

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0926381	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Community Care Of Channing Way	Street Address, City, State 2725 Channing Way, Idaho Falls, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Proficiency Institute (API), the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory technical consultant (TC) on 9/23/2021, the laboratory failed to test PT samples with the regular patient workload by personnel regularly testing complete blood count (CBC) testing. The findings include. 1. A review of PT records from API for Hematology for 2020 events one, two and three and 2021 events one and two identified that one (1) of six (6) testing personnel listed on the CMS 209 performed all Hematology PT events for 2020 and event 1 for 2021. The laboratory failed to have five(5) of six (6) personnel who regularly perform CBC testing perform Hematology PT testing for 2020 and the first event for 2021. 2. An interview with the TC on 9/23/21 at 1:40 pm confirmed that one (1) of six (6) testing personnel performing CBC testing performed all the CBC PT testing for 2020 and the first event of 2021. 3. The laboratory reports performing 730 CBC tests annually.</p>
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>

This STANDARD is not met as evidenced by:
Based on a review of training documentation, competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with the laboratory technical consultant (TC) on 9/23/2021, 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)(7)(8) for 2019 and 2020. The findings include: 1. A review of training and competency assessment records identified one (1) of six (6) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1413(b)(8) for 2019. 2. A review of training and competency assessment records identified four (4) of six (6) testing personnel listed on the CMS 209 failed to have documentation of annual competency which included the six parameters as listed in 493.1413(b)(8) for 2020. 3. An interview with the TC on 9/23/2021 at 1:35 pm confirmed the above findings. 4. The laboratory reports performing 730 CBC tests annually.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a record review of maintenance logs and an interview with the technical consultant (TC) on 9/23/2021, the laboratory failed to perform and document daily, weekly and monthly maintenance for the Sysmex XP-300 hematology analyzer as required by the manufacturer. The findings include: 1. 1. A review of the Sysmex XP-300 maintenance logs for March 2021-August 2021 identified the laboratory failed to perform and document maintenance as required by instrument manufacturer. Daily maintenance was not documented six (6) of 31 days in March, four (4) of 30 days in April, eight (8) of 31 days in May, five (5) of 30 days in June, one (1) of 31 days in July and three of 31 days in August. Weekly maintenance was not documented three (3) of five (5) weeks in March, two (2) of four (4) weeks in April, three (3) of four (4) weeks in May, five (5) of five (5) weeks in June and three (3) of four (4) weeks in August. Monthly maintenance was not documented in April, May and June. 2. An interview with the TC on 9/23/2021 at 2:37 pm confirmed the above findings. 3. The laboratory reports performing 730 complete blood count tests on the Sysmex XP-300 annually.