

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382770	(X3) Date Survey Completed 05/28/2026
Name of Provider or Supplier Unitypoint Clinic Family Medicine Huxley	Street Address, City, State 305 S Hwy 69, Huxley, IA	
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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Lab Housekeeping log and confirmed by interview with the Technical Consultant at 10:25 am on 05/28/2026, the laboratory failed to take and document corrective action when the laboratory refrigerator temperature fell outside the acceptable range for 4 out of 21 days of patient testing from 01/01/2026- 01/30/2026. The findings include: 1. The laboratory's Lab Housekeeping log listed the acceptable temperature range for the laboratory refrigerator as 35.6- 46.4 degrees Fahrenheit (F). 2. The laboratory documented unacceptable temperatures for the laboratory refrigerator on the following dates: *01/05/2026- 35.1 degrees F *01/14/2026- 33.1 degrees F *01/23/2026- 33.9 degrees F *01/27/2026- 35.0 degrees F 3. At the time of the survey, the Technical Consultant confirmed that the laboratory failed to perform and document corrective action for the unacceptable refrigerator temperatures on the dates listed above.</p>