Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2214252	(X3) Date Survey Completed 10/04/2021
Name of Provider or Supplier Hillcrest Urgent Care, Llc	**Street Address, City, State** 1639 N Volusia Ave, Suite D,, Orange City, FL	

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 certification survey was performed on 10/4/21 at Hillcrest Urgent Care, a clinical laboratory located in Orange City Florida. Hillcrest Urgent Care is NOT in compliance with the 42 CFR Part 493, Requirements for Laboratories.
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 record review and interview with the Office Manager, the laboratory was not enrolled in proficiency testing (PT) for the hematology, chemistry, and immunology patient testing performed in 2021. Findings include: The laboratory was unable to provide documentation of PT enrollment for Hillcrest Urgent Care. The interview with the laboratory director on 10/4/21 at 10:30 AM confirmed that Hillcrest Urgent Care had not enrolled in a separate proficiency testing program from the shared onsite accredited laboratory. .
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system since January 2021. The findings include: 1. The laboratory failed to establish a policy and procedure that ensures specimen identification and integrity. See D5203. 2. The laboratory failed to establish a policy and procedure to assess employee competency. See D5209. 3. The laboratory failed to establish a quality assessment program. See D5291. .
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the integrity of patient specimens throughout the entire testing process since January 2021. Findings include: The overall record review of the laboratory's documentation showed the following: 1. Due to lack of accession logs, there is no tracking of which patient samples are received. 2. Due to no final reports being provided during time of survey, it is unable to be determined if the patient specimens were processed and reported in a timely manner. 3. Due to lack of patient requisitions being provided at time of survey, it is unable to be determined if information for patient specimen submission has been recorded. 4. Lack of documentation showing quality control was performed. The interview with the Office Manager on 10/4/21 at 10:30 AM confirmed that Hillcrest Urgent Care did not maintain its own documentation separate from the shared accredited onsite laboratory.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a competency program in place to assess laboratory employees performing patient testing since January 2021. Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Consultant for personnel performing laboratory testing. The

	interview with Office Manager on 10/4/21 at 10:30 AM confirmed that no competency program with Technical Consultant oversight was in place for laboratory personnel. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not have a written quality assessment procedure that described the laboratory's processes for verifying patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance. Findings Include: The laboratory was unable to provide a policy or procedure that monitors, assesses, or corrects problems with verifying patient confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing performance. The Office Manager acknowledged during on interview on 10/4/21 at 10:30am, that there was no procedure available for review that included the information. .
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not have a written quality assessment policy for preanalytic systems. Findings include: The laboratory was unable to provide a quality assessment policy. On 10/4/21 at 10:30 AM, the Office Manager confirmed there was no policy to review. .
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 interview with Office Manager, the laboratory did not meet the condition of analytic systems. Findings include: 1. The laboratory failed to

	have procedures for all tests performed since January 1st, 2021. See D5401. 2. The laboratory failed to verify performance specifications for all testing performed on the instruments used for hematology, chemistry, and immunology. See D5421. 3. The laboratory failed to document monthly maintenance of the DxH 520, AU480, G8, and Access 2 analyzers since January 2021. See D5429. 4. The facility failed to document calibration and calibration verification activity for the DxH 520, AU 480, Access 2, and G8 laboratory analyzers since January 2021. See D5437. 5. The laboratory failed to perform separate quality control for all testing performed since January 2021. See D5441. 6. The laboratory did not have a written quality assessment policy. See 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 interview with the Office Manager the laboratory failed to have procedures for all tests performed since January 1st, 2021. Findings included: The laboratory was unable to provide a procedure manual for all tests performed. White blood count, red blood count, hemoglobin, and hematocrit performed on the DXH 520 hematology analyzer. Glucose, creatinine, total protein, total bilirubin, albumin, calcium, alkaline phosphatase, aspartate aminotransferase, sodium, potassium, chloride, carbon dioxide, direct bilirubin, amylase, lipase, Microalbumin, and iron performed on the AU 480 chemistry analyzer. Hemoglobin A1C performed on the G8 analyzer. Thyroid stimulating hormone, free thyroid 4, free thyroid 3, antithyroid peroxidase, SARS Covid - 19 IgG, testosterone, prostate specific antigen, free prostate specific antigen, vitamin B12, vitamin D25, Folate, and Ferritin performed on the Access 2 analyzer. Interview on 10/4/21 at 10:30AM with the Office Manager confirmed that there were no policies or procedures for the aforementioned tests. He stated that Hillcrest Urgent Care does not maintain separate manuals, documentation, quality control records, or proficiency testing from the active accredited laboratory previously established (West Volusia Family and Sports Medicine 10D2184087) inside the building. Hillcrest Urgent Care has used the same instruments, manuals, reagents, and staff as West Volusia Family and Sports Medicine.
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 interview, the laboratory had not verified performance specifications for testing performed on the instruments used for hematology, chemistry, and immunology testing, (DxH520, AU480, G8, and Access 2) Findings include: The laboratory was unable to provide documentation of performed studies to show accuracy, precision, reportable range, or that the manufacturer's normal ranges are appropriate for their patient population. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not perform separate verification studies of the laboratory instrumentation.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document monthly maintenance of the DxH 520, AU480, G8, and Access 2 analyzers since January 2021. Findings include: The laboratory was unable to provide documentation of analyzer maintenance. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not maintain separate maintenance records of the laboratory instrumentation.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to document calibration and calibration verification activity for the DxH 520, AU 480, Access 2, and G8 laboratory analyzers since January 2021. Findings include: The laboratory was unable to provide documentation of calibrations or calibration verifications performed by Hillcrest Urgent Care. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not perform separate calibrations of the laboratory instrumentation.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 failed to perform separate quality control for all testing performed since January 2021. Findings include: The laboratory was unable to provide documentation that quality control was performed with a separate quality control material than the shared laboratory (West Volusia Family and Sports Medicine) prior to performing testing on Hillcrest Urgent Care patient samples. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not perform quality control separate from West Volusia Family and Sports Medicine.
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 interview with the Office Manager, the laboratory did not have a written quality assessment policy. Findings include: The laboratory was unable to provide a quality assessment policy used to monitor, assess, and correct problems identified in analytic systems. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not have its own quality assessment policy.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory did not have a written quality assessment policy. Findings include: The laboratory was unable to provide a quality assessment policy used to monitor, assess, and correct problems identified in post- analytic systems. The interview with the Office Manager on 10/4 /21 at 10:30AM confirmed the laboratory did not have its own quality assessment policy.

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 failed to provide sufficient over sight of the laboratory's specimen testing process. The findings include: . 1. The Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing. Refer to D6015. 2.. The Laboratory Director failed to ensure the laboratory performed verification procedures prior to patient testing. Refer to D6013. 3. The Laboratory Director failed to ensure the laboratory had a Quality Control system in place. Refer to D6020. 4. The Laboratory Director failed to ensure the laboratory had a Quality Assessment system in place. Refer to D6021. 5. The Laboratory Director failed to ensure the laboratory had a process in place to evaluate personnel competency of the staff performing moderate complexity testing. Refer to D6030. 6. The Laboratory Director failed to ensure the laboratory procedure manual. Refer to D6031. .
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 record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory performed calibrations or calibration verification of the DxH 520, AU480, G8, and Access 2 analyzers. Findings include: The laboratory was unable to provide documentation of performed studies to show accuracy, precision, reportable range, or that the manufacturer's normal ranges are appropriate for their patient population. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not perform separate verification studies of the laboratory instrumentation. Refer to D5437.
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 record review and interview, the laboratory director failed to provide overall management and direction to ensure the laboratory was enrolled in proficiency testing under their CLIA Certificate of Compliance number. Findings include: The laboratory was unable to provide documentation of PT enrollment for Hillcrest Urgent Care. The interview with the laboratory director on 10/4/21 at 10:30 AM confirmed that Hillcrest Urgent Care had not enrolled in a separate proficiency testing program from the shared onsite accredited laboratory. Refer to D2000. .
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 interview the Laboratory Director failed to ensure quality control was performed prior to reporting patient test results and an effective quality control program was maintained since January 2021. Findings include: The laboratory was unable to provide documentation that quality control was performed with a separate quality control material than the shared laboratory (West Volusia Family and Sports Medicine) prior to performing testing on Hillcrest Urgent Care patient samples. The interview with the Office Manager on 10/4/21 at 10:30AM confirmed the laboratory did not perform quality control separate from West Volusia Family and Sports Medicine. Refer to D5441.
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 establish and follow a quality assurance program. Findings included: The laboratory was unable to provide a quality assessment policy to monitor, assess, and correct problems identified in pre-analytic, analytic, and post-analytic systems. Refer D5291, D5391, D5791, D5891 .
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 failed to ensure a personnel competency program was in place to evaluate staff competency. Findings include: The facility was unable to provide documentation of a competency program approved by the Laboratory Director and performed by a Technical Consultant for personnel performing laboratory testing. The interview with the Office Manager on 10 /4/21 at 10:30 am confirmed that no competency program with Technical Consultant over sight was in place for laboratory personnel. Refer to D5209. .
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 interview, the Laboratory Director failed to ensure the laboratory had a written procedure manual for hematology, chemistry, and immunology testing in the laboratory since January 2021. Findings: The laboratory was unable to provide a procedure manual. Findings include: The laboratory was unable to provide a procedure manual for all tests performed. White blood count, red blood count, hemoglobin, and hematocrit performed on the DXH 520 hematology analyzer. Glucose, creatinine, total protein, total bilirubin, albumin, calcium, alkaline phosphatase, aspartate aminotransferase, sodium, potassium, chloride, carbon dioxide, direct bilirubin, amylase, lipase, Microalbumin, and iron performed on the AU 480 chemistry analyzer. Hemoglobin A1C performed on the G8 analyzer. Thyroid stimulating hormone, free thyroid 4, free thyroid 3, antithyroid peroxidase, SARS Covid - 19 IgG, testosterone, prostate specific antigen, free prostate specific antigen, vitamin B12, vitamin D25, Folate, and Ferritin performed on the Access 2 analyzer. Interview on 10/4/21 at 10:30AM with the Office Manager confirmed that there were no policies or procedures for the aforementioned tests. He stated that Hillcrest Urgent Care does not maintain separate manuals, documentation, quality control records, or proficiency testing from the active accredited laboratory previously established (West

	Volusia Family and Sports Medicine 10D2184087) inside the building. Hillcrest Urgent Care has used the same instruments, manuals, reagents, and staff as West Volusia Family and Sports Medicine. Refer to D5401