

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520814	(X3) Date Survey Completed 06/13/2023
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, competency assessment records and an interview with technical supervisor 2 (TS2) on 6/13/2023, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2021 and 2022. The findings include: 1. The CMS 209 identified 13 testing personnel performing bilirubin testing. 2. A review of competency assessment records identified three (3) of 13 testing personnel failed to have a six month competency assessment for bilirubin testing for 2022. 3. A review of competency assessment records identified eight (8) of 13 testing personnel failed to have an annual competency assessment for 2021 and 10 of 13 testing personnel failed to have an annual competency for 2022 for bilirubin testing. 4. An interview with TS2 on 3/13/2023 at 12:18 pm confirmed the above findings. 5. The laboratory reports performing 663 bilirubin tests annually.</p>
D5451	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on a review of quality control (QC) logs, patient test results and an interview with technical supervisor 2 (TS2) on 6/13/2023, the laboratory failed to perform tittered QC for antistreptolysin O (ASO) testing. The findings include: 1. A review of ASO patient test results and QC log identified that the laboratory failed to perform tittered positive QC when patient tests were tittered in 2022 and 2023. 2. An interview with TS2 on 6/13/2023 at 2:00 pm confirmed the laboratory failed to perform tittered QC for ASO testing. 3. The laboratory reports performing 15 ASO tests annually.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on a record review of the Nanoentek Frend instrument verification and an interview with technical supervisor 2 (TS2) on 6/13/2023, the laboratory director failed to ensure that new instrument verifications were adequate. The findings include: 1. A record review of the new instrument verification of the Nanoentek Frend, used for endocrinology and chemistry testing, identified that the laboratory director failed to review and approve the verification results for accuracy, precision and reportable range to ensure that they were adequate before beginning patient testing in May of 2022. 2. An interview with TS2 on 6/13/2023 at 2:11 pm confirmed that the laboratory director failed to review and approve the verifications of the Nanoentek Frend. 3. The laboratory reports performing 38 tests on the Nanoentek Frend annually.