

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2284797	<b>(X3) Date Survey Completed</b>  08/28/2025
<b>Name of Provider or Supplier</b>  Vitalant Cellular Therapy Lab	<b>Street Address, City, State</b>  1524 W 14th St, Ste 120, Rm 238, Tempe, AZ	
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>D5317</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to provide clients written instructions for specimen collection, specimen labeling, specimen storage and preservation and conditions for specimen transportation for five of five tests performed by the laboratory. Findings: 1. On August 28, 2025, at approximately 3:06 PM, the surveyor requested a client services manual or written instructions provided to clients for the collection, labeling, storage, preservation and transportation conditions for testing listed on the form CMS 116. Quality Assurance staff provided the laboratory's client website named "Test Catalog". (<a href="https://vitalant-web-prod-2022-cw-deploy.azurewebsites.net/resources/references/test-catalog">https://vitalant-web-prod-2022-cw-deploy.azurewebsites.net/resources/references/test-catalog</a>). 2. Review of the "Test Catalog" website found no information regarding the collection, labeling, storage preservation and transport for the following tests listed on the form CMS 116: a. White Blood Cell Count (WBC) b. Hemoglobin (HGB) c. Hematocrit (HCT) d. Platelet Count e. Cluster of Differentiation 34 (CD34) 3. During interview on August 28, 2025, at approximately 3:06 PM, laboratory Quality Assurance staff confirmed the above. Word Key: CMS = Centers for Medicare and Medicaid Services</p>