

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1085881	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Community Care Pocatello	Street Address, City, State 1595 Yellowstone Ave, Pocatello, 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 proficiency testing (PT) record review and an interview with the technical consultant, the laboratory failed to test PT samples for complete blood counts (CBCs) by the same personnel who perform patient testing since the last survey on September 7, 2016. Findings: 1. A PT record review from the American Proficiency Institute (API) revealed the laboratory failed to test the PT samples for CBCs by the personnel who routinely test patient CBCs. 2. An interview on April 10, 2018 at 8:20 AM, with the technical consultant, confirmed the laboratory failed to rotate the PT samples among all testing personnel who test patient CBCs since the last survey.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

This STANDARD is not met as evidenced by:
Based on proficiency testing (PT) record review and an interview with the technical consultant, the laboratory director failed to sign the attestation statements from the American Proficiency Institute (API) for the specialty of Hematology for 2017. Findings: 1. An API PT record review from 2017, revealed the laboratory director failed to sign the attestation statements for the specialty of Hematology. 2. An interview on April 10, 2018 at 8:20 AM, with the technical consultant, confirmed the laboratory director failed to sign the attestation statements from 2017.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a record review of final patient reports and an interview with the technical consultant, the laboratory failed to document the name and the address of the laboratory where complete blood counts (CBCs) were reported on patient for the period reviewed between January 7, 2018 through April 5, 2018. Findings: 1. A review of patient CBC test reports, revealed the name and the address of the laboratory failed to be included on the patient's test reports. 2. An interview on April 10, 2018, at 10:15 AM, with the technical consultant, confirmed the name and the address of the laboratory failed to be indicated on final patient reports.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a record review of personnel documents and an interview with the technical consultant, the laboratory failed to follow the laboratory policy to evaluate and document the competency at least semiannually for one new employee during the first year of patient testing on the Sysmex complete blood count (CBC) analyzer used to test CBCs since the last survey on September 7, 2016. Findings: 1. A record review of personnel documents revealed 1 out of 5 testing personnel listed on the CMS-209 Personnel Report form, failed to have a competency assessment performed at least semiannually during the first year of patient testing. 2. An interview on April 10, 2018, at 8:15 AM, with the technical consultant, confirmed the laboratory failed to perform competency at least semiannually on 1 testing personnel.