

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1081769	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier Kootenai Health Post Falls	Street Address, City, State 1300 E Mullan 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of maintenance records for the Roche Cobas C311 and an interview with the technical supervisor on 3/21/2023, the laboratory failed to perform instrument maintenance as required by the manufacturer. The findings include: 1. A review of maintenance records for the Roche Cobas C311 identified that the laboratory failed to complete quarterly maintenance which included replacing the ISE pinch valve tubing and replacing the ISE sipper tubing in April 2022, July 2022, October 2022 and January 2023. 2. An interview with the technical supervisor on 3/21/2023 at 2:09 pm confirmed that quarterly maintenance had not been performed. 3. The laboratory reports performing 101,045 chemistry tests on the Roche Cobas C311 annually.</p>