024. Findings Include: 1. The laboratory failed to return the PT results for the first testing event of 2024 to their PT provider, API, within the time frame specified by the program for the Folate and Vitamin B12 analytes tested in the subspecialty of Routine Chemistry. (Refer to D2093)
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) (d) 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. This STANDARD is not met as evidenced by: Based on record review of the American Proficiency Institute (API) proficiency testing (PT), the laboratory failed to return two out of 11 Routine Chemistry PT results to the PT provider within the timeframe specified which resulted in an unsuccessful score of 0% (percent) for the 1st testing event in 2024. This deficient practice had the potential to affect 544 out of 544 Folate and Vitamin B12 patient tests under the subspecialty of Routine Chemistry from 09/24/2023 through 02/01/2024. Findings Include: 1. Review of the 2024 API PT documentation found the laboratory received the following unsatisfactory PT scores: 1st testing event of 2024: Folate 0% Vitamin B12 0% 2. Review of the API "Proficiency Testing Performance Evaluation" sheet signed and dated by the Laboratory Director on 02/22/2024 found the following statement: "The calibration had failed immediately prior to the PT run and the TP forgot to retest PT after calibration was repeated."
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

	This STANDARD is not met as evidenced by: Based on direct observation and an interview with the sole Testing Personnel (TP), the laboratory failed to be arranged and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies was minimized. This deficient practice had the potential to affect 32,350 out of 32,350 specimens tested in the subspecialties of Routine Chemistry, Endocrinology and Toxicology from 03/30/2023 through 02/18/2025. Findings Include: 1. The Inspector directly observed the laboratory on 02/18/2025 at 1:15 PM and found the laboratory was cluttered and very dusty. A Labnet VX-200 low profile laboratory vortex mixer, which had a visible layer of dust and surface stains, used to mix patient specimens, calibration solutions and quality control solutions was discovered on the floor between the Beckman Coulter AU480 and the Beckman Coulter Access2 instruments. A Powervar Security Plus power supply unit located to the right of the Beckman Access2, and in use, was being used as a table and contained headphones, unlabeled reagent bottles, a bin of used blood collection tubes with the labels peeled off and another visibly dirty empty plastic bin. 2. Direct observation of a shelf directly above the Beckman Coulter AU480 contained seven plastic chemical bottles, trash bags, a tissue box and paper towels. The shelf had a semi-wet brown liquid running down the front. A second shelf located to the left of the Beckman Access2 contained open packages of dog treats, a dog toy, an uncapped CLA buffer bottle, a broken box of surface wipes and a bottle of cleaning solution. 3. Further direct observation of the sole refrigerator revealed several unorganized bags of expired proficiency testing samples, open boxes of calibration materials in use, blood specimens in racks, and unracked unlabled blood specimen vials. Located to the right of the refrigerator was a plastic utility sink with a brown semi-wet substance covering the sides and bottom. 4. The TP confirmed the laboratory was cluttered and needed cleaned. The interview occurred on 02/18/2025 at 1:15 PM. Note: photos of the laboratory were taken for reference.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Consultant (TC) based on the responsibilities of the position, at a frequency determined by the laboratory as specified in the personnel requirements in subpart M for the moderate complexity testing. This deficient practice had the potential to affect 32,350 out of 32,350 patients tested in the subspecialties of Routine Chemistry, Endocrinology, and Toxicology from 03/30/2023 to 02/18/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection and approved by the Laboratory Director on 02/04/2025, found one individual listed and qualified to function as a TC. 2. Review of the laboratory's policy and procedure titled, "4.4 Employee Competency and Annual Performance Evaluation" approved via signature and date by the Laboratory Director on 06/03/2024, and provided on the date of the inspection,

	revealed the following statement: "The review must address the competency of each individual to fulfill the duties and responsibilities of their position." "All laboratory personnel are to be included in this process from personnel involved in specimen collection and processing to those responsible for supervision and compliance." "The laboratory employee must sign and date the evaluation upon review with the immediate supervisor. The laboratory director must also sign and date the annual evaluation of each personnel upon the completion of the review process." 3. Review of the laboratory's competency assessment documentation found no TC competency assessment for 2023. Further review found incomplete "Technical Consultant /Supervisor Competency Evaluation" sheets for 2024 and 2025. 4. The TP confirmed the laboratory failed to complete the TC competency assessment sheets for the TC in 2023, 2024 and 2025 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/18/2025 at 3:20 PM.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures for specimen acceptability and rejection of blood and urine specimens collected for testing. This deficient practice had the potential to affect 32,350 out of 32,350 patients tested under the subspecialties of Routine Chemistry, Endocrinology and Toxicology from 03/30 /2023 through 02/18/2025. Findings Include: 1. Review of the laboratory's policy and procedure titled "7.2 Specimen Collection, Labeling, Handling and Transport", approved via signature and date by the Laboratory Director on 06/03/2024, and provided on the date of inspection, revealed the following statement: "Specimen Receipt and Handling Procedure Assess acceptability of specimen for the test(s) ordered. The collection site or the clinical staff will be notified when the specimen is unacceptable. Notification will be documented that results might be compromised or that the specimen is not acceptable and needs to be re-collected." 2. The inspector requested documentation of the notifications that results might be compromised or that the specimen is not acceptable and needs to be re-collected from the TP. The TP confirmed the laboratory did not document when specimens were unacceptable and was unable to provide the requested information. The interview occurred on 02/18 /2025 at 12:10 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on record review, direct observation and an interview with the Testing Personnel (TP), the laboratory failed to ensure reagents utilized for the processing of moderate complexity Free T3 tests were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect 15,710 out of 15,710 test procedures performed in the subspecialty of Endocrinology between 02/18/2024 through 02/18/2025. Findings Include: 1. Review of the laboratory's policy and procedure titled "8.2 Maintenance" approved by the Laboratory Director via signature and date on 06/03/2024, and provided on the date of inspection revealed the following statement: "Materials Management (Receipt, Storage and Use): Properly discard all reagents and supplies when they exceed their expiration dates." 2. Direct observation of the laboratory's sole refrigerator found one box containing Beckman Coulter Access Free T3 calibration solutions with the expiration date of 11/06/2024. 3. The TP confirmed the box containing Beckman Coulter Access Free T3 calibration solutions was expired. The interview occurred on 02/18/2025 at 12:15 PM. Free T3; Triiodothyronine
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to perform the Elga Medica 7/15 water purification system maintenance as defined by the manufacturer. This deficient practice had the potential to affect 32,350 out of 32,350 patients tested under the subspecialties of Routine Chemistry, Endocrinology and Toxicology from 03/30/2023 through 02/18/2025. Findings Include: 1. Direct observation of the Elga Medica 7/15 water purification system, serial number 0152184875, used for the Beckman Coulter Access2 operation found the system alarm had been manually muted. The TP stated the system was muted due to "the constant beeping alarms". 2. Review of the Elga Medica 7/15 water purification system operator manual found the following alarm conditions: Alarm Conditions Alarms will signal at the following conditions: Replace Ion-exchange Cartridge The ion-exchange cartridge replacement alarm is signaled by an audible alarm and flashing icon at the default setting of 4380 hrs (6 months) of use. Press the button to mute the audible alarm. Follow the instructions to replace the ion-exchange cartridge. (See Section 7.2). Replace UV Lamp The UV lamp replacement alarm is signaled by an audible alarm and flashing icon at the default setting of 8760 hrs (1 year) of use. Press the button to mute the audible alarm. Follow the instructions to replace the UV lamp. (See Section 7.3). Replace Pre-treatment Cartridge The pre-treatment cartridge replacement alarm is signaled by an audible alarm and flashing icon at the default setting of 4380 hrs (6 months) of use. Press the button to mute the audible alarm. Follow the instructions to replace the pre-treatment cartridge. (See Section 7.1). UV failure The UV failure alarm is signaled by an audible alarm and flashing cross over the replace UV icon. Press the button to mute the audible alarm. Follow the instructions to replace the UV lamp. (See Section 7.3). The PURELAB Option-R will continue to run without the UV lamp operating. CAUTION! Long term operation without the UV lamp in operation will compromise performance and is not recommended 3. The Inspector requested the maintenance records for the Elga Medica 7/15 water purification system from the TP. 4. The TP confirmed the

	laboratory did not perform instrument maintenance as required by the manufacturer and was unable to provide the requested documents. The interview occurred on 02/18/2025 at 1:15 PM.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on record review and an interview with the sole Testing Personnel (TP), the Laboratory Director failed to ensure that the quality assessment (QA) program was maintained to assure the quality of Routine Chemistry, Endocrinology and Toxicology testing procedures. This deficient practice had the potential to affect 32,350 out of 32,350 patient tests from 03/30/2023 through 02/18/2025. Findings Include: 1. Review of the laboratory's policy and procedure titled "10.3 Quality Assessment Plan" approved by the Laboratory Director via signature and date on 06/03/2024, and provided on the date of inspection revealed the following statement: "The Plan: A. On a monthly basis, the laboratory supervisor/manager and/or the technical consultant will review laboratory compliance as it relates to the System policies and procedures in this SOP: Organization Facility Personnel Proficiency Testing Laboratory Information System Pre-Analytic Analytic Post-Analytic Quality Assessment This review will be documented on the designated Quality Confirmation Records (QA Manual)." 2. The Inspector requested the laboratory's documentation of QA activities to ensure the quality of laboratory services provided and to identify failures in quality from the TP. The TP confirmed the laboratory did not document any QA activities for 2023, 2024 or 2025 to date. The interview occurred on 02/18/2025 at 1:00 PM.