Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2114201	12/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Summit Clinical Laboratory, Llc	17742 Preston Road #205, Dallas, TX	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2018 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for regulated analyte panels including a Complete Metabolic Panel (CMP), Lipid Panel, Thyroid Panel, tested under the specialty of Chemistry; a Complete Blood Count Panel (CBC) and Prothrombin Time (PT) tested under the specialty of Hematology, which is included in subpart I. Findings include: 1. According to the laboratory's daily activity log, the laboratory tested approximately 280 patients during January, February and March of 2018 for the regulated analyte panels listed above . 2. No documentation was presented for review during the survey conducted on December 19, 2018 and December 20, 2018 to indicate that the laboratory was enrolled in a CMS-approved PT program for the regulated analytes for the panels listed above and listed in subpart I, for which the laboratory performs patient testing. 3. The facility personnel confirmed that the laboratory was not enrolled in a CMS-approved PT program for 2018 for the analyte panels indicated above.
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 review of proficiency testing (PT) records for testing performed in the specialty of Hematology and interview with the facility personnel, the laboratory director failed to sign the PT attestation statement. Findings include: 1. The PT attestation statement presented for review for the second event of 2017 for Hematology lacked the director's signature. 2. The facility personnel confirmed that the PT attestation statement indicated above was not signed by the laboratory director.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for review from 2017 and interview with the facility personnel, (A) the laboratory failed to maintain a copy of all PT records for a minimum of 2 years and (B) failed to maintain copies of the instrument printouts documenting that the PT samples were tested by the laboratory. Findings include: 1. The laboratory performs patient testing in the specialties of Chemistry and Hematology. A1. No PT documentation was presented for review for the 1st, 2nd and 3rd event of 2017 for Coagulation testing, to indicate the laboratory maintained copies of all the PT records, including a copy of the PT program report form used by the laboratory to record results, instrument printouts showing the samples were tested by the laboratory, and the attestation statement signed by the analyst and laboratory director. A2. The facility personnel confirmed that the PT records indicated above could not be located during the survey. B1. No instrument records showing the PT samples were tested by the laboratory were presented for review during the survey for all PT testing performed by the laboratory in 2017 in the specialties of Chemistry and Hematology. B2. The facility personnel confirmed that the laboratory failed to retain the instrument printouts from PT samples tested by the laboratory during 2017.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required

	for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) evaluation for the first and second events of 2017 received by the laboratory from the PT agency and interview with the facility personnel, the laboratory failed to document a self evaluation for the PT test results that received an exception code [26]=Educational Challenge. Findings include: 1. The laboratory did not present any written documentation of a PT self review for the exception code indicated above for analytes tested under the specialty of Hematology for the first and second events of 2017. 2. The PT booklet provided by the PT agency that lists exception codes and code descriptions indicated that the lab should document its review for exception code [26]. 3. The facility personnel acknowledged that there was no documented self evaluation for the PT results that received exception codes.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records, Proficiency Testing (PT) records and interview with the facility personnel, the laboratory failed to document corrective action for unsatisfactory PT scores. Findings include: 1. The laboratory participates in PT for testing performed in the specialty of Chemistry. 2. The laboratory received unsatisfactory PT scores of 20% for the analyte, Total Cholesterol, and 0% for the analyte, Triglycerides, both in the 2nd testing event of 2017. 3. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of the unsatisfactory PT scores, for either analyte. 4. The facility personnel confirmed that the laboratory failed to document corrective action for the unsatisfactory PT scores referenced above.
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 review of Access 2 chemistry analyzer maintenance logs for 2018 and interview with the facility personnel, the laboratory failed to provide documentation of the daily and weekly maintenance for the Access 2 for the month of March 2018 during patient testing under the specialty of Chemistry. Findings include: 1. Patient testing was performed during January, February and March of 2018 on the Access 2.

	The laboratory presented the Access 2 logs for January and February during the survey conducted on December 19th and 20th of 2018. The maintenance logs for March 2018 were not presented during the survey. 2. The facility personnel indicated that the maintenance was performed, but the documentation was missing. 3. According to the laboratory's daily activity log, there were approximately 33 patients tested on the Access 2 during the month of March 2018.
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: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6015 - ensure that the laboratory was enrolled in an HHS approved proficiency testing program for the testing of regulated analytes under the specialty of Chemistry.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing of regulated analytes under the specialty of Chemistry. See D2000 for findings.
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 lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel who

	began patient testing in April 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the testing personnel indicated above.