Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1012182	06/21/2023
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts presented for review for testing performed on the Siemens Viva-Pro analyzer and interview with the General Supervisor (GS), the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of Quality Control (QC) and test reagent material used on the analyzer. Findings include: 1. During the survey conducted on June 21, 2023, no evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the Siemens Viva-Pro toxicology analyzer. The laboratory began patient testing on the analyzer in August 2022. 2. The GS interviewed on June 21, 2023 at 1:10 PM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC and test reagent material used on the analyzer indicated above. 3. The laboratory reports approximately 75,120 patient tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 personnel form, review of the Technical Consultant/Supervisor competency evaluation form and interview with the laboratory general supervisor listed on the CMS-209 (GS-TP1), the laboratory failed to establish written policies and procedures to assess employee and supervisor competency. Findings include: 1. The laboratory's CMS-209 personnel form lists two (2) Technical Consultants and Technical Supervisors (TC-1/TS-1 and TC-2/TS-2), and one (1) general supervisor (GS-TP1). 2. The laboratory lacked documentation of a competency assessment for TC-2/TS-2 listed on the CMS-209 form. 3. The "Technical Consultant/Supervisor Competency Evaluation" form presented for review for TC-1/TS-1 from January 20, 2020 failed to include the laboratory director signature and date, as required on the form. 4. The laboratory lacked a policy or procedure for competency evaluation and documentation of the technical consultant, technical supervisor and general supervisor, including but not limited to, frequency of the competency assessment. 5. The laboratory lacked a policy or procedure for documenting training and competency assessments for persons performing preanalytic (specimen collection) activities in the laboratory. 6. The GS-TP1 interviewed on June 21, 2023 at 11:09 AM confirmed the lack of established policy or procedures for performing and documenting competency assessments for the Technical Consultants, Technical Supervisors, General Supervisor and persons performing preanalytic activities. 7. The laboratory's reported annual test volume is 75,120, in the subspecialty of Toxicology.
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 General Supervisor (GS), two out of two test requisitions reviewed during the survey failed to include the time of specimen collection. Findings include: 1. The laboratory utilizes the Siemens Viva-Pro analyzer for urine drug screen testing and the Sciex API4000 LC/MS analyzer for drug confirmation testing. 2. Two out of two test requisitions presented for review during the survey for MR# 23329 from 11/11/21 and MR# 12195 from 4/13 /23 failed to include the time of specimen collection. 3. The GS interviewed on June 21, 2023 at 12:42 PM confirmed the time of specimen collection was not documented on the test requisitions referenced above.
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's test procedures and interview with the General Supervisor (GS), the laboratory failed to have the current laboratory director approve, sign and date test procedures before use. Findings include: 1. The current laboratory director assigned on the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as laboratory director in the CLIA Federal Database since March 16, 2023. 2. The Laboratory Director failed to approve, sign and date the following test procedures reviewed during the survey: Siemens Viva-ProE Pain Panel, General Operation Pain Panel and Sciex LC/MS Pain Panel. 3. The GS interviewed on June 21, 2023 at 11:01 AM confirmed the test procedures indicated above were not approved, signed and dated by the current laboratory director.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and policies, lack of QC lot correlation documentation and interview with the General Supervisor (GS), the laboratory failed to verify the criteria for acceptability of quality control materials used on the Siemens Viva-Pro toxicology analyzer. Findings include: 1. The laboratory performs a semi-quantitative urine drug screen test on the Siemens Viva-Pro analyzer. The laboratory's reported annual test volume is 75,120. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from August 2022 through the date of the survey on June 21, 2023. 3. The GS interviewed on June 21, 2023 at 1:12 PM confirmed the laboratory failed to verify and document the criteria for acceptability of control materials used on the Siemens Viv-Pro analyzer from August 2022 through June 21, 2023. 4. The number of QC lots used on the analyzer from August 2022 through the date of the survey could not be determined at the time of the survey.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of relative humidity and temperature logs, lack of corrective action documentation and interview with the General Supervisor (GS), the laboratory failed to document corrective action taken for humidity measurements and refrigerator temperatures that were outside the laboratory's established ranges during February 2021. Findings include: 1. The laboratory performs patient testing on the Siemens Viva-Pro and Sciex API4000 LC/MS toxicology analyzers, with a reported annual test volume of 75,120. 2. The log titled, "Laboratory Daily/Weekly Environmental Checks" is used each month to monitor the temperature of one (1) refrigerator, one (1) freezer, the room temperature and the room humidity measurement. The laboratory's established humidity range for the room where patient testing occurs is 20-80%, and the laboratory's established temperature for the refrigerator is 2-8 degrees Celsius. 3. Review of the monthly log, "Laboratory Daily/Weekly Environmental Checks", from February 2021 revealed the documented humidity was not within the laboratory's established humidity range on 18 out of 21 days. 4. Review of the monthly log, "Laboratory Daily/Weekly Environmental Checks", from February 2021 revealed the documented refrigerator temperature was not within the laboratory's established range on 5 out of 21 days. 5. The laboratory failed to document corrective action taken for the humidity measurements and refrigerator temperatures that were outside the laboratory's established ranges on the days indicated above. 6. The GS interviewed on June 21, 2023 at 11:55 AM confirmed the laboratory failed to document corrective action for the humidity measurements and refrigerator temperatures that were outside the laboratory's established ranges for the days indicated above.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of established policies and procedures and interview with the General Supervisor (GS), the laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's

	information system (LIS). Findings include: 1. The test results from the Sciex API4000 LC/MS analyzer are electronically interfaced into the Laboratory Information System (LIS), LimitLIS. 2. No documentation was presented for review during the survey conducted on June 21, 2023 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are electronically interfaced from the LC/MS analyzer into the LIS. 3. The GS interviewed on June 21, 2023 at 12: 27 PM confirmed the laboratory failed to have a system in place to verify the accuracy of patient test results that are electronically sent from the LC/MS analyzer to the LIS.
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 lack of competency assessments for review and interview with the General Supervisor (GS), the technical consultant failed to evaluate and document the performance of two out of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation was presented for review for two out of two testing personnel who began testing patient specimens on the Siemens Viva-Pro analyzer in August 2022. 2. The GS interviewed on June 21, 2023 at 10:39 AM confirmed that the technical consultant failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. The laboratory implemented a new analyzer, Siemens Viva-Pro, in August 2022 for testing in the subspecialty of Toxicology. The laboratory's reported annual test volume is 75,120.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for two out of two testing personnel and interview with the general supervisor (GS), the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for two out of two testing personnel who began patient testing on the Siemens Viva-Pro analyzer in August 2022, in the subspecialty of Toxicology. 2. The GS interviewed on June 21, 2023 at 10:39 AM confirmed the laboratory failed to have documentation of initial training for the two testing personnel indicated above. 3. The laboratory's reported annual test volume is 75,120.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the General Supervisor (GS), the procedures for evaluation of the competency of the staff failed to include assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Findings include: 1. The annual competency assessment records for two out of two testing personnel from 2021 and 2022 for LC/MS Toxicology testing failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The GS interviewed on June 21, 2023 at 10:51 AM confirmed the competency assessment evaluation procedures for LC/MS toxicology testing failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 3. The laboratory performs patient testing on the Sciex API4000 LC/MS analyzer in the subspecialty of Toxicology, with a reported annual test volume of 75,120.