

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1028524	(X3) Date Survey Completed 02/23/2021
Name of Provider or Supplier Upper Valley Family Medicine	Street Address, City, State 711 Rigby Lake Dr #1500, Rigby, ID	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of training documentation and competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 2/23/2021 with the laboratory lead, the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1413(b)(8). The findings include: 1. A review of training and competency records identified that two (2) of nine (9) testing personnel listed on the CMS 209 had start days after the previous survey (6/27/2018) that the laboratory failed to have documentation of six (6) month competency which included the six parameters as listed in 42 C.F.R. 493.1413(b)(8). 2. A review of training and competency records identified four (4) of nine (9) testing personnel listed on the CMS 209 for which the laboratory failed to have documentation of annual competency for 2019 which included the six parameters as listed in 42 C.F.R. 493.1413(b)(8). 3. A review of training and competency records identified six (6) of nine (9) testing personnel listed on the CMS 209 for which the laboratory failed to have documentation of annual competency for 2020 which included the six parameters as listed in 42 C.F.R. 493.1413(b)(8). 4. An interview with the laboratory lead on 2/23 /2021 at 9:10 am confirmed that the laboratory failed to document competency assessments for 2019 and 2020. 5. The laboratory reports performing 13,930 tests annually.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation and interview with the laboratory lead on 2/23/2021, the laboratory failed to ensure their thermometers and timers were calibrated as necessary for accurate and reliable results. The findings include: 1. Based on an observation during a laboratory tour on 2/23/2021 at 11:55 am it was identified that the laboratory failed to have a calibrated thermometer in the refrigerator that stores controls for the Horiba ABX Micros 60, reagents and patient samples to ensure that controls, reagents and samples are stored per manufacturers requirements. 2. Based on an observation during a laboratory tour on 2/23/2021 at 11:55 am it was identified that the laboratory failed to have a calibrated thermometer in the freezer that stores patient samples. 3. Based on an observation during a laboratory tour on 2/23/2021 at 11:56 am it was identified that the laboratory failed to have three (3) of three (3) timers calibrated to ensure accurate timing of patient testing as required by manufacturer. 4. An interview with the laboratory lead on 2/23/2021 at 11:56 confirmed that the laboratory failed to have calibrated thermometers and timers. 5. The laboratory reports performing 16,928 moderate complexity and waived tests annually.