

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399855	(X3) Date Survey Completed 12/16/2020
Name of Provider or Supplier Allina Health Apple Valley Clinic	Street Address, City, State 14655 Galaxie Ave, Apple Valley, 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure microscopic examination proficiency testing samples from 1 of 3 Hematology proficiency testing events in 2019 were tested consistent with the number of times the laboratory routinely tested patient specimens. Findings are as follows: 1. The laboratory performed Hematology and Urinalysis microscopic examination testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:10 a.m. on 12/16/20. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) proficiency provider. 3. The Testing Proficiency Samples procedure located in the API - Policy and Procedure Manual indicated PT samples would be tested in the same manner as patient specimens. In addition, the PT (API) procedure indicated PT can not be done in duplicate if the laboratory does not perform the patient test in duplicate. 4. Microscopic examination PT for Blood Cell Identification (BCI), Pinworm Preparation (PP), Sperm presence /absence (SPM), Urine Sediment (US), Vaginal Wet Preparation (VA), and Vaginal Wet Preparation KOH (VKP) was completed by multiple testing personnel (TP) before the 2019 first event submission deadline as indicated on documents found in the PT manual. See below. 2019 - 1st event Submission deadline 03/29/19 Samples BCI-01 through BCI-05, PP-11, SPM-01, US-01, VA-01, VKP-01 Tested by Date TP1 03/25/19 Former TP VB 03/25/19 5. In an interview at 12:25 p.m. on 12/16/20, the GS confirmed the above finding.</p>