

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2181681	<b>(X3) Date Survey Completed</b> 11/07/2025
<b>Name of Provider or Supplier</b> Stemexpress	<b>Street Address, City, State</b> 1743 Creekside Dr, Folsom, 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>D2121</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) records, and interviews with the quality assurance officer (QAO) and testing personnel (TP), it was determined that the laboratory failed to attain at least 80 percent of the acceptable response resulting to an unsatisfactory performance for the Hemoglobin (Hgb) and Hematocrit (Hct) analytes. The findings include: 1. The laboratory obtained the following PT results from CAP: a.Hgb, first event of 2023 (Q1-2023) Specimen Submitted Expected FH1-01 *6.9 63.5 - 73.1 FH1-02 *11.2 103.1 - 118.7 FH1-03 *13.0 120.3 - 138.5 FH1-04 *12.5 115.8 - 133.3 FH1-05 *6.6 60.9 - 70.1 b. Hct, second event of 2023 (Q2-2023) Specimen Submitted Expected FH1-06 *43.80 38.46 - 43.37 FH1-07 *23.50 20.46 - 23.09 FH1-08 54.80 48.96 - 55.22 FH1-09 37.90 34.22 - 38.59 FH1-10 *56.30 49.42 - 55.74 Legend: * = unsatisfactory score 2. The QAO and TP affirmed by an interview on November 7, 2025, at approximately 9:31 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 2,000 samples annually for the Cell Blood Count that included the Hgb and Hct analytes. Thus, the reliability and quality of Hematology patient results reported could not be assured at the time when the laboratory obtained unsatisfactory scores.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p>

(e)(4)(i) 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 surveyor's review of the proficiency testing documentation for the first and second events of 2023 and interviews with the quality assurance officer and testing personnel; this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2121.