Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1012182	01/21/2025
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
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 lack of accuracy verification documentation for review and interview with the Technical Consultant (TC-1), the laboratory failed to verify the accuracy of urine drug screen testing performed under the subspecialty of Toxicology at least twice annually during 2024. Findings include: 1. The laboratory performs urine drug screens on patient samples utilizing the Siemens Aviva-ProE analyzer with an annual test volume of 13,000. 2. The laboratory failed to provide documentation to indicate the laboratory verified the accuracy of urine drug screen testing testing at least twice annually during 2024. 3. The TC-1 interviewed on 1/21/25 at 10:45 AM confirmed the laboratory failed to verify the accuracy of urine drug screen testing testing at least twice annually during 2024.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the Technical Consultant (TC-1), the laboratory failed to establish

	policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/21/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to Proficiency Testing. 2. The TC-1 interviewed on 1/21/25 at 11:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of written policies and procedures for review and interview with the Technical Consutlant (TC-1), the laboratory failed to establish policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. Findings include: 1. The laboratory performs urine drug screens on patient samples utilizing the Siemens Aviva-ProE analyzer with an annual test volume of 13,000. 2. No documentation was presented for review during the survey conducted on 1/21/25 to indicate the laboratory established policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, and specimen referral. 3. The TC-1 interviewed on 1/21/25 at 10:15 AM confirmed the laboratory failed to provide evidence of the above referenced policies and procedures at the time of the survey
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of temperature records from 2024 and interview with the Technical

	Consultant (TC-1), the laboratory failed to monitor and document the humidity, room, refrigerator and freezer temperatures for one of three days of patient testing. Findings include: 1. The laboratory performs urine drug screens on patient samples utilizing the Siemens Aviva-ProE analyzer with an annual test volume of 13,000. 2. The laboratory records the humidity, room, freezer and refrigerator temperatures on each day of patient testing. 3. The laboratory failed to provide documention demonstrating the humidity, room, freezer and refrigerator temperatures were monitored and recorded on one of three testing dates reviewed during the survey: 11/27/24. 4. The number of patients tested on the dates indicated above could not be determined at the time of the survey. 5. The TC-1 interviewed on 1/21/25 at 10:00 AM confirmed the laboratory failed to monitor and document the humidity and temperatures as indicated above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records from 2023 through 2024, lack of QC lot correlation documentation and interview with the Technical Consultant (TC-1), the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs urine drug screens on patient samples utilizing the Siemens Aviva-ProE analyzer with an annual test volume of 13,000. 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 2023 through 2024. 3. The number of QC lots used on the analyzer from 2023 through 2024 could not be determined at the time of the survey. 4. The TC-1 interviewed on 1/21/2025 at 9:30 AM confirmed the laboratory failed to verify the criteria for acceptability of quality control materials for each lot of QC used on the Siemens Aviva-ProE analyzer from 2023 through 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the technical consultant (TC-1), the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through

	493.1289. Findings include: 1. No QA documentation was provided for review during the survey conducted on 1/21/25 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The facility personnel interviewed on 1/21/25 at 11:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports for urine drug screens and interview with the Technical Consultant (TC-1), three out of three patient test reports failed to include the reference intervals for urine drug screen results on the test reports issued to the individual responsible for using the test results. Findings include: 1. The laboratory performs urine drug screens on patient samples utilizing the Siemens Aviva-ProE analyzer with an annual test volume of 13,000. 2. Three out of three urine drug screen test reports reviewed during the survey failed to include reference intervals or normal values for urine drug screen testing that is performed using the Siemens Aviva-ProE analyzer. Records include: Accession # 112308 from 1/10/24, Accession # 24095 from 6/27/24, and Accession # 26139 from 11/27/24. 3. The TC-1 interviewed on 1/21 /25 at 9:45 AM confirmed the laboratory's test report failed to include the reference intervals or normal values for urine drug screens.