

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0643815	<b>(X3) Date Survey Completed</b>  04/05/2022
<b>Name of Provider or Supplier</b>  Unilab Corp DbA Quest Diagnostics	<b>Street Address, City, State</b>  108 La Casa Via Ste 105, Walnut Creek, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the CMS 096 Proficiency Testing report, records for evaluation laboratory proficiency reporting from CAP (College of American Pathologists), and an interview with the LP (laboratory personnel) on 4/5/2022 between 3:00 p.m. and 4:30 p.m., it was determined that there was one analyte unacceptable (below 80 %) proficiency testing (PT) result for Chemistry. Findings include: 1. On 4/5/2022, an inspection was conducted between 3:00 p.m. and 4:30 p.m. 2. During a review of the laboratory documentation from CAP , it was noted at approximately 4:15 p.m. that there was an unacceptable PT result for Chemistry. The LP recognized these atypical results. 3. Instrument: Siemens Dimension 4. The findings and acceptable ranges were as follows: Cycle 3 2021 Analyte: BUN (Urea Nitrogen) (60 %) 2/5 Unacceptable Sample Actual Result Expected Result/Range CHM-13 24.0 24.5-29.5 CHM-15 10.0 10.1-14.2</p>
<b>D2121</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the CMS 096 Proficiency Testing report, records for evaluation laboratory proficiency reporting from CAP (College of American</p>

Pathologists), and an interview with the LP (laboratory personnel) on 4/5/2022 between 3:00 p.m. and 4:30 p.m., it was determined that there was one blood cell ID unacceptable (below 80 %) proficiency testing (PT) result for Hematology. Findings include: 1. On 4/5/2022, an inspection was conducted between 3:0 p.m. and 4:30 p.m. 2. During a review of the laboratory documentation from CAP , it was noted at approximately 4:00 p.m. that there was an unacceptable PT result for Hematology. The LP recognized these atypical results. 3. The findings and acceptable ranges were as follows: Cycle 2 2020 Analyte: Blood Cell ID (60 %) 2/5 Unacceptable Sample Actual Result Expected Result BCP-11 Mono, Imm. Pro Monocyte BCP- 15 Echinocyte Acanthocyte