

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2231439	(X3) Date Survey Completed 03/01/2024
Name of Provider or Supplier Ezmed Urgent Care	Street Address, City, State 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel report, review of proficiency testing (PT) records, and interview with the clinical coordinator (CC), the laboratory failed to ensure that PT was performed by all testing personnel (TP) who routinely performed patient testing. Findings: 1. The Laboratory Personnel Report (form CMS-209) listed eight TP. 2. Attestation forms for four PT events from 2022 through 2023 were reviewed. 3. The attestation forms from the 2022 3rd event showed that TP #1 and TP #2 performed PT testing and from all three 2023 events showed that TP #1 performed PT testing. 4. During the exit interview on 02/28/2024 at 4:00 PM, the CC confirmed that PT testing was not performed by all TP who routinely tested patient specimens.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the competency procedure and interview with the clinical coordinator (CC), the laboratory failed to ensure that a competency assessment was performed for the technical consultant (TC) in their regular and delegated</p>

	<p>responsibilities. Findings: 1. The procedure titled "Laboratory Personnel Competency Assessment Program" stated "The LD [laboratory director] will perform a competency assessment of the individual serving as the TC, TS [technical supervisor], and/or GS [general supervisor] based on their regulatory responsibilities." 2. The laboratory's TC performed the responsibilities of a TC in addition to LD responsibilities that were delegated by the LD. 3. During the exit interview on 02/28/2024 at 4:00 PM, the CC confirmed that a competency assessment was not performed by the LD for the TC based on the TC's regular and delegated responsibilities.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and email communication with the clinical coordinator (CC), the laboratory did not have documentation that the PT results were reviewed and evaluated for three of four PT events reviewed. Findings: 1. Records for four PT events from 2022 through 2023 were reviewed. 2. The results evaluations provided by the PT provider were present and signed as reviewed by the technical consultant (TC) for the 2023 1st PT event. There were no signed PT results evaluations present for the 2022 3rd or 2023 2nd and 3rd PT events. 3. At 4:06 PM on 03/01/2024, the CC emailed the available PT documents that were scanned by the TC. The documents did not contain the signed PT results evaluations from the 2022 3rd or 2023 2nd and 3rd PT events.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM) and interview with the clinical coordinator (CC), the laboratory's SOPM did not have an approved procedure for performing the Quidel Solana Strep Complete assay. Findings: 1. The laboratory began testing patient specimens using the Quidel Solana Strep Complete test system in August 2023. 2. The SOPM did not include an approved procedure detailing how to perform the Solana Strep Complete testing. 3. During the exit interview on 02/28/2024 at 4:00 PM, the CC confirmed that an approved copy of the Solana Strep Complete testing procedure was not part of the laboratory's SOPM.</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

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 the verification documentation and interview with the clinical coordinator (CC), the laboratory failed to document whether they could obtain performance specifications comparable to those established by the manufacturer for the Quidel Solana Strep Complete test system. Findings: 1. The laboratory began testing patient specimens using the Quidel Solana Strep Complete test system in August 2023. 2. Verification documentation included instructions for performing the "Quidel Molecular Direct Strep Training Panel for Lyra Direct and Solana" which stated was "intended to be used to assist in the training process for Quidel Molecular Direct Assays (Lyra Direct and Solana) for the qualitative detection of Streptococcus pyogenes and Streptococcus dysgalactiae. The panel set consists of twenty-four contrived throat swab specimens that have been spiked with one of two concentrations of Streptococcus pyogenes and Streptococcus dysgalactiae or with negative media." 3. Included in the documentation was the "Quidel Molecular Direct Strep Panel Answer Key" that provided the expected results for the twenty-four contrived throat swab specimens. 4. There was no procedure defining how to compare performance specifications with those established by the manufacturer, including the acceptability criteria, and there was no documentation that the laboratory's results were evaluated against the expected results to confirm that the assay's accuracy and precision met the defined acceptability criteria and the assay was cleared to use for patient testing. 5. During the exit interview on 02/28/2024 at 4:15 PM, the CC confirmed that there was no documentation that the results from the Quidel Molecular Direct Strep Training Panel were evaluated to determine whether performance specifications were comparable with those established by the manufacturer.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the individualized quality control plan (IQCP), the procedure manual, and quality control (QC) records and interview with the clinical coordinator (CC), the laboratory failed to include a quality control plan (QCP) plan in their IQCP and failed to perform QC for the Solana Strep Complete assay with the frequency defined in their quality management plan. Findings: 1. The laboratory is required to test two levels of QC materials each day of testing unless they have written an IQCP. An IQCP includes three components: 1) the risk assessment (RA) which identifies and evaluates potential problems or errors that may occur in the testing process, 2) the quality control plan (QCP) which at least includes the number, type and frequency of testing and criteria for acceptable result(s) of the quality control, and 3) the quality

assessment (QA) which is the continuous process of monitoring the effectiveness of the QCP. 2. The "Laboratory Order Change (Strep A/C/G Testing)" procedure stated "Please note that as of 10/01/2023, Ezmed Timonium will begin to implement the moderate complexity Solana Strep A and C/G assay testing. External quality controls will be performed according to our established IQCP." 3. The laboratory's IQCP only included the RA component and not the QCP and QA components. 4. Though the IQCP did not have the QCP component, the "EZMED UC AKA Care Solution LLC (CLIA 21D2231439) Lab Quality Management Plan" (quality management plan) stated that "2. Systems that will be evaluated include the pre-analytical phase, analytical phase, and post-analytical phase. The relevant tests that will be covered in these system evaluations include Strep Complete panels and TV performed on the Solana" and "External quality controls for Solana laboratory tests listed above in part 2 will be run once every 31 days, every new lot, or every new user, whichever is more frequent, in accordance with the manufacturer's recommendations and the laboratory's approved IQCP." 5. Records showed that QC was run on 06/22/2023, 07/06/2023, and 07/18/2023 for lot number 234724, 09/28/2023 for lot number 240290, and 02/27/2024 for lot number 243386. All QC results were signed by the same testing person. 6. During the exit interview on 02/28/2024 at 4:15 PM, the CC confirmed that the laboratory was not performing external QC for the Solana Strep Complete assay once every 31 days, every new lot, or every new user (whichever was more frequent) as required in their quality management plan.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 temperature records and interview with the clinical coordinator (CC), the laboratory failed to document corrective actions when room temperature, relative humidity, and refrigerator temperatures were out of acceptable range in 13 of 17 months reviewed. Findings: 1. The laboratory recorded room temperature, relative humidity, and refrigerator temperature on a single "Temperature Log" which included the acceptable ranges for each. 2. Temperature logs were reviewed from 09/2022-01/2024. 3. Room temperature was documented as out of acceptable range for 2 of 25 days recorded in 09/2022, 3 of 26 days recorded in 11/2022, 7 of 26 days recorded in 12/2022, 1 of 26 days recorded in 10/2023 and 11/2023, and 5 of 26 days recorded in 01/2024. 4. Relative humidity was documented as out of acceptable range for 3 of 26 days recorded in 11/2022, 7 of 26 days recorded in 12/2022, 2 of 27 days recorded in 01/2023, 3 of 24 days recorded in 02/2023, 7 of 27 days recorded in 03/2023, 1 of 26 days recorded in 11/2023, 5 of 26 days recorded in 12/2023, and 7 of 26 days recorded in 01/2024. 5. Refrigerator temperature was documented as out of acceptable range for 3 of 24 days recorded in 02/2023, 1 of 24 days recorded in 04/2023, 2 of 26 days recorded in 06/2023, 2 of 25 days recorded in 07/2023, 4 of 26 days recorded in 10/2023, 10 of 26 days recorded in 11/2023, 12 of 26 days recorded in 12/2023, and 11 of 26 days recorded in 01/2024. 6. There were no corrective actions documented for any of the out of range values listed above. 7. During the exit interview on 02/28/2024 at 4:15 PM, the CC confirmed that corrective actions were not documented when temperature and humidity values were found to be out of acceptable range.

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, laboratory logs, and proficiency testing (PT) records, and interview with the clinical coordinator (CC), the laboratory director (LD) failed to document quality assessment activities that were defined in the laboratory's procedures. Findings: 1. The procedure titled "EZMED UC AKA Care Solution LLC Communication Plan with Lab Director and Testing Personnel" (communication plan) stated "At the end of each month, the lead TP must email the LD all of the updated logs including the QC logs, temperature and humidity logs, and chart review logs. These logs will be reviewed by the LD and e-signed by the LD." 2. The communication plan also stated "PT results will be automatically reported to the state/CLIA and then forwarded to the LD for review and approval. All PT results must be reviewed, approved, and signed by the LD." 3. The "EZMED UC AKA Care Solution LLC (CLIA 21D2231439) Lab Quality Management Plan" (quality management plan) stated "All communications with the lab director will be done through our email chain and saved into a folder for future reference. If documents need to be reviewed by the lab director, he will electronically sign and have the designee physically sign and date on his behalf. The designee will leave a note specifying that the lab director has electronically signed everything. Alternatively, the laboratory director may visit the lab to perform in-person review of all required documents, which will take the place of the email communication." 4. The quality management plan also stated that "PT will be reviewed by the laboratory director." 5. The PT results evaluations were not signed as reviewed by the LD (cross-refer to tag D5211 for details). 6. There were no records that the LD electronically or manually signed the QC logs, temperature and humidity logs, and chart review logs. 7. During an interview on 02/28/2024 at 3:49 PM, the CC confirmed that the LD received the emails, but did not electronically sign the documents indicating that they were reviewed by the LD. The CC also stated that the LD was onsite at the laboratory on 01/02/2024 and was available by phone when there were issues, but that there was no documentation of the LD's site visits or telephone communications.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the clinical coordinator (CC), the technical consultant failed to ensure that the six-month competency assessment was performed on time for testing personnel (TP) #4.

Findings: 1. The Laboratory Personnel Report (form CMS-209) listed eight TP. 2. Initial training for TP #4 was documented as completed on 07/09/2023 and there were no records for a six-month competency assessment around 01/2024. 3. During an interview on 02/28/2024 at 12:15 PM, the CC confirmed that the six-month competency evaluation for TP #4 was overdue.