Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2231439	02/26/2026
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 and interview with the laboratory director (LD), the testing personnel (TP) failed to sign forms attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods in three of five PT events reviewed. Findings: 1. Records for five PT events were reviewed (2024 1st - 3rd and 2025 1st - 2nd events). 2. The laboratory performed PT for bacteriology and beginning in the 2024 3rd event routine chemistry. 3. The attestation forms were signed by the LD but not the TP for the following events: a. 2024 3rd event for bacteriology b. 2025 1st event for bacteriology and routine chemistry c. 2025 2nd event for routine chemistry 4. The attestation forms for the 2025 2nd bacteriology event were missing. 5. During the exit interview on 02/26 /2026 at 1:45 PM, the LD confirmed that the TP didn't sign the forms attesting to the routine integration of PT samples into the patient workload in three out of five PT events.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to verify accuracy of group C/G Streptococcus at least twice annually in 2024 and 2025. Findings: 1. The laboratory performed the Quidel Solana Strep Complete assay which included detection of group A and group C /G Streptococcus species. 2. At 1:00 PM on 02/26/2026 the LD stated that the PT provider didn't offer detection of group C/G Streptococcus species during the 2024 events. 3. There was no documentation that the laboratory verified the accuracy of group C/G Streptococcus species at least twice in 2024. 4. The PT provider began offering PT for the full Solana Strep Complete assay in 2025. 5. The laboratory did not report results to the PT provider for group C/G Streptococcus species in the 2025 2nd event because there was an issue with the assay and did not submit results to the PT provider for the 2025 3rd event. 6. The Solana Strep Complete assay was used to report patient results until 02/16/2026 and results from at least two patients were reported after the 2025 2nd event: accession number 601311 on 06/24/2025 and accession number 608328 on 07/14/2025. 7. There was no documentation that the accuracy of group C/G Streptococcus species was verified a 2nd time in 2025 (results were submitted for the 2025 1st event). 8. During the exit interview on 02/26/2026 at 1:45 PM, the LD confirmed that the accuracy for group C/G Streptococcus species on the Solana Strep Complete assay was not verified at least twice annually in 2024 and 2025.
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 review of instrument verification records and interview with the laboratory director (LD), the laboratory failed to demonstrate that performance specifications for the Quidel Triage Cardiac Panel and D-Dimer assays were comparable to those established by the manufacturer for accuracy, precision and reportable range. Findings: 1. The laboratory performed testing with the Quidel Triage Cardiac Panel and D-dimer assays from 05/04/2024-09/28/2025. 2. Installation and verification records showed that five calibration levels were run in duplicate. There was no additional verification data. 3. There was no verification procedure available and no summary that detailed what the manufacturer's performance specifications were for accuracy and precision and whether the laboratory obtained comparable results. 4. The following measurable ranges were reported by the manufacturer: a. Creatine kinase MB: 1.0-80 ng/mL b. Myoglobin: 5.0-500 ng/mL c. Troponin I: 0.05-30 ng/mL d. D-dimer: 100-5,000 ng/mL 5. The five calibrators that were tested reported the following values: a. Creatine kinase MB: 2.3-75.7 ng/mL b. Myoglobin: 40.6-331 ng /mL c. Troponin I: 0.1-25.2 ng/mL d. D-dimer: 248-3,960 ng/mL 6. There was no acceptability criteria defined for how close to the minimum and maximum values of the measurable range must be tested to ensure that the instrument met the manufacturer's stated ranges. 7. During the exit interview on 02/26/2026 at 1:45 PM,

	the LD confirmed that there was no documentation demonstrating that the laboratory's performance specifications for accuracy, precision, and reportable range were comparable to those established by the manufacturer.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of temperature records, and interview with the laboratory director (LD), the laboratory failed to document corrective actions taken when temperature and humidity values were outside of acceptable ranges in six of 22 months reviewed. Findings: 1. The laboratory's Quality Assurance Plan stated that "If at any point, the temperature of the refrigerator, freezer, room, or the humidity of the room is out of range, ensure that no objects are blocking the thermometer, and that the thermometer is placed correctly (ex. Not on the refrigerator door), and wait half an hour and recheck before recording. If the temperatures are out of range, report directly to the lead MA, clinical manager, or laboratory director." 2. Temperature records from 03/2024-12/2025 were reviewed (22 months). 3. Refrigerator temperatures were documented outside acceptable range on 1 of 26 days recorded in 01/2025 and 2 of 23 days recorded in 02/2025. 4. Room temperatures were documented outside acceptable range on 1 of 26 days recorded in 01/2025, 1 of 23 days recorded in 02/2025, 3 of 24 days recorded in 03/2025, 2 of 27 days recorded in 07/2025, 3 of 24 days recorded in 10/2025, and 17 of 27 days recorded in 12/2025. 5. Humidity was documented outside acceptable range on 4 of 26 days recorded in 01/2025. 6. No corrective actions were documented for any of the out-of-range values. 7. During the exit interview on 02/26/2026 at 1:45 PM, the LD confirmed that corrective actions were not documented when temperature and humidity values were recorded outside acceptable ranges.
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 review of verification records and interview with the laboratory director (LD), the LD failed to ensure that there were procedures for performing verification for the Quidel Triage Cardiac Panel and D-dimer assays and failed to ensure that the laboratory performance specifications for precision, accuracy, and reportable range were comparable to the manufacturer's. Cross-refer to tag D5421.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD), the LD failed to ensure unacceptable PT results were investigated to identify problems that required corrective action in three of five PT events reviewed. Findings. 1. The laboratory did not have a procedure for performing and evaluating PT samples. The Internalized Quality Control Plan for the Solana Complete Strep assay stated: a. "Proficiency testing results reviewed and mediated ASAP as required" b. "Unexpected errors investigated ASAP and remediated" c. "In the event of unexpected results or errors with the Solana instrument, all patient testing must be suspended immediately" 2. Records for five PT events were reviewed (2024 1st - 3rd and 2025 1st - 2nd events). 3. The laboratory received scores of 80% for group A Streptococcus in three out of five events reviewed (2024 1st, 2024 2nd, and 2025 2nd). Three of 15 PT samples were reported positive when the expected result was negative. There was no investigation to identify if corrective actions were required for the false positive PT results or if patient results could have been affected. 4. The laboratory received scores of 60% for creatine kinase MB (CK-MB) and troponin I in the 2025 2nd event. It was documented that PT sample 5 was misplaced and the PT provider not notified, but there was no further investigation into the unacceptable results for PT sample 1 for CK-MB and PT sample 3 for troponin I. 5. During the exit interview on 02/26/2026 at 1:45 PM, the LD confirmed that there were no investigations into unacceptable PT results to determine if corrective actions were required or patient results potentially affected.
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 review of the procedure manual and interview with the laboratory director (LD), the LD failed to ensure that temperature and humidity logs were reviewed monthly as stated in the Quality Assurance Plan (QA Plan). Findings: 1. The QA Plan stated that "All temperature and humidity logs are reviewed monthly by the lab director (or lab designee) for approval to ensure that all recorded temperatures and humidity percentages are within normal range." 2. Temperature logs showed that the LD or designee did not review the logs monthly as stated in the QA Plan. a. Logs from 09/2024 were reviewed on 11/04/2024 b. Logs from 02/2025-03/2025 were reviewed on 04/25/2025 c. Logs from 04/2025-05/2025 were reviewed on 07/09/2025 d. Logs from 07/2025 were reviewed on 09/12/2025 e. Logs from 09/2025-11/2025 were reviewed on 12/28/2025 3. The laboratory did not document corrective actions for temperature and humidity values that were outside acceptable range. Cross-refer to tag D5785. 4. During the exit interview on 02/26/2026 at 1:45 PM, the LD confirmed that the temperature records were not reviewed monthly by the LD or designee as stated in the QA plan and there were no corrective actions documented for out-of-range temperature and humidity values.