Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1033968	03/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Stark Family Health Center Inc	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the Laboratory Director (LD) failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for one out of five of the reviewed American Proficiency Institute (API) PT events. All patient testing performed in this laboratory between the third testing event, due 10/27/2021, and the second testing event due, 06/08/2022, in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "SOP & QC CORR", policy and procedure manual, provided for the inspection, did not find any letter from the LD delegating the PT attestation to the TC. 2. Further review of the laboratory's "Delegated Responsibilities" document revealed only the following PT statements: "4. Testing of proficiency samples are in accordance with CLIA requirements. 5. Review of proficiency testing performance, including recommendations on corrective action and documentation." 3. Review of the laboratory's 2021, 2022 and 2023 API PT event documentation, provided on the date of the inspection, revealed the previous TC attested as the LD on 03/30/2022 for the first testing event of 2022 without a written delegation letter from the LD. 4. The Inspector requested the LD's letter delegating PT attestation to a qualified and listed TC from the TC and TP. The TC and TP confirmed that the LD did not specifically delegate this duty in writing and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/29/2023 at 11:15 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: Based on record review and an interview with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to successfully participate in a Proficiency Testing (PT) program for C-Reactive Protein (CRP), Rheumatoid Factor (RF) and SARS-CoV-2 IgG (immuno-gamma-globulin) for the third testing event of 2022, for 25-OH (hydroxy) Vitamin D and CO2 (carbon dioxide) for the third testing event of 2021, for Sodium (Na) for the third testing event of 2022, for Thyroid Stimulating Hormone (TSH) for the first testing event of 2022 and for Thyroglobulin Antibody (Anti-TG) and Thyroid Microsomal Antibody (Ab)/Anti-TPO (TMA/Anti-TPO) for the third testing event of 2022. All patient testing performed under the subspecialties of Immunology, Routine Chemistry and Endocrinology in this laboratory from the second testing event of 2021 through the first testing event of 2023 had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to attain an American Proficiency Institute (API) PT analyte score of at least 80% (percent) of acceptable responses for CRP, RF and SARS-CoV-2 IgG for the third testing event of 2022. (Refer to D2075) 2. The laboratory failed to return the PT results for the third testing event of 2022 to their PT provider, API, within the time frame specified by the program for the analytes tested in the subspecialty of Immunology. (Refer to D2081) 3. The laboratory failed to attain an API PT score of at least 80% acceptable responses for 25-OH Vitamin D and CO2 for the third testing event of 2021 and for Na for the third testing event of 2022. (Refer to D2087) 4. The laboratory failed to attain an API PT score of at least 80% of acceptable responses for TSH for the first testing event of 2022 and for Anti-TG and TMA/Anti-TPO for the third testing event of 2022. (Refer to D2098) 5. The laboratory failed to return the PT results for the third testing event of 2022 to their PT provider, API, within the time frame specified by the program for the analytes tested in the subspecialty of Endocrinology. (Refer to D2100)
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte

	in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to attain an American Proficiency Institute (API) proficiency testing (PT) analyte score of at least 80% (percent) of acceptable responses for C-Reactive Protein (CRP), Rheumatoid Factor (RF) and SARS-CoV-2 IgG (immuno-gamma-globulin) for the third testing event of 2022. All patient CRP, RF and SARS-CoV-2 IgG testing performed in this laboratory in the subspecialty of Immunology between the second testing event of 2022 and the first testing event of 2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's API PT documentation for the third PT testing event of 2021 through the first PT testing event of 2023 revealed the laboratory performed the third PT event of 2022 on 12/03/2022, did not submit their results to API and was scored a 0% for CRP, RF and SARS-CoV-2 IgG. 2. Further review of the laboratory's third PT event of 2022 found self-assessment documentation and the following note: "All results in range but none submitted (Not currently running any of these tests but kept PT going to be able to re-introduce tests in future)" TP initials 3. The TP confirmed, although not performing patient testing on the specified analytes at the time of the third PT event of 2022, the laboratory performed the tests on the PT samples, did not submit the PT results to API, was scored a 0% by API for the analytes CRP, RF and SARS-CoV-2 IgG and performed a self-evaluation. The interview occurred on 03/29/2023 at 11:30 AM.
D2081	GENERAL IMMUNOLOGY CFR(s): 493.837(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 and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to return the proficiency testing (PT) results for the third testing event of 2022 to their PT provider, American Proficiency Institute (API), within the time frame specified by the program. This resulted in a score of zero percent (%) for the testing event and is unsatisfactory performance. All patient C-Reactive Protein (CRP), Rheumatoid Factor (RF) and SARS-CoV-2 IgG (immuno-gamma-globulin) testing performed in this laboratory in the subspecialty of Immunology between the second testing event of 2022 and the first testing event of 2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's API PT documentation for the third PT testing event of 2021 through the first PT testing event of 2023 revealed the laboratory performed the third PT event of 2022 on 12/03/2022 and did not submit their results to API. 2. Further review of the laboratory's third PT event of 2022 found self-assessment documentation and the following note: "All results in range but none submitted (Not currently running any of these tests but kept PT going to be able to re-introduce tests in future)" TP initials 3. The TP confirmed, although not performing patient testing on the specified analytes at the time of the third PT event of 2022, the laboratory

	performed the tests on the PT samples, did not submit the PT results to API, was scored a zero % by API for the subspecialty of Immunology and performed self-evaluation. The interview occurred on 03/29/2023 at 11:30 AM.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to attain an American Proficiency Institute (API) proficiency testing (PT) score of at least 80 percent (%) of acceptable responses for 25-OH (hydroxy) Vitamin D and CO2 (carbon dioxide) for the third testing event of 2021 and for Sodium (Na) for the third testing event of 2022. All patient 25-OH (hydroxy) Vitamin D and CO2 testing performed between the second testing event of 2021 and the first testing event of 2022 and all patient Na testing between the second testing event of 2022 and the first testing event of 2023, in this laboratory, in the subspecialty of Routine Chemistry had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's API PT documentation for the third PT testing event of 2021 through the first PT testing event of 2023 revealed the laboratory scored the following: Third testing event 2021 50%; 25-OH Vitamin D 60%; CO2 Third testing event 2022 0%; Na (clerical error) 2. The TP confirmed the laboratory was scored a 50% for 25-OH Vitamin D, a 60% for CO2 on the third PT event of 2021 and a 0% due to a clerical error for Na on the third PT event of 2022. The interview occurred on 03/29/2023 at 11:30 AM.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to attain an American Proficiency Institute (API) proficiency testing (PT) score of at least 80% (percent) of acceptable responses for Thyroid Stimulating Hormone (TSH) for the first testing event of 2022 and for Thyroglobulin Antibody (Anti-TG) and Thyroid Microsomal Antibody (Ab) /Anti-TPO (TMA/Anti-TPO) for the third testing event of 2022. All patient TSH testing performed in this laboratory between the third testing event of 2021 and the second testing event of 2022 and all Anti-TG and TMA/Anti-TPO testing performed in this laboratory between the second testing event of 2022 and the first testing event of 2023 in the subspecialty of Endocrinology had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's API PT documentation for the third PT testing event of 2021 through the first PT testing event of 2023 revealed the laboratory scored 60% for TSH on the first PT event of 2022. 2. Further review of the laboratory's API PT documentation for third testing event of 2022 found the Anti-TG and TMA/Anti-TPO testing was performed, the results were never submitted to API, API scored these analytes a 0% and the laboratory conducted

	a self evaluation. 3. The TP confirmed the laboratory scored a 60% for TSH on the first PT event of 2022 and a 0% for Anti-TG and TMA/Anti-TPO for the third PT event of 2022. The interview occurred on 03/29/2023 at 11:30 AM.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to return the proficiency testing (PT) results for the third testing event of 2022 to their PT provider, American Proficiency Institute (API), within the time frame specified by the program. This resulted in a score of zero percent (%) for the testing event and is unsatisfactory performance. All patient Thyroglobulin Antibody (Ab) (Anti-TG) and Thyroid Microsomal Ab/Anti-TPO (TMA/Anti-TPO) testing performed in this laboratory in the subspecialty of Endocrinology between the second testing event of 2022 and the first testing event of 2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's API PT documentation for the third PT testing event of 2021 through the first PT testing event of 2023 revealed the laboratory performed the third PT event of 2022 on 12/03/2022 and did not submit their Anti-TG and TMA /Anti-TPO results to API. 2. Further review of the laboratory's third PT event of 2022 found self-assessment documentation and the following note: "All results in range but none submitted (Not currently running any of these tests but kept PT going to be able to re-introduce tests in future)" TP initials 3. The TP confirmed, although not performing patient testing on the specified analytes at the time of the third PT event of 2022, the laboratory performed the tests on the PT samples, did not submit the PT results to API, was scored a zero % by API for the subspecialty of Endocrinology and performed self-evaluation. The interview occurred on 03/29/2023 at 11:30 AM.
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: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures to assess the competency of the TC based on the responsibilities of the position and at a frequency determined by the laboratory as specified in the personnel

	requirements in subpart M for the moderately complex testing procedures performed in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. This deficient practice had the potential to affect 108,027 out of 108,027 patient tests performed between 05/26/2021 through 03/29/2023. Findings Include: 1. Review of the laboratory's "SOP & QC CORR" policy and procedure manual, provided on the date of the inspection, did not find any mention of competency assessment procedures for the TC based on the responsibilities of the position, at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 03/29/2023, revealed one individual listed and qualified by the Laboratory Director to function as a TC. 3. Review of the laboratory's TC competency assessment documentation conducted on 11/15/2022 and 03/15/2023, did not find any signatures and dates and the TC confirmed on 03/29 /2023 at 9:20 AM that the Laboratory Director conducted these assessments virtually. 4. The Inspector requested the laboratory's policy and procedure for the competency assessment for the TC and the competency assessment documentation for the TC based on the responsibilities of the position from the TC and TP. The TC and TP confirmed the laboratory did not establish a policy and procedure for the assessment of the TC, did not assess the competency of the TC in person based on the responsibilities of the position, at a frequency determined by the laboratory and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/29/2023 at 9:20 AM. SOP; Standard Operating Procedures QC; Quality Control CORR; Correlation
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems with the moderately complex testing procedures in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. This deficient practice had the potential to affect all patient testing procedures performed in this laboratory between 05/26/2021 through 03 /29/2023. Findings Include: 1. The laboratory failed to ensure that the laboratory's reagents were not used when they had exceeded their expiration dates. (Refer to D5417) 2. The laboratory failed to perform and document maintenance protocol which was necessary for accurate and reliable test results and test result reporting in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. (Refer to D5433) 3. The laboratory failed to calibrate the AU480, Access 2 and Vitros 5600 analyzers when quality control (QC) materials reflected unusual and consistent shifts in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. (Refer to D5439) 4. The laboratory failed to take and document necessary QC corrective actions to ensure the reporting of accurate and

	reliable moderate complexity patient testing in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology when there were unusual QC shifts and trends. (Refer to D5783)
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Based on direct observation and an interview with the Testing Personnel (TP), the laboratory failed to ensure that the laboratory's reagents were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect 108,027 out of 108,027 patient testing procedures conducted in this laboratory in the subspecialty of Immunology, Routine Chemistry, Endocrinology and Toxicology between 05/25/2021 through 03/29/2023. Findings Include: 1. Review of the laboratory's "8.2 Maintenance" policy and procedure, provided on the date of the inspection, found the following instruction: "Properly discard all reagents and supplies when they exceed their expiration dates." 2. Direct observation, on 03/29/2023 at 3:10 PM, of the laboratory and reagent storage areas revealed the following expired reagents: Quantity - Reagent 1 - NaOH (sodium hydroxide); RICCA lot# 2912810, expired 11/2021 4 - AcT Rinse Shutdown Diluent lot#102123F, expired 04/11/2022 1 - Citranox; Beckman Coulter lot#630001, expired 07/31/2018 3 - ISE Buffer Solution; Beckman Coulter lot#M006036, expired 11/30/2021 1 - Hyrochloric Acid Solution 1 Normal lot#1711509, expired 04/28/2019 3. The TP confirmed the above listed reagents were expired, however did not know how to dispose of any of them. The interview occurred on 03/29/2023 at 3:10 PM.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to perform and document maintenance protocol which was necessary for accurate and reliable test results and test result reporting in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. All patient testing performed in this laboratory from 05/26/2021 through 03/29/2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "8.2 Maintenance" policy and procedure, provided on the date of the inspection, found the following instructions for instrument maintenance: "Instrument maintenance will follow manufacture procedures and

	periodic guidelines of daily, weekly, monthly, semi-annually and annually. Instrument function checks will be performed according to the manufacturer requirements. Documentation will be maintained in the maintenance book, Instrument maintenance, function checks and corrective actions are documented with date and initials on the instrument logs." 2. Review of the laboratory's "AU480 Maintenance Schedule", "Access 2 System Maintenance Log", "ISE Maintenance Schedule" and "Vitros 5600" maintenance logs from July and October of 2021, January, April, July, October, November and December of 2022 and January, February and March of 2023 revealed the following dates of undocumented instrument maintenance procedures: July of 2021: AU: No daily maintenance 22/31 days Access: No daily maintenance 18/31 days No weekly maintenance procedures No weekly system checks ISE: No daily maintenance 22/31 days No 3-month maintenance October of 2021 AU: No daily maintenance 22/31 days Access: No daily maintenance 22/31 days No weekly system checks ISE: No daily maintenance 22/31 days January of 2022 AU: No daily maintenance 23/31 days Access: No daily maintenance 23/31 days No weekly system checks ISE: No daily maintenance 23/31 days Vitros: No daily maintenance 19/31 days April of 2022 AU: No daily maintenance 21/30 days Access: No daily maintenance 21/30 days No weekly system checks Vitros: No daily maintenance 17 /30 days July of 2022 AU: No daily maintenance 23/31 days Access: No daily maintenance 23/31 days 1/4 weekly maintenance checks are on a day that no daily maintenance was performed No weekly system checks Vitros: No daily maintenance 19/31 days No 6 month maintenance October of 2022 AU: No daily maintenance 23 /31 days Access: No daily maintenance 23/31 days No weekly maintenance 1/5 weeks No weekly system checks Vitros: No daily maintenance 18/31 days November of 2022 AU: Duplicate logs with inconsistent days No daily maintenance 26/30 days and 23/30 days Access: Duplicate logs with inconsistent days No daily maintenance 21/30 days and 26/30 days No weekly system checks Vitros: No daily maintenance 26/30 days December of 2022 AU: No daily maintenance 22/31 days Access: No daily maintenance 22/31 days 4/4 weekly maintenance checks are on days that no daily maintenance was performed No weekly system checks Vitros: No daily maintenance 20/31 days January of 2023 AU: No daily maintenance 22/31 days Access: No daily maintenance 18/31 days 4/4 weekly maintenance checks are on days that no daily maintenance was performed No weekly system checks Vitros: No daily maintenance documentation No weekly maintenance documentation No monthly maintenance documentation February of 2023 AU: No daily maintenance 20/28 days Access: No daily maintenance 20/28 days 4/4 weekly maintenance checks are on days that no daily maintenance was performed No weekly system checks Vitros: No daily maintenance 16/28 days No monthly maintenance documentation March of 2023 AU: No daily maintenance 19/31 days Access: No daily maintenance 15/31 days No weekly system checks Vitros: No daily maintenance 15/31 days 3. Further review of the laboratory's "8.2 Maintenance" policy and procedure and "AU480 Maintenance Schedule", "Access 2 System Maintenance Log", "ISE Maintenance Schedule" and "Vitros 5600" maintenance log found no instructions for indicating days in which no patient testing occurred on the maintenance logs. 4. The Inspector requested clarification regarding duplicate documents with conflicting indication of maintenance procedures and how the laboratory indicates days in which no patient testing was performed from the TC and TP. Although the TP is the sole TP, the TP confirmed their confusion in documenting the maintenance performed on the AU, Access 2, ISE and Vitros instruments, maintenance on instruments continued even though patient testing sporadically ceased and could not provide any further clarification. The TC and TP confirmed the laboratory had many days without any indication of maintenance procedures or any method to indicate days in which no patient testing was performed. The interviews occurred on 03/29/2023 at 12:17 PM.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Technical Consultant (TC) and Testing Personnel (TP), the laboratory failed to calibrate the AU480, Access 2 and Vitros 5600 analyzers when quality control (QC) materials reflected unusual and consistent shifts in the subspecialties of Immunology, Routine Chemistry and Endocrinology. All patient testing performed in this laboratory between 05/26/2021 and 03/29/2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "SOP & QC CORR" policy and procedure manual, provided on the date of the inspection, found the following instructions: "Calibration is the process of method standardization through the testing and adjusting an instrument or test system to establish a correlation between the measurement of the substance being tested and the actual concentration of the substance." "All tests that require calibration must be calibrated according to the following schedule...whenever there is unacceptable control results that cannot be resolved by changes in reagents, control material or instrument maintenance." 2. Review of the laboratory's 2021, 2022 and 2023 QC Levy-Jennings graphs, provided on 04/10/2023 and 04/11/2023, revealed consecutive QC data point shifts with no documentation of corrective action, evaluation, re-run, calibration, patient testing re-runs, etc. for the following analytes: Analyte - QC Level - QC Data Shift 2021-2022 Uric Acid Level 1 - 16 low (08/10/21-10/15/21) Level 2 - 21 low (08/14/21-10/15/21) Iron Level 1 - 21 high (06/11/21-09/07/21) 14 high (12/30/21-03/01/22) Level 2 - 34 high (06/21/21-09/07/21) 34 high (09/28/21-03/01/21) CK Level 1 - 69 low (06/04/21-04/26/22) 19 low (06/22/21-08/10/21) Level 2 - 29 low (08/17/21-11/27/21) 30 low (12/07/21-04/20/22) 2023 TSH Level 1 - 9/9 shifted low FT4 Level 2 - 9/9 shifted high PSA Level 1 - 9/9 shifted low (near 2SD) Level 2 - 9/9 shifted low (2/9 near 2SD) Ferrintin Level 1 - 6/9 shifted high Level 2 - 6/9 shifted high FT3 Level 1 - 9/9 shifted high Level 2 - 9/9 shifted low - 03/23/23 out 3SD no repeat VitD Level 1 - 9/9 shifted high - 03/10/23 and 03/17/23 at 2SD Level 2 - 8/9 shifted high - 03/23/23 and 04/3/23 at 2SD Trig Level 2 - 9/9 shifted high - 03/15/23 and 03/20/23 at 2SD Gluc Level 3 - 7/9 shifted low - 03/01/23

	and 03/22/23 near 2SD TP Level 2 - 7/9 shifted high Alb Level 1 - 9/9 shifted high Level 3 - 9/9 shifted high K Level 1 - 8/9 shifted low Na Level 3 - 7/9 shifted low Phos Level 1 - 9/9 shifted low - 7/9 >= 3SD and 02/09/23 at 2SD Level 3 - 8/9 shifted low Cret Level 3 - 9/9 shifted high - 03/13/23, 03/15/23, 03/20/23, 03/22/23 at 2SD BUN Level 3 - 9/9 shifted high Ca Level 1 - 8/9 shifted high - 03/01/23, 03/08/23, 03 /13/23, 03/15/23 at 2SD - 03/17/23 >3SD no repeat Tbili Level 3 - 7/9 shifted high Alkp Level 1 - 9/9 shifted low - 03/20/23 >2SD no repeat 3. The Inspector requested the laboratory's documentation of evaluation and corrective action for the above mentioned QC shifts from the TC and TP. The TP provided, in an electronic mail (email) on 04/11/2023 at 7:14 PM, only one glucose QC re-run and one sodium recalibration in March 2023. Another request for evaluation and corrective action for the above listed shifted analyte QC results identified was responded to on 04/12/2023 by the TP; "this is all I have currently". No further requested documentation was provided.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to perform and document necessary quality control (QC) corrective actions to ensure the reporting of accurate and reliable moderate complexity patient testing in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology when there were unusual QC shifts and trends. This deficient practice had the potential to affect all patient testing procedures performed in this laboratory between 05/26/2021 through 03/29/2023. Findings Include: 1. Review of the laboratory's 2021, 2022 and 2023 QC documentation for the testing performed found QC results shifted above or below the mean without evidence of documented corrective action and patient testing continued to be performed. 2. Further review of the laboratory's 2023 QC Levy-Jennings documentation provided for the inspection revealed the following consistent QC data points shifted and/or trended above or below the mean, however no corrective action was documented: March 2023 Total Protein Level 2; 7/9 shifted below the mean Albumin Level 1; 9/9 shifted above the mean Level 3; 9/9 shifted above the mean Potassium Level 1; 8/9 shifted below the mean Sodium Level 3; 7/9 shifted below the mean Phosphorus Level 1; 9/9 shifted below the mean Level 3; 8/9 shifted below the mean Creatinine Level 3; 9/9 shifted above the mean Blood Urea Nitrogen Level 3; 9/9 shifted above the mean Calcium Level 1; 8/9 shifted above the mean Total Bilirubin Level 3; 7/9 shifted above the mean Alkaline Phosphotase Level 1; 9/9 shifted below the mean Thyroid Stimulating Hormone Level 1; 9/9 shifted below the mean Free T4 Level 1; 9 /9 shifted above the mean Prostatic Specific Antigen Level 1; 9/9 shifted below the mean Level 2; 9/9 shifted below the mean Ferritin Level 1; 6/9 shifted above the mean Level 2; 6/9 shifted above the mean Free T3 Level 1; 9/9 shifted above the mean Level 2; 9/9 shifted below the mean Vitamin D Level 1; 9/9 shifted above the mean

	Level 2; 9/9 shifted above the mean Triglyceride Level 3; 9/9 shifted above the mean Glucose Level 3; 7/9 shifted below the mean 3. The Inspector requested the laboratory's 2021, 2022 and 2023 documentation of QC corrective action from the TP. The TP provided corrective action documentation, via electronic mail (email) on 04/11 /2023 at 7:14 PM, of one glucose QC re-run and one sodium recalibration in March 2023. No further requested documentation was provided.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on record review and an interview with the Technical Consultant (TC) and the Testing Personnel (TP), the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart in the subspecialties of Immunology, Routine Chemistry and Endocrinology. All patient Immunology, Routine Chemistry, Endocrinology and Toxicology testing procedures performed in this laboratory from 05/26/2021 to 03/29/2023 had the potential to be affected by this deficient practice. Findings Include: 1. The Laboratory Director failed to ensure that the quality control (QC) program was maintained to assure the quality of Immunology, Routine Chemistry and Endocrinology testing procedures. (Refer to D6020) 2. The Laboratory Director failed to ensure the laboratory's quality assessment program was maintained to assure the quality of all patient testing procedures performed in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. (Refer to D6021) 3. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. (Refer to D6031)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the Laboratory Director failed to ensure that the quality control (QC) program was maintained to assure the quality of Immunology, Routine Chemistry and Endocrinology testing procedures. This deficient practice had the potential to affect all patient testing in this laboratory between 05/26/2021 through 03 /29/2023. Findings Include: 1. Review of the laboratory's "SOP & QC CORR" policy and procedure manual, found "8.6 Quality Control Plan", unapproved by the Laboratory Director via signature and date, provided on the date of the inspection revealed the following statements: "This laboratory has established a Quality Control

	Plan to assure quality results and guarantee patient safety. The Quality Control Plan consists of: 1. Review of manufacturer instructions 2. Establishing type and frequency of quality control 3. Establishing acceptable limits 4. Determining appropriate multi-rules to use for interpreting quality control runs 5. Interpretation of quality control data 6. Review of quality control compliance" "A quality control program must be capable of detecting errors throughout the complete analytical process: *the test system (instruments & reagents) *environmental conditions *the testing personnel" 2. Review of the laboratory's 2021, 2022 and 2023 QC Levy-Jennings graphs, provided on 04/10/2023 and 04/11/2023, revealed consecutive QC data point shifts without documentation of corrective action, evaluation, re-run, calibration, patient testing re-runs, etc. for the following analytes: Analyte - QC Level - QC Data Shift 2021-2022 Uric Acid Level 1 - 16 low (08/10/21-10/15/21) Level 2 - 21 low (08/14/21-10/15/21) Iron Level 1 - 21 high (06/11/21-09/07/21) 14 high (12/30/21-03/01/21) Level 2 - 34 high (06/21/21-09/07/21) 34 high (09/28/21-03/01/21) CK Level 1 - 69 low (06/04/21-04/26/22) 19 low (06/22/21-08/10/21) Level 2 - 29 low (08/17/21-11/27/21) 30 low (12/07/21-04/20/22) 2023 TSH Level 1 - 9/9 shifted low FT4 Level 2 - 9/9 shifted high PSA Level 1 - 9/9 shifted low (near 2SD) Level 2 - 9/9 shifted low (2/9 near 2SD) Ferrintin Level 1 - 6/9 shifted high Level 2 - 6/9 shifted high FT3 Level 1 - 9/9 shifted high Level 2 - 9/9 shifted low - 03/23/23 out 3SD no repeat VitD Level 1 - 9/9 shifted high - 03/10/23 and 03/17/23 at 2SD Level 2 - 8/9 shifted high - 03/23/23 and 04/03/23 at 2SD Trig Level 2 - 9/9 shifted high - 03/15/23 and 03/20/23 at 2SD Gluc Level 3 - 7/9 shifted low - 03/01/23 and 03/22/23 near 2SD TP Level 2 - 7/9 shifted high Alb Level 1 - 9/9 shifted high Level 3 - 9/9 shifted high K Level 1 - 8/9 shifted low Na Level 3 - 7/9 shifted low Phos Level 1 - 9/9 shifted low - 7/9 >= 3SD and 02 /09/23 at 2SD Level 3 - 8/9 shifted low Cret Level 3 - 9/9 shifted high - 03/13/23, 03 /15/23, 03/20/23, 03/22/23 at 2SD BUN Level 3 - 9/9 shifted high Ca Level 1 - 8/9 shifted high - 03/01/23, 03/08/23, 03/13/23, 03/15/23 at 2SD - 03/17/23 >3SD no repeat Tbili Level 3 - 7/9 shifted high Alkp Level 1 - 9/9 shifted low - 03/20/23 >2SD no repeat 3. The Inspector requested the laboratory's documentation of evaluation and corrective action for the above mentioned QC shifts from the TC and TP. The TP provided, in an electronic mail (email), on 04/11/2023 at 7:14 PM, only one glucose QC re-run and one sodium recalibration in March 2023. Another request for evaluation and corrective action for the above listed shifted analyte QC results identified was responded to on 04/12/2023 by the TP; "this is all I have currently". No further requested documentation was provided.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the Laboratory Director failed to ensure the laboratory's quality assessment program was maintained to assure the quality of all patient testing procedures performed in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. This deficient practice had the potential to affect

	48,240 patient tests performed between 03/2022 to 03/29/2023. Findings Include: 1. Review of the laboratory's "Quality Assessment" and "Quality Assessment Plan" policies and procedures provided on the date of the inspection, found the following statements: "The laboratory will continually monitor, identify, evaluate, investigate, manage, correct and document incidents and problems that occur as a result of non-compliance with laboratory policies and procedures or errors, accidents, or unexpected events." "This laboratory has implemented and maintains a Quality Assessment Plan which follows the structure and contents of this SOP. The records generated from this plan are located in a separate binder 'Quality Assessment Plan, Records and Reviews.' This plan is designed to monitor the quality of testing performed and to provide a system to identify and correct any problems detected. The laboratory director is responsible for the overall Quality Assessment Plan and for correction of any problems detected." "This Plan will be evaluated on an annual basis for its ability to achieve...goals. Adjustments will be made to records to ensure ongoing compliance with policies and procedures...Planned quality assessment activities will be assigned to a particular month...An activity from each system needs to be planned for at least once annually..." 2. The Inspector requested the laboratory's quality assessment documentation from 05/2021 through 03/29/2023 from the TC and TP. The TC and TP confirmed that the laboratory did not conduct and document quality assessment activities since the previous TC separated employment from this facility in 03/2022 and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/29/2023 at 2:15 PM.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. All patient Immunology, Routine Chemistry, Endocrinology and Toxicology testing procedures performed in this laboratory from 05/26/2021 to 03/29 /2023 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "SOP & QC CORR" policy and procedure manual, provided on the date of inspection, did not find the Laboratory Director's approval via signature and date. 2. The Inspector requested the laboratory's policies and procedures, approved by the Laboratory Director via signature and date from the TC and TP. The TP confirmed the approved policies and procedures were not available and therefore was unable to provide the requested documentation on the date of the inspection. The TC stated they had already discussed revising the policy and procedure manual with the Laboratory Director and TP. The interviews occurred on 03 /29/2023 at 2:05 PM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the TC failed to follow written policies and procedures to assess and document the competency of the TP as specified in the personnel requirements in subpart M for the moderately complex testing procedures performed in the subspecialties of Immunology, Routine Chemistry, Endocrinology and Toxicology. This deficient practice had the potential to affect 108,027 out of 108,027 patient tests performed between 05/26/2021 through 03/29/2023. Findings Include: 1. Review of the laboratory's "SOP & QC CORR" policy and procedure manual, provided on the date of the inspection revealed instructions for annual TP competency assessments. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 03/29/2023, revealed one individual listed and qualified by the Laboratory Director to function as a TC and another individual to function as a TP. 3. Review of the laboratory's TP competency assessment documentation conducted on 11 /15/2022, found the signature and date of the TC, however, the TC and TP confirmed on 03/29/2023 at 9:20 AM that the TC conducted this assessment virtually. 4. The Inspector requested the laboratory's 2022, in person, competency assessment documentation for the TP from the TC and TP. The TC and TP confirmed the TC assessed the TP virtually, did not assess the competency of the TP in person in 2022 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/29/2023 at 9:20 AM.