

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520814	(X3) Date Survey Completed 07/08/2025
Name of Provider or Supplier Pediatric Center	Street Address, City, State 3430 Washington Pkwy, Idaho Falls, ID	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on a direct observation, a review of manufacturer's instructions for use (IFU) and an interview with the laboratory supervisor on 7/08/2025, the laboratory failed to follow the IFU for specimen processing for testing on the NanoEntek frend. The findings include: 1. A direct observation of the Globe Scientific centrifuge identified that the centrifuge speed and time were set at 3500 RPM for 3 minutes. 2. The NanoEntek frend IFUs for Thyroid-Stimulating Hormone (TSH), free thyroxine (FT4) and 25-hydroxy vitamin D stated that samples are to be centrifuged for 10 minutes at 3,000 RPM identifying that the laboratory failed to follow manufacturer's sample processing requirements. 3. An interview with the laboratory supervisor on 7/8/2025 at 10:49 am confirmed that they were not centrifuging samples at the correct speed and length of time for TSH, FT4 and 25-hydroxy vitamin D. 4. The laboratory reports performing 554 tests annually on the NanoEntek frend.</p>