Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2278006	11/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Total Point Urgent Care	590 Birch Rd, Hollister, MO	

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
D0000	An initial survey was completed on November 7, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1403 Condition: Laboratory Director 42 C.F.R. 493.1409 Condition: Technical Consultant 42 C.F.R. 493.1415 Condition: Clinical Consultant 42 C.F.R. 493.1421 Condition: Testing Personnel
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2023, interview with the testing personnel (TP) #1 and laboratory owner, the laboratory failed to provide attestation documentation for one of one PT testing events in 2023. Findings: 1. Review of PT records for 2023 showed the laboratory could not provide attestation records for testing personnel and the laboratory director to show routine integration of samples into the patient workload for the following proficiency testing events: 2023 Hematology/Coagulation-2nd event 2. Interview with the TP #1 and laboratory owner on November 7, 2023 at 10:30 AM confirmed the laboratory could not provide PT testing events attestation records for one PT testing events in 2023.
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 review of American Proficiency Institute proficiency testing (PT) records for 2023 and interview with testing personnel (TP) #1 and laboratory owner, the laboratory failed to maintain a copy of all instrumentation data printouts for one of one PT events in 2023. Findings: 1. Review of 2023 PT records showed no instrument data printouts for 2023 Hematology/Coagulation- second event. 2. Interview with the TP #1 and laboratory owner on November 7, 2023 at 10:30 AM confirmed the laboratory failed to maintain a copy of all instrumentation data printouts.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency records for 2023, interview with the testing personnel (TP) #1 and laboratory owner, the laboratory failed to establish a means to verify the accuracy of the Cepheid Genexpert analyzer for four of four analytes twice yearly. Findings: 1. Review of proficiency records for 2023 showed the laboratory failed to prove accuracy on the non-regulated analytes: SARS-CoV-2, respiratory syncytial virus (RSV), influenza A and influenza B. 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 10:30 AM confirmed the laboratory failed to verify the accuracy of four non-regulated analytes twice annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of procedures, review of temperature logs, observation of quality control (QC) and supplies, performance specifications, CBC quality control, and Cepheid Genexpert QC the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure an procedure manual is available (Refer to D5401); the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer (D5413);

	the laboratory failed to ensure laboratory QC and supplies were not used when they had exceeded their expiration date (Refer to D5417); the laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to include two control materials each day of patient testing for CBC testing (Refer to D5447); the laboratory failed to perform a positive and negative quality control for SARS CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) each day of patient testing (Refer to D5449); and the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory failed to ensure an approved procedure manual is available. Findings: 1. Review of procedures showed no procedure for the: - Sysmex XP300 hematology analyzer - Cepheid Genexpert analyzer for SARS-CoV-2, respiratory syncytial virus (RSV), influenza A and influenza B - Piccolo Xpress chemistry analyzer - testing personnel competency - proficiency testing 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 11:00 AM confirmed the laboratory failed to ensure an procedure manual is available.
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 operator's guide for the Cepheid Genexpert Xpress PCR analyzer, review of laboratory temperature logs, and interview with the testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer for 288 of 288 days from January 23, 2023 to date November 7, 2023. Findings: 1. Review of the operator's guide for the Cepheid Genexpert Xpress PCR analyzer states, "Your laboratory must meet the following requirements: Operating Temperature: 15 - 30 degrees Celsius. Relative Humidity: 20% - 80%, non-condensing." 2. Review of laboratory temperature logs from January 23, 2023 to date November 7, 2023 showed no documented room temperature or humidity for the PCR testing room for 288 of 288 days. 3. The laboratory was unable to provide the number

	of PCR tests performed from January 23, 2023 to date November 7, 2023 while the room temperature and humidity were not documented. 4. Interview with the TP #1 on November 7, 2023 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of laboratory refrigerator, laboratory room temperature supplies, and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory failed to ensure laboratory quality control (QC), and supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory refrigerator showed the following still in use: - 1 bottle BRT liquid assayed chemistry & lipid lot #2204012-1 expiration 9/30/23 - 1 bottle BRT liquid assayed chemistry & lipid lot #2204012-2 expiration 9/30/23 - 1 box BRT verification samples lot #2206001 expiration 10/31/23 - 1 bottle Sysmex EightCheck X-TRA - L lot# 31650710 expiration 09/20/2023 - 1 bottle Sysmex EightCheck X-TRA - N lot# 31650711 expiration 09/20/2023 - 1 bottle Sysmex EightCheck X-TRA - H lot# 31650712 expiration 09/20/2023 - 1 bottle Sysmex SCS-1000 lot# 32480525 expiration 10/08/2023 2. Observation of room temperature supplies showed the following still in use: - 3 blood culture bottles lot #0004059496 expiration 11/5/23 - 2 blood culture bottles lot #004059424 expiration 10/20/23 - 9 BD vacutainer Na Citrate lot #2291888 expiration 7/31/23 - 10 BD vacutainer K2 EDTA lot #2292119 expiration 10/31/23 - 10 BD vacutainer Na Citrate lot #2259112 expiration 9/30/23 3. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 10:00 AM confirmed the laboratory failed to ensure laboratory QC and supplies were not used when they had exceeded their expiration date.
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 review of the performance verification procedures for the Sysmex XP-300 hematology analyzer and the lack of performance verification procedures for the Cepheid Genexpert Xpress PCR analyzer, patient results, and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review

	of the performance specifications for the Sysmex XP-300 hematology analyzer showed the laboratory failed to verify accuracy, precision, reportable range, and that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in January 2023. 2. Lack of performance specifications for the Cepheid Genexpert Xpress PCR analyzer showed the laboratory failed to verify accuracy, precision, reportable range, and that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: SARS-CoV 2, influenza A, influenza B, and respiratory syncytial virus (RSV) prior to the beginning of patient testing in January 2023. 3. Review of patient results confirmed the laboratory was performing patient testing on the Sysmex XP-300 hematology analyzer and the Cepheid Genexpert Xpress PCR analyzer on the day of the survey, November 7, 2023. The laboratory was unable to provide the number of patient tests performed on the Sysmex XP-300 hematology analyzer and the Cepheid Genexpert Xpress PCR analyzer from January 2023 to date November 7, 2023. 4. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Sysmex XP-300 hematology analyzer quality control (QC), patient results, and interview with the testing personnel (TP) #1, the laboratory failed to include two acceptable control materials of different concentrations for complete blood count (CBC) testing for 41 of 41 patient testing days. Findings: 1. Review of the Sysmex XP-300 hematology analyzer quality control (QC) from September 21, 2023 to date November 7, 2023 showed two acceptable levels of CBC QC were not performed for 41 of 41 patient testing days due to the laboratory using Sysmex Eightcheck X-TRA quality control material that expired on September 20, 2023. 2. The laboratory was unable to provide the number of patient tests performed on the Sysmex XP-300 hematology analyzer from September 21, 2023 to date November 7, 2023. 3. Interview with the TP #1 on November 7, 2023 at 10:00 AM confirmed the laboratory failed to include two control materials each day of patient testing for CBC testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the Cepheid Genexpert Xpress quality control (QC) records from January 23, 2023 to date November 7, 2023, review of patient results and interview with the testing personnel (TP) #1, the laboratory failed to perform a positive and negative quality control for SARS CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) each day of patient testing. Findings: 1. Review of the Cepheid Genexpert Xpress quality control (QC) records from January 23, 2023 to date November 7, 2023 showed the laboratory failed to perform a positive and negative quality control each day of patient testing for SARS CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV). 2. The laboratory was unable to provide the number of patient tests performed on the Cepheid Genexpert Xpress PCR analyzer from January 23, 2023 to date November 7, 2023 while QC was not performed. 3. Interview with the TP #1 on November 7, 2023 at 10:00 AM confirmed, the laboratory failed to perform a positive and negative quality control for SARS CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Sysmex XP300 quality control (QC) records, and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory failed to establish criteria for acceptability of complete blood count (CBC) control materials providing quantitative results. Findings: 1. Review of the Sysmex XP300 QC records showed the laboratory did not establish, document, and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative hematology QC for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit, mean corpuscular volume (MCV), MCH, MCHC, platelets and automated differential. 2. The laboratory was unable to provide the number of patient tests performed on the Sysmex XP300 analyzer from January 2023 to date November 7, 2023. 3. Interview with the TP #1 and laboratory owner on November 7, 2023 at 10: 00 AM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
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 patient test reports and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory failed to include the address of the laboratory location where the test was performed on the patient test report. Findings: 1. Review of patient test report from 10/07/2023 for SARS CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) showed no address of the laboratory location where the tests were performed. 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 11:00 AM confirmed the laboratory failed to include the address of the laboratory location where the test was performed on the patient test report.
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 lack of personnel documentation, review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2023, review of the laboratory's procedures, review of Sysmex XP-300 analyzer quality control (QC) procedure, Cepheid Genexpert analyzer QC procedure, review of patient test reports, lack of testing personnel (TP) training documents, lack of available delegation of duties for the technical consultant and interviews, the laboratory director (LD) failed to provide overall management and direction to the laboratory. The laboratory failed to provide academic credentials to qualify the LD for moderate complexity testing (Refer to D6003); the LD failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance (Refer to D6018); the LD failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory (Refer to D6019); the LD failed to ensure approved quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur (Refer to D6021); the LD failed to ensure that patient test reports include pertinent information required for interpretation (Refer to D6026); the LD failed to ensure four of four TP received the appropriate training prior to performing patient testing in 2023 (Refer to D6029); and the LD failed to specify, in writing, the responsibilities and duties of the technical consultant (Refer to D6032).
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 personnel documentation, and interview with the testing personnel (TP) #1, and the laboratory owner, the laboratory failed to provide academic credentials to qualify the laboratory director for moderate complexity testing. Findings: 1. Lack of the personnel documentation showed the laboratory failed to provide documentation (academic credentials) to show the laboratory director was qualified to manage and direct the personnel and performance of moderate complexity testing. 2. Interview with the TP #1 and laboratory owner on November 7, 2023 at 11: 00 AM confirmed the laboratory failed to provide academic credentials to qualify the laboratory director for moderate complexity testing.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of 2023 proficiency testing (PT) and interview with testing personnel (TP) #1 and laboratory owner, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Findings: 1. Review of 2023 PT 2nd event hematology showed no review of complete blood count (CBC) and automated differential results. 2. Interview with the TP #1 and laboratory owner on November 7, 2023 at 10:30 AM confirmed the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2023 American Proficiency Institute (API) proficiency testing (PT) for 2023, interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory for one of one PT events. Findings: 1. Review of 2023 PT showed no corrective action plan for: MCV HSY-10 unacceptable 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 10:30 AM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of Sysmex XP300 analyzer quality control (QC) procedure, Cepheid Genexpert analyzer QC procedure and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure approved quality assessment programs were established to assure the quality of

	laboratory services and to identify failures in quality as they occur. Findings: 1. Review of laboratory procedures showed no approved quality assessment program. 2. Review of Sysmex XP300 analyzer procedure showed no approved procedure for the acceptability of QC. 3. Review of Cepheid Genexpert analyzer procedure showed no approved procedure for the acceptability of QC. 2. Interview with the TP #1 and laboratory owner on November 7, 2023, at 10:30 AM confirmed the LD failed to ensure quality assessment programs were established to assure the quality of laboratory services and to identify failures in quality as they occur.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory director failed to ensure that patient test reports include pertinent information required for interpretation. Findings: 1. Review of complete blood count (CBC) patient test report from October 20, 2023 showed no pertinent reference interval (normal values) available for interpretation for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC). 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 11:00 AM confirmed the laboratory director failed to include pertinent reference interval (normal values) on the CBC patient test report.
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 testing personnel (TP) training documents and interview with the testing personnel (TP) #1 and the laboratory owner, the laboratory director (LD) failed to ensure four of four TP received the appropriate training prior to performing patient testing in 2023. Findings: 1. Lack of TP training documents showed TP #1, TP #2, TP #3 and TP #4 had no documented training before patient testing was performed in 2023. 2. Interview with the TP #1 and the laboratory owner on November 7, 2023 at 11:00 AM confirmed the LD failed to ensure TP received the appropriate training before performing patient testing.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of available delegation of duties for the technical consultant and interview with the laboratory owner, the laboratory director failed to specify, in writing, the responsibilities and duties of the technical consultant engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Findings: 1. No delegation of duties for the technical consultant was available on November 7, 2023. 2. Interview with the laboratory owner on November 7, 2023 at 11:00 AM confirmed that the laboratory director failed to specifically delegate in writing the responsibilities and duties of the technical consultant.
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 review of personnel records, technical consultant accessibility and training /competency the laboratory failed to meet the condition of technical consultant. The laboratory failed to provide documentation of academic credentials and laboratory training or experience for the technical consultant (Refer to D6035); the technical consultant failed to be accessible to the laboratory (Refer to D6037); the technical consultant failed to ensure the training/competency for two testing personnel (TP) included direct observation (Refer to D6047); and the technical consultant failed to evaluate and document the performance of three TP at least semiannually during the first year the individual tests patient specimens (Refer to D6053).
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 personnel records and interview with the laboratory owner, the laboratory failed to have the required documentation to qualify one of one technical consultant. Findings: 1. The laboratory failed to have academic credentials and laboratory training and/or experience for the technical consultant. 2. Interview with the laboratory owner on November 7, 2023 at 10:45 AM confirmed, the laboratory failed to have the required documentation to qualify the technical consultant.
D6037	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on confidential interview, review of paperwork, interview with testing personnel (TP) #1 and laboratory owner, the technical consultant failed to be accessible to the laboratory. Findings: 1. Confidential interview on November 7, 2023 when asked about technical consultant the confidential interviewee stated "I really don't know who you are talking about. I have never met her.". 2. Review of quality control, training/competency, procedures, and proficiency testing showed no technical consultant oversight. 3. Interview with TP #1 and laboratory owner on November 7, 2023 at 10:30 AM confirmed the technical consultant failed to be accessible to the laboratory.

D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of training/competencies, interview with the testing personnel (TP) #1 and laboratory owner, the technical consultant failed to ensure the training /competency for two of two TP included direct observation. Findings: 1. Review of training/competency for TP #1 and TP #4 showed training/competency did not include direct observation. 2. Interview with TP #1 and laboratory owner on November 8, 2023 at 10:30 AM, confirmed the technical consultant failed to ensure the training/competency for two TP included direct observation.
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 lack of personnel records and interview with the testing personnel (TP) #1, the technical consultant (TC) failed to evaluate and document the performance of three of four testing personnel (TP) at least semiannually during the first year the individual tests patient specimens in 2023. Findings: 1. Lack of performance evaluations showed the TC failed to perform the semi-annual competency evaluation for TP #1, TP #3 and TP #4 in 2023. 2. Interview with the TP #1 on November 7, 2023 at 10:00 AM, confirmed the TC failed to evaluate and document the performance of three TP at least semiannually during the first year the individual tests patient specimens.
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 laboratory personnel credentials and interviews, the laboratory failed to employ a clinical consultant who meets the requirements of 493.1419 of this subpart and provides clinical consultation to the laboratory. The laboratory failed to provide academic credentials to qualify one of one clinical consultant (Refer to 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 personnel documentation, and interview with the laboratory owner, the laboratory failed to provide academic credentials to qualify one of one clinical consultant. Findings: 1. Lack of the personnel documentation showed the laboratory failed to provide documentation (academic credentials) to qualify the clinical consultant. 2. Interview with the laboratory owner on November 7, 2023 at 11:00 AM confirmed the laboratory failed to provide academic credentials to qualify 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 interview with the laboratory owner, the laboratory failed to provide academic qualifications required to perform moderate complexity testing for two of four testing personnel. (Refer to D6065)
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 academic credentials and interview with the laboratory owner, the laboratory failed to provide academic credentials to qualify two of four testing personnel (TP). Findings: 1. The laboratory could not provide academic credentials to show testing personnel #1 and testing personnel #3 were qualified to perform moderate complexity testing. 2. Interview with the laboratory owner on November 7,

	2023 at 11:00 AM confirmed the academic credentials needed to qualify testing personnel #1 and #4 were not available for review.