Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 13D1028002	**(X3) Date Survey Completed** 08/24/2022
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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Proficiency Institute (API) for BD Affirm testing and an interview with the clinic manager on 8/24/21, the laboratory failed to retain all PT documents and sign the attestation statements. The findings include: 1. A review of PT documents from API identified that the laboratory failed to retain any PT documents for BD Affirm testing for events one, two and three in 2021. 2. A review of PT documents from API for 2022 event one identified that the laboratory director and testing personnel failed to sign the attestation statement for BD Affirm testing. 3. An interview with the clinic manager on 8/24/2022 at 1:33 pm confirmed the above findings. 4. The laboratory reports performing 170 BD Affirm tests annually. 5. This is a repeat deficiency from the previous inspection on 1/5/2021.
D2025	BACTERIOLOGY CFR(s): 493.823(c)

	Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Proficiency Institute (API) for BD Affirm testing, the Center of Medicare and Medicaid Services (CMS) individual laboratory PT scores report (155D) and an interview with the clinic manager on 8/24/21, the laboratory failed to participate in 2022 event two. The findings include: 1. A review of the laboratory's CMS 155D report identified that the laboratory scored zero (0) for API PT 2022 event two for BD Affirm testing. 2. A review of the laboratory's API PT documentation identified that the laboratory failed to participate in PT for BD Affirm testing for 2022 event 2. 3. An interview with the clinic manager on 8/24/2022 at 1:42 pm confirmed that they were unable to return their results before the submission deadline. 4. The laboratory reports performing 170 BD Affirm tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the clinic manager on 8/24/2022, the laboratory failed to have written policies and procedures to assess testing personnel training and competency and failed to assess training and competency in 2021 and 2022. The findings include: 1. The CMS 209 identified 11 testing personnel performing moderate complexity testing. 2. A review of training and competency assessment records identified two (2) testing personnel hired after the last inspection (1/5/2021) that failed to have documentation of initial training. 3. A review of training and competency assessment records identified one (1) testing personnel that failed to have a six month competency assessment. 4. A review of training and competency assessment records identified 8 of 11 testing personnel that failed to have annual competency assessments for 2021 and 9 of 11 testing personnel that failed to have annual competency assessments for 2022. 5. An interview with the clinic manager on 8/24/2022 at 1:20 pm confirmed the above findings. 6. The laboratory reports performing 170 tests annually. 7. This is a repeat deficiency from the previous inspection on 1/5/2021.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from the American Proficiency

	Institute (API) for BD Affirm testing and an interview with the clinic manager on 8/24/21, the laboratory failed to have the laboratory director (LD) review and evaluate PT results for 2021 and 2022. The findings include: 1, A review of the laboratory's API PT documentation identified that the laboratory failed to have documentation of the LD's review and evaluation of PT results for BD Affirm testing for 2021. 2. A review of the laboratory's API PT documentation identified that the laboratory failed to have documentation of the LD's review and evaluate the PT results for BD Affirm testing for 2022 event one and two. 3. An interview with the clinic manager on 8/24/2022 at 1:40 pm confirmed that the LD had not reviewed or evaluated PT results for 2021 and 2022. 4. The laboratory reports performing 170 BD Affirm tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of laboratory temperature logs and an interview with the clinic manager on 8/24/2022, the laboratory failed to document temperatures each day of patient BD Affirm testing as required by the testing manufacturer. The findings include: 1. A review of the laboratory's temperature logs identified that the laboratory failed to document the heat block temperature for BD Affirm testing for the months of May, June, July and August of 2022. 2. A review of the laboratory's temperature logs identified that the laboratory failed to document room temperature as required by the manufacturer for BD Affirm testing in 2021 and 2022. 3. An interview with the clinic manager on 8/24/2022 at 2:09 pm confirmed the above findings. 4. The laboratory reports performing 170 BD Affirm tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel documents and an interview with the clinic manager on 8/24/2022, the laboratory failed to have a laboratory director that meets the qualification requirements since January 2022. See D6003
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory

personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral

	pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, personnel documents and an interview with the clinical manager on 8 /24/2022, the laboratory failed to have a qualified laboratory director. The finding include: 1. A review of personnel documents for the person listed as laboratory director on the CMS 209 identified that the laboratory failed to hire a laboratory director with one year of directing or supervising experience or with 20 continuing medical education credit hours in laboratory practice after the previous laboratory director left in December 2021. 2. An interview with the clinic manager on 8/24/2022 at 1:15 pm confirmed that the laboratory director failed to have the required experience to be qualified as a laboratory director. 3. The laboratory reports performing 170 tests annually.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory personnel documents and an interview with the clinic manager on 8/24/2022, the laboratory failed to have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. See D6035
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel report, a review of laboratory personnel documents and an interview with the clinic manager on 8/24/2022, the individual identified as the technical consultant (TC) failed to meet the qualifications for laboratory training and experience in the specialty of microbiology, for moderate complexity testing as defined at 42 C.F.R.493. 1411 . The findings included: 1. The individual identified on the CMS 209 as the TC has documentation of a diploma and licence as a doctor of medicine, but failed to have documentation of one (1) year of laboratory experience in non-waived testing in the specialty of microbiology. 2. The individual identified as the TC has been performing in this capacity from January 2022 to present. 3. An interview with the clinic manager

	on 8/24/2022 at 1:15 pm confirmed the above findings. 4. The laboratory reports testing 170 microbiology tests in 2022.