Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1064292	08/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Select Laboratories- Sc Llc	1051 Bill Buyck Blvd, Manning, SC	

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: During a proficiency testing desk review performed on 08/29/2019, based on review of CASPER report 155D and graded reports from American Association of Bioanalysts (AAB), it was determined that the laboratory failed to successfully participate in proficiency testing for the specialty of chemistry, the analyte total lactic acid dehydrogenase (Total LDH) for two consecutive proficiency testing events reviewed (2019, Event 1 and 2019, Event 2). See D2087, D2096
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: During the proficiency testing desk review performed on 08/29/2019, based on review of CASPER report 155D and graded proficiency reports from AA8, it was determined that the laboratory failed to attain a satisfactory score of at least 80% for total lactic acid dehydrogenase (Total LDH) on two consecutive proficiency testing events. Findings include: 1. The CASPER 155D report revealed the following scores for your laboratory's Total LDH: a. 2019, Event 1: 0% b. 2019, Event 2: 0% 2. The scores were confirmed by review of the graded AAB results. Scores less than 80% for these analytes indicate failure or unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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: During a proficiency testing desk review performed on 08/29/2019, based on review of the CASPER 155D report and graded report from AAB, it was determined that the laboratory failed to achieve satisfactory performance for total lactic acid dehydrogenase (Total LDH) in two consecutive testing events (2019, Event 1 and 2019, Event 2). See D2087.