

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2080395	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Ub Laboratories Inc	Street Address, City, State 12633 Hoover St, Garden Grove, 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
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 desk review of CMS proficiency testing (PT) records (i.e. CMS CASPER Reports 0155D entitled, "Individual Laboratory Profile" and CMS CASPER Report 0153D entitled, "Unsuccessful (2 of 3) Report"), it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for each analyte or test in which the laboratory is certified under CLIA. The findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events in the specialties of Routine Chemistry, Endocrinology, and Hematology constituting unsuccessful PT performances. (See D2016, D2107, and D2130)

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: Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analytes, Iron, Total and Magnesium (Mg), resulting in an subsequent unsuccessful performances. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analytes, Iron, Total and Mg, as follows: 2019 2019 2019 Q1 Q2 Q3 Iron, Total 0% 0% 0% Mg 0% 0% 0% Uric Acid 0% 0% 0% Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an non-initial unsuccessful performance for the analytes, Iron, Total; Mg; and Uric Acid.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, T3 Uptake, Triiodothyronine (T3), Thyroid Stimulating Hormone (TSH), Thyroxine (T4), resulting in subsequent unsuccessful performances. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analytes, T3 Uptake, T3, TSH, and T4, as follows: 2018 2019 2019 2019 Q2 Q1 Q2 Q3 T3 Uptake 0% 0% 0% T3 0% 0% 0% 0% TSH 0% 0% 0% 2018 2019 2019 2019 Q2 Q1 Q2 Q3 T4 0% 0% 0% Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an non-initial unsuccessful performances for the analytes, T3 Uptake, T3, TSH, and T4.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on desk review of CMS PT records (CMS CASPER Report 0155D and 0153D, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the analyte, Hematocrit (Hct), resulting in an "initial" (first) unsuccessful performances. The findings include: a. The laboratory failed to maintain successful performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the analyte, Hct, as follows: 2019 2019 Q1 Q3 Hct 40% 60% Q1 = First Testing Event Q3 = Third Testing Event b. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in an initial unsuccessful performance for the analyte, Hct.
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 the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See 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 a desk review of CMS PT records, it was determined the laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under subpart H. of this part. The findings included: For the analytes, Iron, Total; Mg; Uric Acid; T3 Uptake; T3; TSH; and T4, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performances. (See D2016, D2096, and D2107) For the analyte, Hct, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting an initial unsuccessful PT performance. (See D2130)