Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2231439	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ezmed Urgent Care	2219 York Road Suite 106, Timonium, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" (CMS-116) and interview with the testing personnel, the laboratory failed to enroll in an approved proficiency testing (PT) program for Trichomonas vaginalis (TV), Chlamydia trachomatis (CT), and Neisseria gonorrhea (NG) performed on the Cepheid GeneXpert analyzer. Findings: 1. The laboratory listed the following on the CMS-116 under "Section VII. Non-Waived Testing": Analyte/Test Test Name Manufacturer M or H TV TV Cepheid M CT/NG CT/NG Cepheid M 2. On 07/22/2022 at 12:10 PM, the testing person was contacted and confirmed that the laboratory was not enrolled in an approved PT program for TV and CT/NG using the Cepheid analyzer. The cumulative effect of this problem has the potential to result in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which

	it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the testing personnel (TP), the laboratory failed to enroll in an approved proficiency testing (PT) program during 2021 and 2022 to verify the accuracy of the trichomonas vaginalis (TV), chlamydia trachomatis (CT), and neisseria gonorrhea (NG) performed on the Cepheid GeneXpert analyzer. Findings: 1. To meet the PT requirements, the laboratory is required to be enrolled in an approved PT program when performing moderate complexity patient testing. 2. During the exit survey 08/02/2022 at 2:45 PM, the TP confirmed that the laboratory was not enrolled in the appropriate PT modules for testing 2021 and 2022 to ensure the accuracy and reliability of patient test results.
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 interview with the testing personnel (TP), the laboratory did not establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413(b)(8) through (9): Findings: 1. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 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; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 2. Evaluations must be performed at six months and annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 3. During the survey on 07/07/2022 at 2:45 PM, TP provided a "Quality Management Plan" that did not include a written training program along with worksheets for the documentation of the training of the TP who perform pre-analytic, analytical and post analytic procedures.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with the testing person (TP), the laboratory did not have written policies and procedures for providing the medical staff with an interim paper patient report. Findings: 1. According to the TP the patient test results are provided to the medical staff on a sheet of paper and are available in the electronic medical records. 2. During the survey on 07/07/22 at 2:45 PM, the TP confirmed that the procedure manuals did not have written policies and procedures for providing the medical staff with an interim paper patient report.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the testing personnel (TP), the laboratory failed to provide the testing personnel with approved policies and procedures for tests performed on the Cepheid GeneXpert analyzer. Findings: 1. The testing personnel provided several binders with instructions for performing tests on the Cepheid GeneXpert analyzer that were not approved by the laboratory director (LD). The validation studies were initialed and dated by the lead testing person. The document failed to have a signature and approval date showing that the procedure had been approved by the current LD. 2. During the exit survey on 08/02/2022 at 2:45 PM, the TP confirmed that the procedure manual did not contain the required signature and date of approval by the current LD.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the interim paper patient report, the electronic medical record (EMR), and interview with the testing person (TP), the laboratory did not ensure that the interim paper patient report and EMR, included the name of the laboratory listed on the CLIA certificate being surveyed. Findings: 1. The laboratory staff provide the medical staff with an interim paper patient report with the test results from the Cepheid GeneXpert analyzer. The results are also entered into the EMR via an interface with the Cepheid GeneXpert analyzer. 2. The name of the laboratory listed on the CLIA certificate is "Care Solution, LLC" and the name on the interim paper patient report and EMR is "EZMED Urgent Care." 3. During the survey on 07/07 /2022 at 2:450 PM, the TP confirmed that the interim paper patient report and EMR did not include the name of the laboratory listed on the CLIA certificate being surveyed.
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 with the testing personnel, the laboratory director failed to ensure that the laboratory was enrolled in an approved proficiency testing program for moderately complex testing performed at the laboratory. Cross refer to D2000 for details.
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 procedure manual and interview with the testing personnel (TP), the laboratory director did not ensure that the quality management plan was

	implemented to assure the quality of the laboratory services. Findings: 1. The testing personnel provided the surveyor with a quality assessment (QA) program titled "EZMed Timonium Lab Quality Management Plan" and stated that this was the QA program for the laboratory being surveyed. The name on the CLIA certificate in "Care Solution, LLC." The procedure manuals did not have the correct name of the laboratory listed. 2. Number 4 of the "EZMed Timonium Lab Quality Management Plan" states that "Initial evaluation on all laboratory personnel will be conducted at the completion of the 90-day probation period for all new staff followed by annual performance evaluation." According to the TP, the laboratory started performing and reporting test results on May 12, 2021. The only records available showed the initial training of the TP. There was no documentation of a 90-day and annual evaluation of the TP working in the laboratory. Cross refer to Tag D5209. 3. Number 6 of the "EZMed Timonium Lab Quality Management Plan" states that "all testing records on the GeneXpert and Abbott ID Now are stored electronically on a flash drive or hard drive." There were no instructions for how to download the data electronically and where to store the flash drive and how to download the data to the hard drive. 4. Number 7 of the "EZMed Timonium Lab Quality Management Plan" states "Each month, random patient chart quality assurance checks will be performed to ensure that the lab results are being properly input into the patient chart. This will be reviewed by the lab director or designee." There was no documentation available at the time of the survey showing that this review was being performed. 5. Number 9 of the "EZMed Timonium Lab Quality Management Plan" states "EZMed Timonium will maintain continuous enrollment in an approved Proficiency Testing program." On 07/22/2022 at 12:10 PM, the testing person was contacted and confirmed that the laboratory was not enrolled in an approved PT program for moderately complex tests performed at the laboratory. See Tag D2000 for details. 6. The laboratory's QA program failed to include a system for the TP to document and communicate the status of the laboratory with the technical consultant (TC) and laboratory director (LD). The QA program failed to include a system for the TC and LD to communicate with the TP. (Please note: The QA program must include, but is not limited to the following: patient test management, testing methods, quality control, proficiency testing, comparison of test results, relationship of patient information to patient test results, personnel assessment, communication, complaint investigation and quality assessment reviews.) 7. According to Tag D5407 "Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use." The person who "Reviewed and approved" the procedure was not the current LD. 8. During the exit survey on 08/02/22 at 3:15 PM, the TP confirmed that the QA procedures failed to include additional written instructions for all QA activities.
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 review of the procedure manual and interview with the testing person (TP), the laboratory director (LD) failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: 1. During the survey on 07/07 /22 the TP provided the surveyor with three sheets of paper listing the duties for the "Testing Personnel", "Technical Consultant", and "Technical Supervisor/Technical Consultant Delegation." 2. The sheet of paper listed the name of the laboratory as "Small Point Urgent Care, PC." The name on the CLIA certificate of registration is "Care Solution, LLC." 3. The "Testing Personnel" duties that were listed on the sheet of paper were the duties of a General Supervisor, which is not appropriate for testing personnel performing moderately complex testing. 4. The "Technical Consultant" duties that were listed on the sheet of paper referred to the CLIA Technical Supervisor duties- 42 CFR 493.1451, which are not appropriate for moderate complexity testing. The personnel listed at the bottom of the were not qualified as technical consultants. 5. The "Technical Supervisor/Technical Consultant Delegation" duties that were listed on the sheet of paper referred to CLIA 42 CFR 493.1451 (technical supervisor) and 42 CFR 493.1429 (clinical consultant). The laboratory is not performing high complexity testing and the person listed at the bottom of the page is not qualified as a clinical consultant. 6. The "Laboratory Personnel Report (CLIA)" (CMS-209) form provided on 07/07/22, showed that the same person was listed as the technical supervisor (TS) and technical consultant (TC). The laboratory is only performing moderately complex tests, therefore, they do not need a technical supervisor. The sheet of paper labeled "Technical Consultant" did not list the same name that was listed on the CMS-209 as the TC. The three people listed on the sheet of paper labeled "Technical Consultant" were not listed on the CMS-209 as TC. 7. During the survey on 07/07/22 at 2:45 PM, the TP confirmed that there were no other written duties and responsibilities provided by the LD for "Care Solution, LLC."
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with the testing personnel (TP), the technical consultant (TC) failed to ensure that scientific oversight was provided on a monthly basis as defined on the sheet of paper labeled "Technical Consultant Delegation." Findings: During the survey on 07/07/22 at 2:45 PM, the TP confirmed that the laboratory records did not include documentation showing that the TC was reviewing laboratory and quality control records on a monthly basis to ensure that the testing personnel were performing the tests accurately and documenting the required information.