Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0991654	02/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Complete Bio Solutions Inc	6500 Nw 77 Ct, Miami, FL	

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
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 review of the laboratory's proficiency testing records for 2018, the laboratory did not have successful performance in proficiency testing for the subspecialty of general immunology. Refer to D2084. Findings include: Review of the American Proficiency Institute (API) proficiency testing records and the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on February 19, 2019 on or about 10:00 AM, showed that the laboratory had unsatisfactory testing scores for the analyte, rheumatoid arthritis factor, for two out of three testing events in 2018.

D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful participation in proficiency testing for the sub-specialty of general immunology. Findings include: On February 19, 2019 on or about 10:00 AM the American Proficiency Institute (API) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analyte, rheumatoid arthritis factor, as shown below. Event #2, 2018 rheumatoid arthritis factor-40% Event #3, 2019 rheumatoid arthritis factor-60%
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the subspecialty of general immunology. Findings include: On February 19, 2019, on or about 10:00 AM, the American Proficiency Institute (API) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two out of three testing events for the analyte, rheumatoid arthritis factor, in the sub-specialty of general immunology. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2084.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the subspecialty of general immunology. Findings Include: The review of the American Proficiency Institute (API) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on February 19, 2019 on

	or about 10:00 AM showed that the laboratory received unsatisfactory proficiency testing scores as shown below. Event #2, 2018 rheumatoid arthritis factor- 40% Event #3, 2018 rheumatoid arthritis factor- 60%