

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1012182	(X3) Date Survey Completed 04/28/2026
Name of Provider or Supplier Quality Of Life Medical Center, Llc	Street Address, City, State 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2025 and interview with the testing personnel (TP-1), the laboratory director and testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for urine drug screening testing performed on the Viva Pro-E analyzer and participates in two PT events annually. 2. The PT attestation statements presented for review for the first and second events of 2025 lacked the signatures of the laboratory director and testing personnel. 3. The TP-1 interviewed on 4/28/26 at 10:20 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director and testing personnel. 4. The laboratory reports an annual test volume of 21,600 under the specialty of Chemistry.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified</p>

in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on review of Proficiency Testing records from 2025 and interview with the testing personnel (TP-1), the laboratory failed to successfully participate in two out of three consecutive proficiency testing (PT) events under the subspecialty of Routine Chemistry for the analyte, Creatinine (urine), in 2025 resulting in an initial unsuccessful performance. Refer to D2096.

D2094

ROUTINE CHEMISTRY

CFR(s): 493.841(e)

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) records from 2025 and interview with the testing personnel (TP-1), the laboratory failed to undergo appropriate training and employ the technical assistance necessary to correct the PT failures for the analyte, Creatinine (urine) during the first and second events of 2025.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) records from 2025 and interview with the testing personnel (TP-1), the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three consecutive testing events in the subspecialty of Routine Chemistry for the analyte of: Creatinine (urine). Findings include: 1. A review of the 2025 API evaluation reports revealed the following unsatisfactory scores: 2025 event 1, Creatinine, urine 67% 2025 event 2, Creatinine, urine 0% 2. The laboratory performs urine drug screen testing on the Viva Pro-E analyzer under the specialty and Routine Chemistry with an annual test volume of 21,600. 3. The

	<p>laboratory utilizes the urine creatine result as a validation test to ensure acceptable patient samples. 4. The TP-1 interviewed on 4/28/26 at 10:20 AM confirmed the PT failures indicated above.</p>
<p>D2109</p>	<p>TOXICOLOGY CFR(s): 493.845(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2025 and interview with the testing personnel (TP-1), the laboratory received a score of 67% for the analyte, Methadone, qualitative, during the first event of 2025 resulting in an unsatisfactory PT performance. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for urine drug screen testing performed on the Viva Pro-E analyzer under the specialty of Chemistry with an annual test volume of 21,600. 2. The laboratory received a score of 67% for the analyte, Methadone, qualitative, during the first testing event of 2025. 3. The laboratory failed to take corrective action for the unsatisfactory PT results obtained for: Methadone, qualitative, during the first event of 2025. 4. The TP-1 interviewed on 4/28/26 at 10:30 AM confirmed the laboratory failed to take corrective action for the unsatisfactory PT scores obtained for Methadone, qualitative, during the first PT event of 2025.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2025 and interview with the testing personnel (TP-1) on 4/28/26 at 10:20 AM, the laboratory failed to provide evidence of a documented review of the PT results obtained for the first and second testing events of 2025 for testing performed under the specialty of Chemistry. Findings include: 1. The laboratory is enrolled in PT with American Proficiency Institute (API) for urine drug screen testing performed on the Viva Pro-E analyzer and participates in two PT events annually. 2. No written comment or signature was documented by laboratory personnel on the PT records from the first and second events of 2025, to indicate a review and evaluation of the PT results obtained from API. 3. The TP-1 interviewed on 4/28/26 at 10:20 AM confirmed that the PT results indicated above were not reviewed by the laboratory personnel. 4. The laboratory reports an annual test volume of 21,600 under the specialty of Chemistry.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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</p>

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 testing personnel (TP-1), 3 out of 3 test reports failed to include the correct name and laboratory address where the testing was performed. Findings include: 1. The laboratory performs patient testing under the specialty of Chemistry with an annual test volume of 21,600. 2. Three out of three test reports reviewed during the survey (patient #1, patient #2, and patient #3) failed to include the correct name laboratory address where the testing was performed. 3. At the time of the survey conducted on 4/28/26, the laboratory name and address listed in the CLIA database for CLIA# 03D1012182) was "Quality of Life Integrated Health, 6390 E. Broadway, Tucson, AZ 85710." 4. The test reports indicated above listed the resulting lab as "Quality of Life Medical Center, 5390 E. Erickson Dr, Tucson, AZ, 85712." 5. The TP-1 interviewed on 4/28/26 at 10:30 AM confirmed that the laboratory name and address listed on the test reports referenced above was not correct.