Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0091845	11/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Castleton Family Health Center	275 Route 30 North, Bomoseen, VT	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to assess accuracy of hematology proficiency testing (PT) when it failed to participate in PT event 2 of 2023. Findings include: 1. Review on 11/13/2024 of American Proficiency Institute (API) PT records revealed the lab obtained 0% for all complete blood count (CBC) analytes (white blood count, red blood count, hemoglobin, hematocrit, platelet count, and automated white cell differential) for Event 2 of 2023. The lab documented the testing had not been performed in time to submit the results to API and the lab performed testing after the due date. There was no documentation that lab's test results had been assessed with API's acceptable ranges for these analtyes in this event. 2. Interview on 11/13/2024 at 10:00 a.m. with Testing Personnel confirmed the lab failed to participate in the CBC PT event 3 of 2023 and revealed the lab performed the testing after the due date but did not compare their results to the acceptable results for this PT event.
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 record review and staff interview, the laboratory (lab) failed to meet analytic test requirements for bacteriology and hematology testing in 2023 and 2024. Findings include: 1. The lab failed to have written procedures for two new test systems in bacteriology started in April 2023, and hematology started in May 2024. Refer to D5401. 2. The lab's bacteriology and hematology procedures in use were not approved by the Laboratory Director. Refer to D5407. 3. The lab failed to demonstrate it verified performance specifications for precision and reportable range for the new hematology instrument put into use in May 2024. Refer to D5421. 4. The lab failed to perform hematology control testing on two days from 8/1/2024 through 11/13/2024 when patient testing was reported. Refer to D5447. 5. The lab failed to document control procedures and failed to perform a positive and negative control each day of patient testing for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) from April 2023 to November 2024. Refer to D5449. 6. The lab failed to follow the "Laboratory Quality Assurance" policy and monitor quality control testing to identify and correct control problems with bacteriology and hematology control testing in 2023 and 2024. Refer to D5791.
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 record review and staff interview, the laboratory (lab) failed to have written procedures for two new test systems in bacteriology started in April 2023, and hematology started in May 2024. Findings include: 1. Review on 11/13/2024 of the lab's procedure for the Cepheid GeneXpert revealed the procedure did not include instruction for Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG) and was last updated April 2022. Review on 11/13/2024 of the lab's procedure for complete blood counts (CBC) revealed the procedure had not been updated when the lab began testing with the new instrument put into use in May 2024. 2. Interview on 11/13/2024 at 1:00 p.m. with Testing Personnel confirmed the lab's procedures had not been updated to include the new CT/NG test and for the new CBC instrument.
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 record review and staff interview, the bacteriology and hematology

	procedures in use were not approved by the Laboratory Director. Findings include: 1. Review on 11/13/2024 of the lab's procedures revealed the LD had not signed and dated any of the lab's procedures including the procedures in use for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC), and Quality Assurance. 2. Interview on 11/13/2024 at 1:00 p.m. with Testing Personnel confirmed the above finding.
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 record review and staff interview, the laboratory (lab) failed to demonstrate it verified performance specifications for precision and reportable range for the new hematology instrument put into use in May 2024. Findings include: 1. Review on 11/13/2024 of the lab's new instrument validation book for the Sysmex XN-L revealed no studies had been performed by lab personnel to verify precision and reportable range of complete blood count (CBC) analytes. CBC analytes include white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet count and automated differential. 2. Interview on 11/13:2024 at 1:10 p.m. with Testing Personnel confirmed the above finding and revealed the only testing performed by lab personnel was a correlation study before the instrument was put into use in May 2024.
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 record review and staff interview, the laboratory (lab) failed to perform hematology control testing on two days from 8/1/2024 through 11/13/2024 when patient testing was reported. Findings include: 1. Review on 11/13/2024 of complete blood count (CBC) control records revealed no quality control testing was performed on 8/11/2024, 9/21/2024, 9/22/2024, 9/28/2024, 11/2/2024, 11/3/2024, and 11/11/2024. CBC analytes include white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet count and automated differential. 2. Review on 11/13/2024 of patient CBC testing revealed two patient test results were reported on 8/11/2024 and one patient test reported on 11/11/2024. 3. Interview on 11/13/2024 at with Testing Personnel revealed the testing personnel are supposed to run three levels of controls first thing in the morning each day and confirmed the above findings.

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 record review and staff interview, the laboratory (lab) failed to document control procedures and failed to perform a positive and negative control each day of patient testing for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) from April 2023 to November 2024. Findings include: 1. Review on 11/13/2024 of control logs from the Cepheid GeneXpert instrument revealed no quality control testing for CT/NG testing performed since the qualitative patient test began in April 2023. 2. Interview on 11/13/2024 at 12:30 p.m. with Testing Personnel revealed a positive and negative control had been performed on each new lot of CT/NG cartridge and confirmed this documentation could not be found.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to follow the "Laboratory Quality Assurance" policy and monitor quality control testing to identify and correct control problems with bacteriology and hematology control testing in 2023 and 2024. Findings include: 1. Review on 11/13/2024 of the lab's policy titled "Laboratory Quality Assurance" last revised June 2022 revealed as part of the procedure the lab was to monitor quality control testing logs. There was no documentation that control testing logs for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC) testing had been reviewed to determine control testing was performed and acceptable per the lab's procedures. 2. Interview on 11/13/2024 at 2:15 p.m. with Testing Personnel revealed control testing for CT/NG and CBCs are reviewed when performed by the testing personnel for acceptability and not reviewed periodically to ensure procedures are followed.
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 record review and staff interview, the Laboratory Director (LD) failed to fulfill LD responsibilities in 2023 and 2024. Findings include: 1. The LD failed to ensure PT results were evaluated when it failed to participate in proficiency testing event 2 of 2023. Refer to D6018. 2. The LD failed to ensure quality control procedures for bacteriology and hematology were established and maintained. Refer to D6020. 3. The LD failed to ensure a quality assessment program was established and maintained to review control testing and identify and correct failures, and monitor corrective actions. Refer to D6021. 4. The LD failed to ensure approved procedures were available to testing personnel. Refer to D6031.
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 record review and staff interview, the Laboratory Director (LD) failed to evaluate the laboratory's proficiency testing performance when the lab failed to participate in Event 2 of 2023. Cross reference D5215. Findings include: 1. Review on 11/13/2024 of American Proficiency Institute (API) PT records revealed the lab obtained 0% for all complete blood count (CBC) analytes for Event 2 of 2023. The lab documented the testing had not been performed in time to submit the results to API and the lab performed testing after the due date. There was no documentation that the lab evaluated the lab's test results were within API's acceptable ranges and the LD signed off on the corrective action outlined on the PT evaluation report. 2. Interview on 11/13/2024 at 10:00 a.m. with Testing Personnel confirmed the above finding.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure a quality control program for bacteriology and hematology testing were established and maintained in 2024. Cross reference D5547 and D5449. Findings include: 1. Review on 11/13/2024 of Chlalmydia trachomatis and Neisseria gonorrhoeae (CT/NG) control records from April 2023 to present day revealed no record of control testing had ever been performed. 2. Interview on 11/13/2024 at 12: 30 p.m. with Testing Personnel revealed a positive and negative CT/NG control were

	run for each new lot of reagent cartridges received and confirmed there was no documentation in the control records. 3. Review on 11/13/2024 of complete blood count (CBC) control records and patient testing from 8/1/2024 through 11/13/2024 revealed 7 days in which CBC controls had not been performed and 2 of these 7 days patient CBC testing had been performed. 4. Interview on 11/13/2024 at 2:15 p.m. with Testing Personnel confirmed the above finding.
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 record review and staff interview, the Laboratory Director failed to ensure quality assessment programs to review control procedures for bacteriology and hematology testing were established and maintained in 2023 and 2024. Cross reference D5407 and D5791. Findings include: 1. Review on 11/13/2024 of the lab's policy titled "Laboratory Quality Assurance" last revised June 2022 revealed as part of the procedure the lab was to monitory quality control testing logs. There was no documentation that control testing logs for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC) testing had been reviewed to determine control testing performed and acceptable per the lab's procedures. This procedure had not been approved by Laboratory Director. 2. Interview on 11/13/2024 at 2:15 p.m. with Testing Personnel revealed control testing for CT/NG and CBCs are reviewed when performed and not reviewed periodically to ensure procedures are followed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure testing personnel maintain their competency for bacteriology and hematology testing in 2023 and 2024. Cross reference D6051. Findings include: 1. Review on 11 /13/2024 of testing personnel competency assessments from 2023 and 2024 revealed 4

	(TP1, TP2, TP3, and TP4) out of 5 personnel records reviewed documented assessments of test performance had been performed using proficiency testing (PT) but when PT was reviewed the TP1, TP2, TP3, TP4 had not participated and not assessed for test performance for the following: TP1 in June 2023 for Chlamydia trachomatis / Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC). TP2 in May 2024 for CT/NG and CBCs. TP3 in June 2023 and November 2023 for CT /NG. TP4 in November 2023 for CT/NG and in May 2024 for CT/NG and CBCs. Further review of the competency assessments revealed they had been completed and signed off by Testing Personnel, there was no indication the Technical Consultant had reviewed and signed the competency assessments. 2. Interview on 11/13/2024 at 10: 15 a.m. with Testing Personnel confirmed the above finding.
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 record review and staff interview, the Laboratory Director (LD) failed to approve bacteriology and hematology procedures used in 2023 and 2024. Cross reference D5407. Findings include: 1. Review on 11/13/2024 of the lab's procedures revealed the LD had not signed and dated any of the lab's procedures including the procedures in use for Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC), and Quality Assurance. 2. Interview on 11/13/2024 at 1:00 p.m. with Testing Personnel confirmed the above finding. 3. The LD has been in this role since 1/1/2023.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant failed to ensure assessments of test performance for 4 of 5 testing personnel had been performed as part of competency assessments in 2023 and 2024. Findings include: 1. Review on 11 /13/2024 of testing personnel competency assessments from 2023 and 2024 revealed 4 (TP1, TP2, TP3, and TP4) out of 5 personnel records reviewed documented assessments of test performance had been performed using proficiency testing (PT) but when PT was reviewed the TP1, TP2, TP3, TP4 had not participated and not assessed for test performance for the following: TP1 in June 2023 for Chlamydia trachomatis / Neisseria gonorrhoeae (CT/NG) and complete blood counts (CBC). TP2 in May 2024 for CT/NG and CBCs. TP3 in June 2023 and November 2023 for CT /NG. TP4 in November 2023 for CT/NG and in May 2024 for CT/NG and CBCs.

	Further review of the competency assessments revealed they had been completed and signed off by Testing Personnel, there was no indication the Technical Consultant had reviewed and signed the competency assessments. 2. Interview on 11/13/2024 at 10: 15 a.m. with Testing Personnel confirmed the above finding.