Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1012182	05/22/2018
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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for patient testing for one patient record reviewed during the survey. Findings include: 1. The laboratory began patient testing in April 2017 under the sub-specialties of Routine Chemistry and Toxicology, with an approximate annual test volume of 134,744. The laboratory performs a urine drug screen on the Carolina Industries CLC720 analyzer and performs a drug confirmation test using a Sciex API 4000 LC /MS analyzer. 2. Review of test report for patient R.B. indicated a drug screen was performed on 01/23/18 and a drug confirmation test was performed on 01/26/18. 3. No documentation was presented for review during the survey to indicate the laboratory had a written or electronic test requisition for either test performed on the patient indicated above. 4. The facility personnel confirmed that the laboratory did not have an electronic or written copy of the test requisition for testing that was performed on the patient specimen indicated above, and confirmed that the laboratory did not have a system in place at the time of the survey to document and retain patient test requisitions. 5. The number of patients tested without a test requisition could not be determined at the time of the survey.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed

	in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of established and verified performance specification documentation for the Carolina Industries CLC720 analyzer used for urine drug screens and for the Sciex API 4000 LC/MS analyzer used for urine drug confirmation testing and interview with the facility personnel, the laboratory (A) failed to establish the reportable range and reference range for pH and Creatinine testing performed on the CLC720 analyzer and (B) failed to document information regarding interfering substances that may effect the analytical specificity of the LC/MS test system. Findings include. A1. The performance specification documentation presented for review for the Carolina Industries CLC720 analyzer failed to include documentation to indicate the laboratory established the reportable range and reference range for pH and Creatinine testing that is performed on the analyzer. A2. The facility personnel confirmed that the laboratory did not establish or verify the reportable range or reference range for pH and Creatinine testing performed on the analyzer indicated above prior to testing patient specimens. B1. The performance specification documentation presented for review during the survey failed to include documentation regarding interfering substances that may effect and/or inhibit the analytical specificity of the test system, including but not limited to, information regarding the patients' clinical conditions, disease states, and any common medications. B2. The facility personnel acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system. 3. The laboratory started patient testing using the Carolina Industries CLC720 analyzer and the Sciex API 4000 LC/MS analyzer in April 2017 with an approximate annual test volume of 134, 744.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the facility personnel, the laboratory failed to include on the test report the laboratory address where the testing was performed. Findings include: 1. The laboratory performs patient testing in the

	specialty of Chemistry, with an approximate annual test volume of 134,744. The laboratory address listed in the CLIA database for CLIA# 03D1012182 is 5390 E. Erickson Rd., Tucson, AZ 85712. 2. One patient test report reviewed during the survey listed the laboratory address as 5350 E. Erickson Rd., Tucson, 85712. 3. The facility personnel confirmed that the laboratory address where the testing was performed was not listed correctly on the test reports issued by the laboratory since testing began in April 2017.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on lack of verification documentation for testing performed by the laboratory and interview with the facility personnel, the technical supervisor failed to ensure the establishment of the laboratory's test performance characteristics, including the assessment of interfering substances, reference range and reportable range. See D5423 for findings.