Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0699902	07/18/2019
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
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 reviews of the second quarter (Q2-2017), third quarter (Q3-2017) of the Medical Laboratory Evaluation (MLE), second quarter (Q2-2018), third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, and interview with the testing personnel it was determined; that laboratory failed 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. The findings included: a. MLE and API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year: Trigly 60% Q2-2017 Bili, Total 60% Q3-2017 Amylase 0% Q2-2018 Trigly 60% Q3-2018 BUN 60% Q3-2018 Uric Acid 60% Q3-2018 Note: Abbreviations Triglycerides (Trigly) Blood Urea Nitrogen (BUN) b. For seventeen (17) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, seventeen (17) patients could have been affected by the unsatisfactory proficiency testing scores. c. The testing personnel confirmed (7/18 /2019, 14:45) that the laboratory had received an unsatisfactory proficiency testing scores on the above analytes.
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 reviews of the second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing records, and interview with the testing personnel it was determined; that laboratory failed 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. The findings included: a. API reported an unsatisfactory proficiency testing score of 20% for Triiodothyronine (T3) analyte. b. For ten (10) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, ten (10) patients could have been affected by the unsatisfactory proficiency testing scores. c. The testing personnel confirmed (7/18 /2019, 14:45) that the laboratory had received an unsatisfactory proficiency testing score on the above analyte.
D2121	HEMATOLOGY CFR(s): 493.851(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 reviews of the first quarter (Q1-2018), second quarter (Q2-2018) of the American Proficiency Institute (API) proficiency testing records, and interview with the testing personnel it was determined; that laboratory failed 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. The findings included: a. API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event /Year: Monocytes 40% Q1-2018 Granulocytes 20% Q2-2018 Monocytes 0% Q2-2018 b. For fifteen (15) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, fifteen (15) patients could have been affected by the unsatisfactory proficiency testing scores. c. The testing personnel confirmed (7/18 /2019, 14:45) that the laboratory had received an unsatisfactory proficiency testing scores on the above analytes.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Hematology was not met. The laboratory failed to follow its policy and procedure (see D5407), test 3 levels of CBC quality control materials each date of patient testing (see D5441), and failed to establish and follow maintenance and function checks (D5429).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on reviews of the third quarter (Q3-2017) of the Medical Laboratory Evaluation (MLE), first quarter (Q1-2018), third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, and interview with the testing personnel it was determined; that laboratory failed to attain at least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. MLE reported the following unsatisfactory proficiency testing score. Analyte: Score: Event/Year: Folate 50% Q3-2017 API reported the following unsatisfactory proficiency testing score. Analyte: Score: Event/Year: Sed Rate 50% Q1-2018 RDW 60% Q1-2018 API reported the following unsatisfactory proficiency testing score. Analyte: Score: Event/Year: A1C 0% Q3-2018 b. For five (5) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, five patients could have been affected by the unsatisfactory proficiency testing score for Folate. For fifteen (15) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5 /31/2018, fifteen (15) patients could have been affected by the unsatisfactory proficiency testing score for Sed Rate and RDW. For three (3) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, three (3)patients could have been affected by the unsatisfactory proficiency testing score for A1C. c. The testing personnel confirmed (7/18/2019, 14:45) that the laboratory had received an unsatisfactory proficiency testing scores on the above analytes.
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 reviews of the laboratory's policies and procedures manual and interview with the testing personnel, it was determined; that the laboratory failed to have a protocol in place when changes occur in the laboratory. The findings included: a. On the day of the survey (7/18/2019) the protocols in place had multiple versions and dates presented to the surveyors: i. Quality Control Log Policy and Procedure (P & P) for Hematology versions included four different titles and three different dates of approval (03/03/2004, 1/23/2007, and 1/31/2007).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 reviews of records, the lack of the documentation for maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer, and interview with the testing personnel; it was determined that the

	laboratory failed to provide the documentation of the instrument performance. The findings included: a. The laboratory failed to show any instrument (Beckman Coulter AcT Diff 2) preventive maintenance logs from January 2017 to the day of the survey (7/18/2019). b. For fifteen (15) out of twenty (20) random patient sampling test results covering period from 9/27/2017 to 5/31/2018, fifteen (15) patient could have been affected by the lack of instrument maintenance performance. c. The testing personnel confirmed (7/18/2019, 14:45) that the laboratory had no records to show of the above instrument's preventive maintenance.
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 review of records, lack of documentation provided, and interview with the testing personnel; it was determined that the laboratory failed to perform and document quality control (QC) procedures for Hematology Complete Blood Count (CBC) tests. The findings included: a. On the day of the survey (7/18/2019), the laboratory has no documentation of QC performed from January 2017 up to the day of the survey. b. One of the laboratory's Hematology CBC QC policy versions stated: "All QC values are to be recorded in the log book, including all report control results and out of control results." c. The testing personnel confirmed (7/18/2019, 14:45) that the laboratory has no QC documentation performed from January 2017 up to the day of the survey.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on reviews, lack of documentation, and interview with the testing personnel, it was determined; that the Laboratory Director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality

	laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. See D 5407, D 5429, and D 5441.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of records, lack of documentation provided, and interview with the testing personnel; it was determined that the Technical Consultant failed to perform and document quality control (QC) procedures for Hematology Complete Blood Count (CBC) tests. See D5441.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review and the lack of documentation for competency assessments and interview with the testing personnel, for twenty (20) out of twenty (20) random patient test records reviewed from 9/27/2017 to 5/31/2018, it was determined that the Laboratory Director/Technical Consultant failed to perform and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: The findings included: a. There was no documentation to show that the testing personnel for two (2) out of two (2) were evaluated during the first six months and annually thereafter for Routine Chemistry, Endocrinology, and Hematology. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. The testing personnel confirmed (7/18/2019, 14:45) that no competency assessments were performed and documented by the Laboratory Director/Technical Consultant.