

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411284	(X3) Date Survey Completed 10/19/2021
Name of Provider or Supplier Logan Health Care Columbia Falls	Street Address, City, State 1675 Talbot Road, Columbia Falls, MT	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Mount) for years 2019, 2020 and 2021. See D6015</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of proficiency testing records from American Proficiency Institute (API), the test volume report and interview with Technical Consultant (TC) #1, the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Mount) for years 2019, 2020 and 2021. Findings: 1. Review of Test Volume Report revealed 70 KOH Preps/ Wet Mount combination were performed in the last twelve months from 10/19/2021. 2. Review of 2019, 2020 and 2021 American Proficiency Institute (API) Testing Program records lacked documentation of proficiency testing for KOH Preps and Wet Mounts. 3. Interview with the (TC)#1 on October 19, 2021 at 3:00 PM confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for Mycology (KOH Preps) and Parasitology (Wet Mount), for years 2019, 2020 and 2021