

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2027091	(X3) Date Survey Completed 03/21/2022
Name of Provider or Supplier Arthritis Specialty Center	Street Address, City, State 1448 E Center St #B, Pocatello, 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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a record review of the Beckman Coulter DxH 500 instrument verification, the Alcor miniiSED instrument verification and an interview with the laboratory manager on 3/21/2022, the laboratory director failed to ensure that the instrument verifications were adequate. The findings include: 1. A record review of the new instrument verification of the Beckman Coulter DxH 500, used for hematology testing, identified that the laboratory director failed to review and approve the verification results for accuracy, precision, reportable range and carryover to ensure that they were adequate before beginning patient testing on 11/1/2021. 2. A record review of the new instrument verification of the Alcor miniiSED, used for sedimentation rate testing, identified that the laboratory director failed to review and approve the verification results for accuracy, precision, reportable range and carryover to ensure that they were adequate before beginning patient testing on 3/20/2020. 3. Interviews with the laboratory manager on 3/21/2022 at 2:11 pm and 3:42 pm confirmed that the laboratory director failed to review and approve the verifications of the Beckman Coulter DxH 500 and Alcor miniiSED . 4. The laboratory reports performing 45,362 hematology tests annually.</p>