

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2011399	(X3) Date Survey Completed 03/22/2024
Name of Provider or Supplier Northwest Specialty Hospital	Street Address, City, State 1593 E Polston Ave, Post 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Association of Bioanalysts (AAB) and an interview with the technical consultant (TC) on 3/22/2024, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2023 and 2024. The findings include: 1. A review of PT documents from AAB identified that the laboratory failed to have the performing testing personnel and the laboratory director attest that PT samples were tested in the same manor as patient samples for event three in 2023 for the specialty of routine chemistry. 2. A review of PT documents from AAB identified that the laboratory failed to have the performing testing personnel and the laboratory director attest that PT samples were tested in the same manor as patient samples for event one in 2024 for the specialty of routine chemistry. 3. An interview with the TC on 3/22/2024 at 9:35 am confirmed the above findings. 4. The laboratory reports performing 2,600 routine chemistry tests annually.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all</p>

personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and an interview with the technical consultant (TC) on 3/22/2024, the Laboratory Director (LD) failed to approve laboratory policies and procedures for laboratory personnel to follow. The findings include: 1. A review of the laboratory's policies and procedures identified that the LD failed to approve policies and procedures that included but are not limited to i-STAT testing performance, i-STAT Analyzer/Point of Care Testing, Test Method Validation, CLIA Competency Testing, Proficiency Testing, Reporting Laboratory Quality and Safety Concerns, Laboratory Leadership: Authority, Responsibility and Delegation of Duties, and CLIA Compliance for laboratory personnel to follow. 2. An interview with the TC on 3/22/2024 at 10:28 am confirmed that the LD failed to approve laboratory policies and procedures. 3. The laboratory reports performing 2,600 tests annually.