Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0710009	10/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Summit Medical Associates Pc	1874 Piedmont Rd Ste 500-E, Atlanta, GA	

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
D0000	A proficiency testing desk review was completed on October 9, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from the American Association of Bioanalysts (AAB), the laboratory failed to maintain satisfactory performance for the Rhesus

	factor D(RHO) analyte # 875 on events 3 of 2016 and event 1 of 2018 resulting in the second unsuccessful occurrence for D(RHO). Findings include: Refer to D 2153 & D 2155
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from the American Association of Bioanalysts (AAB), the laboratory failed to maintain satisfactory performance for the Rhesus factor D(RHO) analyte # 875 on event 3 of 2016. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #875 D(RHO) on event 3 of 2016 with a score of 80%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts(AAB)confirmed the laboratory failed D(RHO) on Event 3 of 2016.
D2155	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from the American Association of Bioanalysts (AAB), the laboratory failed to maintain satisfactory performance for the Rhesus factor D(RHO) analyte # 875 on event 1 of 2018 resulting in the second unsuccessful occurrence for D(RHO). Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #875 D(RHO) event 1 of 2018 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts(AAB)confirmed the laboratory failed D(RHO) on event 1 of 2018 for failure to participate, resulting in the second unsuccessful performance.
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 an in-office desk review of proficiency testing records, the laboratory director failed to ensure the laboratory maintained compliance with successful Rhesus factor D(RHO) analyte # 875 proficiency testing (PT) on event three of 2016 and failed to ensure the laboratory participated in PT on event one of 2018, resulting in the second unsuccessful PT occurrence for Rho(D). Findings include: Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on an in-office desk review of proficiency testing records, the laboratory director failed to ensure the laboratory maintained compliance with successful Rhesus factor D(RHO) analyte # 875 proficiency testing (PT) on event three of 2016 and failed to ensure the laboratory participated in PT on event one of 2018, resulting in the second unsuccessful PT occurrence for Rho(D). 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #875 D(RHO) on event 3 of 2016 with a score of 80% and event 1 of 2018 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB)confirmed the laboratory failed D(RHO) on Event 3 of 2016 and confirmed the laboratory failed D(RHO) on event 1 of 2018 for failure to participate, resulting in the second unsuccessful performance.