Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2076284	01/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jasper County Health Ventures	1501 1st Ave E, Newton, IA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of proficiency testing records and confirmed by laboratory personnel, identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the laboratory failed to enroll in a proficiency testing program for the anlaytes: erythrocyte count, hematocrit, hemoglobin, leukocyte count, platelet count, and automated white blood cell differentials in 2021. The findings include: 1. The laboratory began performing erythrocyte count, hematocrit, hemoglobin, leukocyte count, platelet count, and automated white blood cell differential on 1/7/2021. 2. At the time of the survey, the laboratory did not have proficiency testing records or a confirmation of PT enrollment for the listed analytes.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on lack of Cell-Dyn Emerald instrument printouts, review of patient test reports, and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the laboratory failed to retain the Cell-Dyn Emerald complete blood cell (CBC) instrument printouts for three out of three patients from 1/7/2021 - 1/20/2021. The findings include: 1. Patient A had a CBC performed on 1/10/2021. 2. Patient B had a CBC performed on 1/13/2021. 3. Patient C had a CBC performed on 1/14/2021. 4. The laboratory manually entered the CBC results from the Cell-Dyn Emerald instrument printout into the Laboratory Information System (LIS). The laboratory shredded the Cell-Dyn Emerald instrument printouts after entering patient results into the LIS. 5. At the time of the survey, the laboratory did not have the CBC Cell-Dyn Emerald instrument printouts for patient identifiers A, B and C.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observations made at the time of the survey; lack of Cell-Dyn Emerald instrument printouts and performance specification records; review of Form CMS-116 Clinical Laboratory Improvement Amendments Application for Certification, patient test reports, the Laboratory Procedure Manual, temperature records, Cell-Dyn 18 Plus quality control assay sheets and background checks; and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report); the laboratory failed to meet hematology requirements for: establishing procedures for specimen labeling as specified in standard D5311; establishing procedures for defining critical values and the course of action to take when a test system becomes inoperable as specified in standard D5403; ensuring the laboratory director approves, signs and dates the procedure manual as specified in standard D5407; monitoring temperature storage of quality control and calibration materials as specified in the standard D5413; documenting quality control expiration dates as specified in standard D5415; verifying performance specifications as specified in D5421; documenting function checks as specified in the standard D5431; and ensuring the test report indicates the name and address of the testing facility as specified in the standard D5805.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by:

	Based on review of the Laboratory Procedure Manual and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 11: 30 am on 1/20/2021, the laboratory failed to have a written policy that included the process for labeling specimens, including patient name or unique patient identifier and, when appropriate, specimen source. At the time of the survey, the specimen collection policy did not include specimen labeling criteria.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Laboratory Procedure Manual and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report), at approximately 11:30 am on 1/20/2021; the laboratory failed to have a procedure defining critical or panic values and the course of action to take when a test system becomes inoperable.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Laboratory Procedure Manual and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 11: 30 am on 1/20/2021, the laboratory director failed to approve, sign, and date the Laboratory Procedure Manual. The findings include: 1. The laboratory had a general Laboratory Procedure Manual that contained all of the laboratory's policies and procedures. 2. The Laboratory Procedure Manual had a cover page for the laboratory director to approve, sign and date all of the policies and procedures. 3. At the time of the survey, the laboratory director did not approve, sign and date the Laboratory Procedure Manual cover page.

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 review of the laboratory temperature records, the CMS-116 Clinical Laboratory Improvement Amendments Application for Certification and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the laboratory failed to document the refrigerator temperature for three out of 20 days from 1/1/2021 - 1/20/2021. The findings include: 1. The CMS-116 application section IV - Hours of Laboratory Testing indicated the laboratory operated seven days a week. 2. At the time of the survey, the laboratory did not document the temperature for the refrigerator that stored quality controls and calibrators on 1/2/2021, 1/3/2021, and 1/15/2021.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations made at the time of the survey, review of the Cell-dyn 18 Plus assay sheet and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 1/20/2021, the laboratory failed to document expiration dates for three out of three lot numbers of hematology quality controls (QC). The findings include: 1. The laboratory stored the "in use" hematology QC vials in the door of the refrigerator. 2. The "in use" QC included three vials with lot numbers: low (L0321, expiration date 3/5/2021), normal (N0321, expiration date 3/5/2021) and high (H0321, expiration date 3/5/2021). 3. The QC assay sheet stated that the QC vials have an 8 consecutive day open tube stability expiration date. 4. At the time of the survey, the laboratory did not document the expiration date on the "in use" QC vials.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10: 00 am on 1/20/21, the laboratory failed to verify the performance specifications of accuracy, precision, reportable range and reference intervals for the Cell-Dyn Emerald hematology analyzer. The findings include: 1. The laboratory obtained the Cell-Dyn Emerald hematology analyzer from a different facility. 2. The laboratory started performing complete blood cell count testing using the Cell-Dyn Emerald hematology analyzer on 1/7/2021. 3. Laboratory personnel identifier #4, confirmed the laboratory did not verify the performance specifications of accuracy, precision, reportable range and reference range on the Cell-Dyn Emerald after being moved to the laboratory.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of Cell-Dyn Emerald operator's guide, hematology background checks and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/21, the laboratory failed to document the hematology background check on one out of three days of patient testing from 1/7/2021 - 1/20/2021. The findings include: 1. The Cell-Dyn Emerald operator's guide stated background checks must be performed each day of patient testing. 2. On 1/13/2021, Patient identifier B had a complete blood cell count performed. 3. At the time of the survey, the laboratory did not have records of a background count being performed on 1/13/2021.
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 review of the Form CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, patient test reports and confirmed

	by laboratory personnel identifier #4 (refer to Laboratory Personnel Report) at approximately 10:00 am on 01/20/2021, the laboratory failed to indicate the name and address of the testing facility for two out of two patient test reports from 1/7/2021 - 1 /20/2021. The findings include: 1. Patient identifier B had a CBC performed on 1/13 /2021. 2. Patient identifier C had a CBC performed on 1/14/2021. 3. The Form CMS-116 CLIA Application for Certification indicated the name and address of the facility as Newton Express Care Clinic, 1501 1st Ave E, Newton, IA, 50208. 4. The test report for the above two individuals did not have the correct name and address of the testing facility.
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 observations made at the time of the survey; lack of personnel and proficiency testing records, and Cell-Dyn Emerald instrument printouts and performance specification records; review of Form CMS-116 Clinical Laboratory Improvement Amendments Application for Certification, Form CMS-209 Laboratory Personnel Report, patient test reports, the Laboratory Procedure Manual, temperature records, Cell-Dyn 18 Plus quality control assay sheets and background checks; and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report); the laboratory director failed to meet educational requirements as specified in D6003. Additionally, the laboratory director failed to meet the responsibility requirements including: ensuring the laboratory verified performance specifications as specified in D6013, ensuring the laboratory enrolled in proficiency testing as specified in D6015, ensuring the laboratory employed testing personnel with the appropriate education and training as specified in D6029, and ensuring the laboratory had the appropriate policies and procedures as specified in D6031.
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 lack of laboratory personnel records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1/20/2021, the laboratory failed to have documentation to qualify the laboratory director, identifier #1. At the time of the survey, the laboratory did not have qualifications for the laboratory director.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/21, the laboratory director failed to ensure the laboratory verified the performance specifications of accuracy, precision, reportable range, and reference range for the Cell-Dyn Emerald hematology analyzer. Refer to D5421.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on lack of proficiency testing (PT) records and confirmed by laboratory personnel, identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the laboratory director failed to ensure the laboratory enrolled in an approved PT program for the analytes: erythrocyte count, hematocrit, hemoglobin, leukocyte count, platelet count, and automated white blood cell differential in 2021. Refer to D2000.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of personnel records, review of the Form CMS-209 Laboratory Personnel Report and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1/20/2021, the laboratory director failed to employ laboratory personnel with the appropriate education and training for five out of five testing personnel who performed moderate complexity testing. Refer to D6065 and D6066
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Manual and confirmed by identifier #4 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 1/20/2021; the laboratory director failed to ensure the laboratory had written policies that included the process for labeling specimens, defining critical values and the course of action to take when a test system becomes inoperable. Refer to D5311 and D5403.
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 observations made at the time of the survey; lack of personnel and proficiency testing records and Cell-Dyn Emerald instrument printouts and performance specification records; review of Form CMS-116 Clinical Laboratory Improvement Amendments Application for Certification, Form-209 Laboratory Personnel Report, patient test reports, the Laboratory Procedure Manual, temperature records, Cell-Dyn 18 Plus quality control assay sheets and background checks; and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report); the technical consultant failed to meet educational requirements as specified in D6034. Additionally, the technical consultant failed to meet reasonability requirements including: ensuring the laboratory verified performance specifications as specified in D6040, ensuring the laboratory enrolled in an approved proficiency testing program as specified in D6041, and ensuring the testing personnel received training as specified in D6045.
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 lack of laboratory personnel records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1 /20/2021, the laboratory failed to have documentation to qualify the technical consultant, identifier #1. At the time of the survey, the laboratory did not have qualifications for the technical consultant.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10: 00 am on 1/20/21, the technical consultant failed to ensure the laboratory verified the performance specifications of accuracy, precision, reportable range, and reference range for the Cell-Dyn Emerald hematology analyzer. Refer to D5421.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on lack of proficiency testing (PT) records and confirmed by laboratory personnel, identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the technical consultant failed to ensure the laboratory enrolled in an approved PT program for the analytes: erythrocyte count, hematocrit, hemoglobin, leukocyte count, platelet count, and automated white blood cell differential in 2021. Refer to D2000.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on lack of personnel records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1/20/2021,

	the technical consultant failed to ensure that five out of five testing personnel received documented training prior to performing moderate complexity testing. Refer to D6066.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on lack of personnel records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report), the clinical consultant failed to meet the educational requirements as specified in D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on lack of laboratory personnel records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1 /20/2021, the laboratory failed to have documentation to qualify the clinical consultant, identifier #1. At the time of the survey, the laboratory did not have qualifications for the clinical consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on lack of personnel records and Cell-Dyn Emerald instrument printouts; review of Form CMS-209 Laboratory Personnel Report and patient test reports, and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report); the testing personnel failed to meet educational requirements as specified in D6065. Additionally, the testing personnel failed to meet responsibility requirements including: documenting training prior to reporting patient results as specified in D6066; retaining the Cell-Dyn Emerald compete blood cell count instrument printouts as specified in D6070.

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 lack of personnel records, review of Form CMS-209 Laboratory Personnel Report, and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 01/20/2021, the laboratory failed to have documentation to qualify five out of five testing personnel (identifiers #2 - #5) who perform moderate complexity testing. The findings include: 1. The CMS-209 Personnel Report, indicated identifiers #2 - #5 as testing personnel performing moderate complexity testing. 2. At the time of the survey, the laboratory did not have qualifications for testing personnel identifiers #2 - #5.
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 lack of personnel records, review of Form CMS-209 Laboratory Personnel Report and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 9:40 am on 1/20/2021, the testing personnel failed to document training prior to performing moderate complexity testing for five out of five testing personnel (identifiers #2 - #5). The findings include: 1. The CMS-209 Personnel Report, indicated identifiers #2 - #5 as testing personnel performing moderate complexity testing. 2. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #2 - #5.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on lack of Cell-Dyn Emerald instrument printouts, review of patient test

	reports, and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/20/2021, the testing personnel failed to retain the Cell-Dyn Emerald complete blood cell (CBC) instrument printouts for three out of three patients from 1/7/2021 - 1/20/2021. Refer to D3031.