| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2080395 | 06/19/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ub Laboratories Inc | 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 |
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| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>D-2087 Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for total Bilirubin (Bili), Sodium (Na), Calcium (CA), Glucose (Glu) and Albumin (Alb) between 2017 thru 2018 PT events were unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used AU 640 chemistry analyzer to perform routine chemistry and report Basic Metabolic (BMP) panel, and Comprehensive Metabolic (CMP) Panel. b. The laboratory enrolled its proficiency testing (PT) program with College of American Pathologist (CAP) PT provider. c. The laboratory attained scores of 20 % for analyte of Bili and Na in the 2nd 2017 PT event were unsatisfactory analyte performance. d. The laboratory attained scores of 60 % for analyte of CA and Glu in the 2nd 2018 PT event were unsatisfactory analyte performance. e. The laboratory attained a score of 60 % for analyte of Alb in the 3rd 2018 PT event was unsatisfactory analyte performance. f. The laboratory performed routine chemistry for approximately 40 patient specimens monthly. g. The TC and TP affirmed (6/19/19 @ 12:20 PM) that the laboratory failed to attain scores of at least 80 percent of acceptable responses for analyte of Bili, Na, CA, Glu, and Alb between the 2nd 2017 and 3rd 2018 PT events were unsatisfactory analyte performance for the testing events. |
| **D2088** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(b) |

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| | Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for its routine chemistry was unsatisfactory performance. The findings included: a. The laboratory used AU 640 chemistry analyzer to perform routine chemistry in a total of 20 analyte, and report Basic Metabolic (BMP) panel, and Comprehensive Metabolic (CMP) Panel and other analyte including but not limited to Albumin, total protein, Calcium, Glucose, total Bilirubin, AST ... b. The laboratory enrolled its PT program with College of American Pathologist (CAP) PT provider. c. The laboratory attained a score of 47% an overall testing event score for routine chemistry in the 1st 2019 PT event was unsatisfactory performance. d. The laboratory performed routine chemistry panel for approximately 40 patient specimens monthly. e. The TC and TP affirmed (6/19/19 @ 12:20 PM) that the laboratory attained a score of 47% an overall testing event score for routine chemistry in the 1st 2019 PT event was unsatisfactory performance. |
| **D2098** | ENDOCRINOLOGY<br>CFR(s): 493.843(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Triiodothyronine (T3), TSH between 2017 and 2018 PT events were unsatisfactory analyte performance for the testing events. The findings included: a. The laboratory performed endocrinology, including, but not limited to Triiodothyronine (T3), TSH testing. b. The laboratory enrolled its PT program with College of American Pathologists (CAP) PT provider. c. The laboratory attained score of 40 % for TSH in the 3rd 2017 PT event was unsatisfactory performance. d. The laboratory attained score of 0 % for T3 in the 2nd 2018 PT event was unsatisfactory performance. e. The laboratory performed TSH for approximately 22 patient specimens monthly. f. The laboratory performed T3 for approximately 2 patient specimens monthly. g. The TC and the TP affirmed (6/19/19 @12:25 PM) that the laboratory failed to attain at least 80% of acceptable responses for T3 and TSH between the 3rd 2017 and the 2nd 2018 PT events were unsatisfactory analyte performance for the testing events. |
| **D2109** | TOXICOLOGY<br>CFR(s): 493.845(a)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP). it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for TDM (Therapeutic Drug Management) including but not limited to Valproic Acid (VA) and Lithium (Li) between 2017 and 2019 were unsatisfactory analyte performance for the testing events. The findings included: a. The laboratory performed TDM including, but not limited to VA and Li testing. b. The laboratory enrolled its PT program with College of American Pathologists (CAP) PT provider. c. The laboratory attained score of 40 % for VA in the the 2nd 2017 PT event was unsatisfactory performance. d. The laboratory attained score of 0 % for VA in the 1st 2019 PT event was unsatisfactory performance. e. The laboratory attained score of 0 % for Li in the 1st 2019 PT event was unsatisfactory performance f. The laboratory performed VA for approximately 7 patient specimens monthly. g. The laboratory performed Li for approximately 22 patient specimens monthly h. The TC and TP affirmed (6/19/19 @12:25 PM) that the laboratory failed to attain at least 80% of acceptable responses for VA and Li between the 2nd 2017 and the 1st 2019 PT testing events were unsatisfactory analyte performance for the testing events. |
| **D2121** | HEMATOLOGY<br>CFR(s): 493.851(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for complete blood cell counts (CBC) was unsatisfactory performance. The findings included. a. The laboratory used Sysmex XT 1800i to perform CBC, including, but not limited to White blood cell (WBC) with cell differentials, Red blood cells (RBC), Hemoglobin (Hgb), Hematocrit (Hct) and Platelet count (Plt). b. The laboratory enrolled its PT program with College of American Pathologists (CAP) PT provider. c. The laboratory attained a score of 70 % for an overall testing event score in the 1st 2019 CBC PT event was unsatisfactory performance. d. The laboratory performed CBC for approximately 22 patient specimens monthly. e. The TC and TP affirmed (6/19/19 @12:25 PM) that the laboratory failed to attain an overall testing event score of at least 80 percent for CBC in the 1st 2019 PT was unsatisfactory performance. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on observation of the laboratory facility, review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory failed to effectively review, monitor, assess and follow written policies and procedures and to assure that the laboratory maintain and provide quality laboratory services reflected in the general quality assessment system, primarily proficiency testing events between 2017 and 2019. The findings included: a. The laboratory failed to attain scores of at least 80% for testing indivual analyte or overall in a subspecialty performed by the laboratory and failed to take remedial actions to prevent PT failures in the future between the 2nd 2017 PT and the 1st 2019 PT events. b. See D-2087, D-2088, D-2098, D-2109, and D-2121 |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory operations, review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory, and failed to ensure that the laboratory performed test procedures, and recorded and reported test results promptly, accurate, and proficiently in compliance with general laboratory systems. The findings included: a. The laboratory failed to effectively review, monitor, assess, and evaluate written policies and procedures in general laboratory system and failed to take remedial actions to prevent PT failures in the future, see D-5293. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory testing consultant (TC) and the laboratory personnel (TP), it was determined that the laboratory director failed to be responsible for testing |

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| | PT specimens for CBC, routine chemistry, endocrinology and TDM as required under subpart H of 42 CFR part 493 between 2017 and 2019 PT events. The findings included: a. The laboratory failed to attained at least scores of 80% for either individual or overall routine chemistry testing. See D-2087 and D-2088. b. The laboratory failed to attained at least scores of 80% for endocrinology testing. See D-2098. c. The laboratory failed to attained at least scores of 80% for TDM testing. See D-2109. d. The laboratory failed to attained at least scores of 80% for CBC testing. See D-2121. e. The laboratory failed to effectively review, monitor, assess, and evaluate written policies and procedures in general laboratory system, and failed to take remedial actions to prevent PT failures in the future. See D-5293. |