Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1012182	01/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Quality Of Life Medical Center, Llc	5390 E Erickson Drive, Tucson, AZ	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) evaluations for 2019 and interview with the facility personnel, the laboratory failed to evaluate and review the PT results for Urine Drug testing. Findings include: 1. The laboratory participated in PT provided by CAP, performing 2 separate testing events for each program during 2019. The PT programs included Urine Drug Adulterant (DAI-2019, A & B) and Drug Monitoring for Pain Management (DMPM-2019, A & B). 2. No documentation of a review, including a written comment and signature, was presented during the survey that indicated the laboratory director or designee reviewed the PT results for each testing event of 2019. 3. The facility personnel acknowledged that the PT results indicated above were not evaluated and reviewed.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and

	indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test requisitions and interview with the facility personnel, the laboratory's test requisition failed to include the test(s) to be performed. Findings include: 1. The laboratory performs patient testing under the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 102,720. The laboratory performs a drug screen on the Carolina Industries CLC720 analyzer and a confirmation drug screen on the AB Sciex API4000 LC/MS analyzer. 2. The test requisition (MR# 25181) reviewed during the survey conducted on January 20, 2021 indicated the lab tests as "Drug Screen" and "Drug Confirmation". 3. The laboratory failed to produce documentation, whether on the test requisition or in laboratory policy, to indicate the specific analytes that are tested by the laboratory on the Carolina Industries CLC720 analyzer for a 'Drug Screen'. 4. The laboratory failed to produce documentation, whether on the test requisition or in laboratory policy, to indicate the specific analytes that are tested by the laboratory for a 'Drug Confirmation' performed on the AB Sciex API4000 LC/MS analyzer. 5. The urine drug screen performed by the laboratory on the CLC720 analyzer tests for the following analytes: 6-Acetyl Morphine, DRI Amphetamine, Benzodiazepine, Buprenorphine, Cocaine, Methadone, Ethanol, Opiate, Oxycodone, Cannabinoid, Urine Creatinine, and pH. 6. The urine drug confirmation performed by the laboratory on the API4000 LC/MS analyzer tests for the following drug classes: Methadone, Amphetamines, Muscle Relaxant, Benzodiazepines, Opiate, Tapentadol, Fentanyl, Methylenedioxyamphetamine, Heroin, Hypnotic, Oxycodone, Tramadol, PCP, Synthetic Opioid, Buprenorphine, Cannabinoid and Cocaine. 6. The facility personnel confirmed that the test requisitions reviewed during the survey failed to include the specific analytes tested in a Urine Drug Screen and a Urine Drug Confirmation.
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 laboratory policy and procedure manual presented for review during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1. The laboratory's procedure manual presented for review during the survey conducted on January 20, 2021 failed to include the approval, signature and date of the laboratory director. 2. The facility personnel acknowledged that the procedure manual was not signed and dated by the laboratory director at the time of the survey.
D6128	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 annually after the first year, 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. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the facility personnel, the laboratory failed to document the competency evaluation of one testing personnel for 2019. Findings include: 1. No 2019 competency evaluation was presented for review for one out of one testing personnel. 2. The facility personnel confirmed the testing personnel indicated above was missing a competency evaluation for 2019.