Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2082356	03/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Xyz Medical, Llc	104 W Ohio St, Ste 200, Coalgate, OK	

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	The recertification survey was performed on 03/23,24/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, testing person, and laboratory assistant at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director and testing person failed to sign a proficiency testing attestation statement for one of three SARS-CoV-2 Molecular proficiency testing events reviewed in 2022. Findings include: (1) On 03/23/2023 a review of SARS-CoV-2 Molecular proficiency testing records for 2022 identified the following for one of three events: (a) Second COV2-B 2022 Event - The attestation statement had not been signed by the laboratory director and the testing person. (2) The findings were reviewed with the laboratory manager who stated on 03/23/2023 01:25 pm the attestation statement had not been signed by the laboratory director and testing person.

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 a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of three MRS5M (Methicillin-Resistant Staphylococcus aureus Screen, Molecular) events reviewed. Findings include: (1) On 03/23/2024 a review of MRS5M proficiency testing records for 2022 identified the following for three of three events: (a) First 2022 Event - Five of five results had not been graded by the proficiency testing program (samples MRSM-01, MRSM-02, MRSM-03, MRSM-04, MRSM-05). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results; (b) Second 2022 Event - Five of five results had not been graded by the proficiency testing program (samples MRSM-06, MRSM-07, MRSM-08, MRSM-09, MRSM-10). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results; (c) Third 2022 Event - Five of five results had not been graded by the proficiency testing program (samples MRSM-11, MRSM-12, MRSM-13, MRSM-14, MRSM-15). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded results; (2) The records were reviewed with the laboratory manager who stated on 03/23/2023 at 01:20 pm, the laboratory had not performed a self-evaluation to evaluate the results that were not graded by the proficiency testing program.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person, the laboratory failed to verify the accuracy of confirmatory urine drug testing at least twice annually during the review period of June 2021 through the current date. Findings include: (1) On 03/23/2023 at 09:40 am, the testing person stated the laboratory performed confirmatory urine drug testing using the AB Sciex 4500 analyzer; (2) A review of proficiency testing records and interview with the laboratory manager and testing person on 03/23/2023 at 11:40 am confirmed the laboratory did not participate in proficiency testing for the analytes Flurazepam, MDEA (Methyl diethanolamine), Nitrazepam, Tapetadol, and Triazolam; (3) A review of records from June 2021 through the current date identified the above testing had not been verified for accuracy at least twice annually between 06/29/2021 and 09/08/2022; (4) The records were reviewed with the laboratory manager and testing person. Both stated on 03/23/2023 at 01:30 pm, the testing had not been verified for accuracy at least twice annually as shown above.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the testing person, the laboratory failed to ensure the humidity was maintained as required by the manufacturer of the AB Sciex 4500 analyzer for nine of 14 months. Findings include: (1) On 03/23/2023 at 09:40 am, the testing person stated the laboratory performed confirmatory urine drug testing using the AB Sciex 4500 analyzer in the room denoted by the laboratory as "Room 3"; (2) A review of the Operator's Manual on page 34 under the heading, "Humidity Requirements" stated "Relative humidity from 35%-50%"; (3) A review of laboratory humidity records for Room 3 from January 2022 through February 2023 identified the humidity readings were less than 35% for nine of 14 months as follows: (a) January 2022 - 21 of 21 humidity readings were documented as less than 35%; (b) February 2022 - nine of 15 humidity readings were documented as less than 35%; (c) March 2022 - 12 of 23 humidity readings were documented as less than 35%; (d) April 2022 - two of 21 humidity readings were documented as less than 35%; (e) October 2022 - three of 21 humidity readings were documented as less than 35%; (f) November 2022 - eight of 20 humidity readings were documented as less than 35%; (g) December 2022 - 11 of 21 humidity readings were documented as less than 35%; (h) January 2023 - 15 of 20 humidity readings were documented as less than 35%; (i) February 2023 - five of 18 humidity readings were documented as less than 35%. (4) The records were reviewed with the testing person who stated on 03/23/2023 at 03:20 pm, the laboratory humidity in room 3 had not been maintained as required by the manufacturer as shown above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person, the laboratory failed to ensure three of three urine centrifuges were functioning properly for during the review period of 2022. Findings include: (1) On 03 /23/2023 at 01:00 pm, the testing person stated the following: (a) Urinary Tract

	Infection (UTI) Panel testing was performed using the Qiagen QiaCube and Roche LC 480 Lightcycler. The following centrifuges were used to process urine specimens for analysis: (i) Thermo Scientific Legend Micro21 - Used in the extraction process for urine specimens at a speed of 14,800 rpm (revolutions per minute) for five minutes; (ii) Eppendorf 5810 - Used to concentrate urines for testing at a speed of 4000 rpm for 10 minutes. (b) Urine Drug Confirmatory testing was performed using the AB Sciex 4500 analyzer and the following centrifuge was used to process urine specimens for analysis: (i) Thermo Scientific ST8 - Used for spinning plates containing urine specimens, calibrators, and standards at a speed of 3700 rpm for 15 minutes. (2) A review of the policy titled, "Centrifuge Use and Maintenance" required the centrifuges be checked on an annual basis; (3) A review of centrifuge records for 2022 identified the following for the checks performed on 12/12/2022: (a) Thermo Scientific Legend Micro21 - Although the centrifuge speed had been checked at 14,798 rpm, there was no documentation the timer had been checked for accuracy; (b) Eppendorf 5810 - Although the centrifuge speed had been checked at 3998 rpm, there was no documentation the timer had been checked for accuracy; (c) Thermo Scientific ST8 - Although the centrifuge speed had been checked at 3699 rpm, there was no documentation the timer had been checked for accuracy. (4) The records were reviewed with the laboratory manager and testing person. Both stated on 02/23/2023 at 02:30 pm, the laboratory had not ensured the centrifuge timers had been checked for accuracy as shown above.