

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0681658	(X3) Date Survey Completed 05/14/2019
Name of Provider or Supplier Unitypoint Health - Grinnell	Street Address, City, State 101 W Washington St, Suite 100, Montezuma, 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 temperature records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 05/14/2019, the laboratory failed to perform and document corrective action when the reagent refrigerator temperature fell outside the acceptable range for nine out of 23 days of patient testing in August 2018. The findings include: 1. The laboratory recorded refrigerator temperatures in the morning and afternoon each day of patient testing. 2. The Temperature and Humidity Log listed 2-8 degrees Celsius as the acceptable range for refrigerator temperatures. 3. The laboratory documented the refrigerator temperature as zero degrees Celsius on the following dates: 08/09/2018 (PM), 08/17/2018 (AM), and 08/21/2018 (AM). 4. The laboratory documented the refrigerator temperature as one degree Celsius on the following dates: 08/01/2018 (PM), 08/06/2018 (PM), 08/14/2018 (AM and PM), 08/15/2018 (AM and PM), 08/21/2018 (PM), 08/24/2018 (PM), and 08/30/2018 (PM). 5. At the time of the survey, personnel identifier #5 confirmed that the laboratory did not perform or document corrective action when the refrigerator temperatures fell outside the acceptable range on the previously listed dates.</p>