

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D1028002	(X3) Date Survey Completed 01/05/2021
Name of Provider or Supplier Heritage Health Coeur D'Alene	Street Address, City, State 1090 Park Place, Coeur D'Alene, 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
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> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review, and an interview with the laboratory manager on 01/05/2021, the laboratory director failed to sign and date the PT attestation statements provided by the American Proficiency Institute (API). The findings include: 1. A record review of PT documents revealed that no API PT attestation statements were signed and dated by the laboratory director for all events performed in 2020. 2. An interview with the laboratory manager on 01/05/2021 at 10:30 AM confirmed the above findings. 3. The laboratory reports performing 250 patient specimens on the BD Affirm analyzer 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 record review of personnel training and competency assessments, the CMS-209 personnel form, and an interview with the laboratory manager on 01/05/21, the laboratory failed to follow written policies and procedures to assess competency for testing personnel. The findings include: 1. A review of competency assessments revealed that ten of ten testing personnel did not have annual competency assessed by the technical consultant listed on the CMS-209 personnel form for the BD Affirm. 2. Nine of ten testing personnel listed on the CMS-209 personnel form did not have 6-month competency assessment documented for the BD Affirm. 3. An interview with the laboratory manager on 01/05/2021 at 9:20 AM confirmed the above findings. 4. The laboratory reports performing 250 patient specimens on the BD affirm analyzer annually.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on record review of competency assessment documentation, the CMS-209 personnel form, and an interview with the laboratory manager on 01/05/2021, the technical consultant failed to ensure that the training and competency of the testing personnel was documented. The findings include: 1. A record review of competency assessments revealed that ten of ten testing personnel did not have competency assessed by the technical consultant listed on the CMS-209 personnel form for the BD Affirm. 2. Nine of ten testing personnel listed on the CMS-209 personnel form did not have 6-month competency assessment documented for the BD Affirm. 3. An interview with the laboratory manager on 01/05/2021 at 9:20 AM confirmed the above findings. 4. The laboratory reports performing 250 patient specimens on the BD Affirm analyzer annually.

D6065

TESTING PERSONNEL QUALIFICATIONS
 CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review of educational documents, the CMS-209 personnel form, and an interview with the laboratory manager on 01/05/2021, the laboratory failed to maintain diplomas/educational documents for the listed testing personnel. The findings include: 1. A review of diplomas and educational documents revealed that seven of ten testing personnel listed on the CMS-209 personnel form did not have the required educational documents available at the time of survey. 2. An interview with the laboratory manager on 01/05/2021 at 9:15 AM confirmed the above findings. 3. The laboratory reports performing 250 patients specimens on the BD Affirm analyzer annually.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on record review of training documentation, the CMS-209 personnel form, and an interview with the laboratory manager on 01/05/2021, the laboratory failed to document the training of the testing personnel for the BD Affirm analyzer prior to testing patient specimens. The findings include: 1. A review of testing personnel training documentation revealed that ten of ten testing personnel listed on the CMS-209 personnel form had no initial training documented for the BD Affirm analyzer prior to testing patient specimens. 2. An interview with the laboratory manager on 01/05/2021 at 9:20 AM confirmed the above findings. 3. The laboratory reports performing 250 patient specimens on the BD Affirm analyzer annually.