

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2030182	(X3) Date Survey Completed 10/17/2025
Name of Provider or Supplier Caremed Clinic Llc	Street Address, City, State 4719 Highway 90, Marianna, 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 announced CLIA validation survey was conducted at Caremed Clinic LLC on 10 /16-17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 493.1205 Condition: Analytic Systems D6000 493.1403 Condition: Moderate Complexity Laboratory Director
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, the laboratory failed to have a policy that included imminently life-threatening test results, or panic or alert values, or a protocol for reporting these values (See D5403); failed to ensure that controls in the Specialty Hematology were labeled with open and expiration dates (See D5415); failed to ensure verification of performance specifications for multiple analytes and tests in the Subspecialties of General Chemistry, Endocrinology and Virology prior to patient testing. (See D5421); failed to ensure two levels of controls were performed and documented in the Subspecialty of Endocrinology (See D5447); and failed to failed to ensure positive and negative controls were performed and documented in the Subspecialty of Virology (See D5449).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have a policy that included imminently life-threatening test results, or panic or alert values, or a protocol for reporting these values. Findings Included: 1. Review of procedure manual (last reviewed by the Laboratory Director on 06/20/2025) revealed that there was no procedure that included imminently life-threatening test results, or panic or alert values, or a protocol for reporting these values. 2. Review of 2 of 2 Patient report revealed the following: a.) Patient #1 was tested for Complete Blood Count on 10/6 /2023 and had a 3.24 red cell count (RBC), 7.1 Hemoglobin (Hgb), and 23.8 Hematocrit (Hct) and was listed as an abnormal CBC. b.) Patient #2 was tested for Triglycerides on 7/22/2025 with a critical high of 755 for Triglycerides. 3. On 10/17 /2025 at 10:30 AM, the Technical Consultant confirmed no procedure for identifying, reporting, and identifying imminently life threatening results, or panic, or alert values and that both of the aforementioned Patients should have been identified as critical values.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on Record review and interview, the laboratory failed to ensure that controls in the Specialty Hematology were labeled with open and expiration dates for three out of three levels of complete blood count (CBC) controls prior to patient testing. Findings included: 1. On 10/16/2025 at 11:54 PM, The XN-L Check controls for the Sysmex hematology analyzer, levels 1, 2 and 3 (L1, L2, and L3) were in use with no open date

or expiration date written on the vials. 2. Review of insert for the XN-L Check Hematology control for Sysmex XN-L analyzers read, "open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees Celsius (C) after being recapped." 3. On 10/18/2025 at 3:00 PM, Testing Personnel #A confirmed there were no open and expiration dates written on hematology controls.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 failed to ensure verification of performance specifications for multiple analytes and tests in the Subspecialties of Endocrinology and Virology prior to patient testing Findings Included: 1. Review of the Laboratory's records of Verification of Performance Specifications of the Cepheid GeneXpert IV revealed there was no documentation of accuracy, precision and reportable ranges for Xpert Xpress Cov-2/Flu/RSV, Xpert Xpress MVP, Xpert Xpress CT/GC and Xpert Xpress Strep A with no signature indicating approval completed by the Laboratory Director. 2. Review of the laboratory's records of Verification of Performance Specifications Beckman Coulter Access 2 revealed there was no documentation of accuracy, precision and reportable range for sex hormone binding globulin(SHBG);documentation of accuracy and reportable ranges for follicle stimulating hormone, luteinizing hormone, Ferritin, Folate, Free Thyroxine (FT4), Prostate-Specific Antigen (PSA), Thyroid-Stimulating Hormone (TSH), testosterone (testo), and Vitamin B12 (VB12). There was no signature indicating approval from the Laboratory Director. 3. Review of laboratory management computer system revealed the following: a. 378 patients were tested for Chlamydia trachomatis from 1/1/2023 to 10/16/2025. b. 362 patients were tested for Neisseria gonorrhoeae from 1/1/2023 to 10/16/2025. c. 127 patients were tested for Bacterial vaginosis from 1/1/2023 to 10/16/2025. d. 82 patients were tested for Candida species from 1/1/2023 to 10/16/2025. e. 40 patients were tested for trichomoniasis from 1/1/2023 to 10/16/2025. f. 216 patients were tested for SARS-CoV-2, influenza A, influenza B, Respiratory syncytial virus from 1/1/2024 to 10/16/2025. g. 393 patients were tested for Strep A from 1/1/2024 to 10/16/2025 h. 23 patients were tested for Sex hormone binding globulin from 1/1/2024 to 10/16/2025 I. 121 patients were tested for Prostate-Specific Antigen from 1/1/2024 to 10/16/2025. J. 501 patients were tested for Ferritin from 1/1/2024 to 10/16/2025. 4. Review of Beckman Coulter Access 2 Patient Reports revealed the following: a. 2 Patients were tested for Ferritin on 8/22/2025. b. 2 Patients were tested for Ferritin on 8/28/2025. c. 2 Patients were tested for Ferritin on 9/5/2025. d. 2 Patients were tested for Ferritin on 9/25/2025. e. 1 Patient was tested for Folate on 8/22/2025. f. 1 Patient was tested for Folate on 8/28/2025. g. 1 Patient was tested for Folate on 9/18/2025. h. 1 Patient was tested for Folate on 9/24/2025. i. 1 Patient was tested for Folate on 9/25/2025. j. 1 Patient was tested for FT4 on 8/22/2025. k. 2 Patients were tested for FT4 on 8/28/2025. l. 2 Patients were tested for FT4

on 9/5/2025. m. 1 Patient was tested for PSA on 8/22/2025. n. 2 Patient was tested for PSA on 8/28/2025. o. 1 Patients were tested for Testo on 8/28/2025. p. 1 Patient was tested for Testo on 9/5/2025. q. 1 Patient was tested for Testo on 9/25/2025. r. 1 Patient was tested for TSH on 8/25/2025. s. 1 Patient was tested for TSH on 9/3/2025 t. 1 Patient was tested for TSH on 9/5/2025 u. 1 Patient was tested for TSH on 9/25/2025. v. 2 Patients were tested for VB12 on 8/22/2025. w. 1 Patient was tested for VB12 on 9/3/2025. x .2 Patient was tested for VB12 on 9/25/2025. 5. On 10/17/2025 at 5:06 PM , Laboratory Director , Testing Personnel #A ,Office Manager and Technical Consultant confirmed laboratory failed to complete performance specifications that included accuracy , precision, and reportable ranges for the above analytes or tests before Patient testing was performed.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on Record review and interview, the laboratory failed to ensure three levels of controls were performed and documented in the Subspecialty of Endocrinology for seven out of seven analytes (Ferritin, Folate , Free Thyroxine(FT4), Prostate-Specific Antigen (PSA), Thyroid-Stimulating Hormone(TSH), testosterone(testo), and Vitamin B12(VB12) on five of five days that Patient testing was performed. Findings Included: 1. Review of General Chemistry Controls on Beckman Coulter Access 2 revealed the following: A. Ferritin: a. Only Level 2 Ferritin controls were run on 8/22/2025 and 8/22/2025 b. No Ferritin controls were run on 9/5/2025 and 9/25/25. B. Folate: a. Only Level 2 Folate control was run on 8/22/2025. b. No Folate controls were run on 8/28/2025 ,9/18/2025, and 9/25/2025. c. Only Level 3 Folate control was run on 9/24/2025. C. PSA: a. Only Level 2 PSA control was run on 8/22/2025 b. No PSA controls were run on 8/28/2025 D. FT4: a. No FT4 controls were run on 8/22/2025,8/28/2025 and 9/5/2025 E. Testo: a. Only Level 2 Testo control was run on 8/22/2025. b. No testo controls were run on 9/5/2025 and 9/25/2025 E. TSH: a. No TSH controls were run on 8/28/2025,9/3/2025,9/5/2025, and 9/25/2025. F. VB12: a. No VB12 controls were run on 8/28/2025 ,9/3/2025, and 9/25/2025. 2. Review of Beckman Counter Access 2 patient Reports revealed the following 32 patients were tested and reported:: a. 2 Patients were tested for Ferritin on 8/22/2025. b. 2 Patients were tested for Ferritin on 8/28/2025. c. 2 Patients were tested for Ferritin on 9/5/2025. d. 2 Patients were tested for Ferritin on 9/25/2025. e. 1 Patient was tested for Folate on 8/22/2025. f. 1 Patient was tested for Folate on 8/28/2025. g. 1 Patient was tested for Folate on 9/18/2025. h. 1 Patient was tested for Folate on 9/24/2025. i. 1 Patient was tested for Folate on 9/25/2025. j. 1 Patient was tested for PSA on 8/22/2025. k. 2 Patient was tested for PSA on 8/28/2025. l. 1 Patient was tested for FT4 on 8/22/2025. m. 2 Patients were tested for FT4 on 8/28/2025. n. 2 Patients were tested for FT4 on 9/5/2025. o. 1 Patients was tested for Testo on 8/22/2025. p. 1 Patient was tested for Testo on 9/5/2025. q. 1 Patient was tested for Testo on 9/25/2025. r. 1 Patient was tested for TSH on 8/28/2025. s. 1 Patient was tested for TSH on 9/3/2025 t. 1 Patient was tested for TSH on 9/5/2025 u. 1 Patient was tested for TSH on 9/25/2025. v. 2 Patients were tested for VB12 on 8/28/2025. w. 1 Patient was tested for VB12 on 9/3/2025. x. 2 Patient was tested for VB12 on 9/25/2025. 3. Review of the General Laboratory Procedure signed by Laboratory Director on 06/20/2025 read, "All quality control must be documented daily by the performing technologist. review

	of QC will be performed monthly by the director or qualified designee." 4. Review of Access Hybritech free PSA Free Prostate-Specific Antigen Instructions for Use read, "Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period. 21 Include Access Hybritech free PSA QC or other commercially available quality control materials that cover at least two levels of analyte. Access Hybritech free PSA QC is provided with two sets of ranges." 5. On 10/17/2025 at 5:06 PM, the Laboratory Director, Testing Personnel #A, Office Manager and Technical Consultant confirmed three levels of controls were not run for Ferritin, Folate, FT4, PSA, TSH, Testo, and VB12 on 8/22/2025, 8/28/2025 ,9/3/2025, 9/5/2025, 9/15/2025,9/18/2025, 9/24/2025 and 9/25/2025 before Patient testing on Beckman Coulter Access 2.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run external positive and negative controls in the Subspecialty of Virology for Xpert Xpress SARS-CoV-2, influenza A, influenza B, Respiratory syncytial virus (Cov-2/Flu/RSV), Xpert Xpress Bacterial vaginosis, Vulvovaginal candidiasis, Candida group, C. glabrata/krusei, and trichomoniasis (MVP) , Xpert Xpress Chlamydia trachomatis and Neisseria gonorrhoeae (CT/GC) and Xpert Xpress Streptococcus pyogenes Group A Strep (Strep A) before Patient testing. Findings Included: 1. Review of Cepheid GeneXpert IV control records revealed no documentation for positive and negative controls run for Xpert Xpress Cov-2/Flu/RSV, Xpert Xpress MVP, Xpert Xpress CT/GC and Xpert Xpress Strep A for instrument in current use. 2. Review of Xpert Xpress MVP instructions for use read,"12.2 External Controls Use external control materials in accordance with local, state, federal regulations, and accreditation requirements." 3. Review of laboratory management computer system revealed the following: a. 378 patients were tested for Chlamydia trachomatis from 1/1/2023 to 10/16/2025. b. 362 patients were tested for Neisseria gonorrhoeae from 1/1/2023 to 10/16/2025. c. 127 patients were tested for Bacterial vaginosis from 1/1/2023 to 10/16/2025. d. 82 patients were tested for Candida species from 1/1/2023 to 10/16/2025. e. 40 patients were tested for trichomoniasis from 1/1/2023 to 10/16/2025. f. 216 patients were tested for SARS-CoV-2, influenza A, influenza B, Respiratory syncytial virus from 1/1/2024 to 10/16/2025. g. 393 patients were tested for Strep A from 1/1/2024 to 10/16/2025 4. On 10/17/2025 at 5:06 PM, the Laboratory Director,Testing Personnel #A, Office Manager and Technical Consultant confirmed no positive and negative controls run on Xpert Xpress Cov-2/Flu/RSV, Xpert Xpress MVP, Xpert Xpress CT/GC and Xpert Xpress Strep A.
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 interview, the laboratory director failed to provide overall management and direction to ensure the laboratory had a policy that included imminently life-threatening test results, or panic or alert values, or a protocol for reporting these values(D6030); failed to ensure that controls in the Specialty Hematology were labeled with open and expiration dates; failed to ensure verification of performance specifications for multiple analytes and tests in the Subspecialties of Routine Chemistry, Endocrinology, and Virology prior to Patient testing (D6013); failed to ensure two levels of controls were performed and documented in the Subspecialty of Endocrinology; and failed to ensure positive and negative controls were performed and documented in the Subspecialty of Virology (D6020).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure verification of performance specifications for multiple analytes and tests in the Subspecialties of Endocrinology and Virology prior to patient testing. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the Laboratory Director failed to ensure that controls in the Specialty Hematology were labeled with open and expiration dates (See D5415); failed to ensure two levels of controls were performed and documented in the Subspecialty of Endocrinology (See D5447); and failed to failed to ensure positive and negative controls were performed and documented in the Subspecialty of Virology (See D5449).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 interview, the laboratory director failed to ensure that the laboratory had a policy that included imminently life-threatening test results, or panic or alert values, or a protocol for reporting these values. (See D5403)