

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0691046	(X3) Date Survey Completed 06/11/2025
Name of Provider or Supplier Chi St Francis Health	Street Address, City, State 2400 St Francis Drive, Breckenridge, MN	
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
D0000	. The CHI St. Francis Health laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on June 10-11, 2025. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance .
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one of two microscopic examinations performed by the laboratory at least twice annually in 2024. Findings are as follows: 1. The laboratory performed Vaginal Wet Prep (VWP) microscopic examinations as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:12 p.m. on June 10, 2025. 2. The laboratory performed proficiency testing using the American Proficiency Institute (API) provider in 2024. 3. Documentation of twice annual VWP microscopic examination accuracy verification was not included during review of the 2024 API Proficiency Testing Comparative Evaluations found in the API-PT 2024 binder provided by the laboratory. The laboratory was unable to provide the missing documentation upon request. 4. The laboratory performed 33 VWP microscopic examinations in 2024 as indicated by the GS in an interview at 8:41 a.m. on 6/11/25. In the interview, the GS confirmed the above findings.</p>