Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0699902	02/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Century Medical Group	15243 Vanowen St Ste 101, Van Nuys, CA	

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
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review on the proficiency testing (PT) performance records, corrective actions record for the year 2021, and interview with the laboratory's technical consultant (TC) and testing person (TP) on February 9, 2022; the laboratory failed to document any remedial actions or training for unsatisfactory Free Thyroxine PT performance. The findings include: 1. The laboratory participated in the American Proficiency Institute PT program for the year 2021, obtaining an unsatisfactory analyte performance for Free Thyroxine; however, the laboratory failed to document any corrective actions or training for unsatisfactory analyte performance. 2. The TC and TP affirmed on February 9, 2022, at approximately 11:30 a.m. that the laboratory received an unsatisfactory score for free Thyroxine analyte for the third event in 2021 (Q3-2021) event and did not document any remedial actions or training for the unsatisfactory performance. 3. The laboratory's testing declaration form, signed by the laboratory director on February 8, 2022, stated that the laboratory performed approximately 1400 Free Thyroxine tests annually
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 the lack of documentation, review of testing personnel competency assessment records, five (5) randomly chosen patient records review, and interview with the technical consultant (TC) and testing personnel (TP) on February 9, 2022, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency for the years 2020 and 2021. Findings include: 1. Based on review of the laboratory's policies and procedure and competency evaluations' records the laboratory failed to establish and follow written policies and procedures for competency assessment of the TC and TP. 3. The laboratory fail to provide documentation of training or competency assessment for the TC and TP performing testing at the laboratory for the year 2020 and 2021. 4. This deficient practice was affirmed by interview with the TC and TP on February 9, 2022, at approximately 1:00 p.m.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the technical consultant (TC), it was determined; that the laboratory failed to update protocols in place when changes occurred in the laboratory and the effective date and signature of approval by the laboratory director (LD) of such changes. The findings included: 1. On the day of the survey February 9, 2022, at approximately 1: 00 p.m. the procedure manual in place had not been updated to reflect current testing performed in the laboratory. 2. The TC affirmed on February 9, 2022, at approximately 12:00 p.m. that the laboratory failed to update and the LD sign, and date all testing protocols. 3. Based on the test volumed declared and signed by the LD on February 8, 2022 the laboratory processes and reports approximately 27,600 samples annually.
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 the surveyor's observation, lack of maintenance protocol and documentation, and interview with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to establish and document a maintenance and calibration protocol for thermometers used in the laboratory that ensures its continued performance necessary for reliable storage temperature of samples and reagents. The findings included: 1. The laboratory uses non-digital thermometers to measure daily temperature of the refrigerator and freezer where testing samples and reagents are stored. 2. Based on surveyor observation during tour of the laboratory on February 9, 2022, at approximately 10:45 a.m., the thermometers described above used in the laboratory were calibrated by the TC; however, there was no written protocol, logs of calibration, or serial number of the manually calibrating thermometer used for calibration. 3. The TC and TP affirmed that the laboratory failed to establish a calibration protocol for the thermometers described in 1. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 27,600 samples annually.
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 review of records, random patient sampling, lack of documentation for the Beckman Coulter AcTdiff2 calibration verification, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to perform and document calibration verification procedures for the years 2020 and 2021. The findings included: 1. On the day of the survey 02/9/2022 at approximately 12:30 p.m., the TC and TP failed to provide documentation for the calibration verification for Beckman Coulter Beckman Coulter AcTdiff2 instrument for the years 2020 and 2021. 2. For three (3) out of five (5) random patient sampling test results reviewed, covering period from 5/14/2020 to 11/18/2021, the laboratory analyzed and reported cell blood counts (CBC) on patient's samples during the time when the laboratory did not perform calibration verification for the Beckman Coulter

	AcTdiff2. 3. Based on the laboratory's annual declaration submitted for the year 2020, the laboratory analyzed and reported approximately 8,000 CBC tests without performing calibration verification every six months or whenever it is needed. 4. The TC and TP affirmed on February 9, 2022, at approximately 1:00 p.m. that the laboratory failed to perform calibration verification every six months or whenever it is needed on the Beckman Coulter AcTdiff2.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's observation, review of the laboratory quality control (QC) records, logs of patients' results, lack of QC policy and procedure, and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to establish quality control procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the frequency of the QC materials when performing Urinalysis examinations. 1. On the day of the survey February 9, 2022, at approximately 11:45 a.m., the surveyor observed that QC was not performed or documented whenever Urinalysis procedures were performed. 2. For three (3) out of five (5) random patient test results reviewed for Urinalysis examinations performed, no QC was performed or documented. 3. The TC and TP confirmed on February 9, 2022, that the laboratory lacked an established policy and procedure for QC when Urinalysis tests are performed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of all laboratory personnel competency evaluations for the years

	2020 and 2021, the lack of signed and dated laboratory written policies and procedures and lack of quality control for Urinalysis and calibration verification documentation for the Beckman Coulter CBCs, lack of corrective action reports on unsuccessful proficiency testing, and interview with the testing personnel and the technical consultant; the laboratory director failed to ensure that policies and procedures are established and followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209, D5407, D5433, D5439, and D5441.