Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2011485	09/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Um Shore Emergency Center At Queenstown	115 Shore Way Dr, Queenstown, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory failed to document a self-evaluation of PT scores that were not graded by the PT provider. Findings: 1. Gram stain PT sample GS-05 was not graded in the 2022 1st Microbiology PT event. 2. Oxycodone PT sample UDS-04 was not graded in the 2022 2nd Chemistry - Miscellaneous PT event. 3. Vaginal wet preparation PT sample VA-02 was not graded in the 2022 2nd Hematology /Coagulation PT event. 4. Blood cell identification PT samples ECI-02 and ECI-05 were not graded in the 2023 1st Hematology/Coagulation PT event. 5. There was no documentation that the laboratory's results for the above PT samples were compared with the results listed in the PT provider's data summary to verify accuracy. 6. During the survey on 09/15/2023 at 5:45 PM, the TP confirmed that there was no documentation that ungraded PT results were self-evaluated.
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 review of the validation data and interview with the testing person (TP), the laboratory failed to have an approved procedure defining the step-by-step instructions for the validation of the Roche cobas e411 (endocrinology analyzer) and Roche cobas c311 (chemistry analyzer). Findings: 1. For establishment of performance specifications, the laboratory provided instrument printouts with raw data for accuracy, precision, reportable range, and normal patient values as their validation documentation for the Roche cobas e411 and Roche cobas c311. 2. There were no written policies or procedures that explained what samples were used for each of the validation printouts, the step-by-step instructions on how the validation was performed, nor the acceptance criteria to determine if the assay validation data provided acceptable results. 3. During the validation survey on 09/15/2023 at 5:45 PM, the TP confirmed that the laboratory did not have written procedures defining how to perform the validation and approve the results.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the testing personnel (TP), the laboratory failed to document what corrective actions were taken when weekly QC results were unacceptable. Findings: 1. The laboratory had an individualized quality control plan to perform two levels (levels 1 and 3) of external quality control for the Abbott i-STAT instrument on a weekly basis. 2. The laboratory documented corrective actions taken when QC failed on a pink log titled "QC Corrective Action" (QC log). The QC log included columns to record the date, time, instrument, and QC cartridge type when QC failed as well as what corrective actions were taken. There was a section at the bottom of the log to document monthly review. 3. A summary of the weekly QC results was documented on a white log titled

	"Weekly Abbott QC" (weekly log). The weekly log included columns to document the cartridge type, lot number and expiration date, and whether the two levels of QC passed for each of the two i-STAT instruments in use. 4. On 01/03/2022, the QC log showed that level 1 QC failed for the CG4+ cartridge on the i-STAT instrument "C". There was no documentation of any corrective actions taken. The QC log stated that "level 1 failed 2X Instrument C not in use for patient samples on 1-3-22." The weekly log stated "Level 1 failed X2. Instrument 'C' not in use for patients" but indicated that QC passed for level 1 of CG4+ on instrument "C" on 01/09/2022. 5. There was no documentation on either log of what corrective actions were taken to bring QC back into range, when patient testing resumed on instrument "C", and whether any patients tested the week prior to 01/03/2022 were adversely affected. The QC log was reviewed by the laboratory director on 02/10/2022 and the weekly log was reviewed by the laboratory director on 03/03/2022 and another individual on 02/02/2022. 6. During the survey on 09/15/2023 at 5:45 PM, the TP confirmed that on 01/03/2022, level 1 QC for the CG4+ cartridge on instrument "C" failed and there was no documentation of what corrective actions were taken or whether patients results from the pervious week were reviewed to ensure they were not adversely affected.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the validation records for the Roche cobas e411 (endocrinology analyzer) and Roche cobas c311 (chemistry analyzer), and interview with the testing personnel (TP), the laboratory director (LD) failed to ensure that the laboratory had an approved procedure for the validation of the new chemistry analyzers, "CalCheck" package insert for "alternative verifier" and that any failures found during the validation were followed up with documentation of the investigation to determine that the validation was acceptable. Findings: 1. The "Alternate (Quantitative) Method Comparison" summary for Digoxin showed that 3 of 17 specimens failed to meet the acceptable bias criteria. There was no validation procedure defining the acceptable bias criteria and how many specimens could fail and the validation would still be acceptable. 2. The linearity summary for "proBNP" (Brain natriuretic peptide) indicated that "The results are NON-LINEAR." This comment was circled on the summary and accepted by the LD on 11/14/2022. The TP stated that the LD had contacted the manufacturer and an "alternative verifier" was tested. These documents were part of the validation packet but were not identified as alternative verifiers. The summary worksheet included this statement: "Process samples according to the instructions in the corresponding CalChek package insert." There was no validation procedure defining how to evaluate the linearity and the CalChek package insert was not available for review. 3. The linearity summary for "proBNPX" (Brain natriuretic peptide) indicated that "The results are NON-LINEAR." This comment was circled on the summary and there was no signature and date of approval by the LD. The TP stated that the LD had contacted the manufacturer and an "alternative verifier" was tested. These documents were part of the validation packet but were not identified as alternative verifiers. The summary worksheet included this statement: "Process samples according to the instructions in the corresponding CalChek package insert."

	There was no validation procedure defining how to evaluate the linearity and the CalChek package insert was not available for review. 4. During the validation survey on 09/15/2023 at 5:45 PM, the TP confirmed that the validation procedures were not available at the time of the survey.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 the performance evaluation records and interview with the testing person (TP), the technical consultant (TC) failed to ensure that the semiannual performances were performed. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209 form) listed ten TP. Two of the ten TP listed had not had the semiannual performance evaluation performed. 2. TP#2 and TP#9 from the CMS-209 form had their initial training documented on 2/2023. At the time of the survey the semiannual performance evaluation had not been documented. 3. During the validation survey on 09/15/2023 at 5:45 PM, the TP confirmed that the semiannual performance evaluation had not been performed.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the "Carryover Evaluation" policy, carryover worksheets and interview with the testing person (TP), the general supervisor (GS) failed to ensure that once the Roche cobas e411 (endocrinology analyzer) and Roche cobas c311 (chemistry analyzer) were validated and reporting patient test results that they carryover evaluation continued to be performed. Findings: 1. The "Carryover Evaluation" policy states "Carryover studies are performed every 6 months on instruments that do not use disposable tips." 2. The carryover worksheets show that the last time a carryover study was performed was on 12/01/22 for the old chemistry analyzers. 3. The Roche cobas e411 was used for patient testing in November 2022 and the Roche cobas e311 was used for patient testing in January 2023. At the time of the survey on 09/15/2023 both analyzers were overdue for the performance of the carryover study. 3. During the validation survey on 09/15/2023 at 5:45 PM, the TP confirmed that the laboratory carryover studies had not been performed at the required 6 month interval.