

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2283558	<b>(X3) Date Survey Completed</b>  02/13/2025
<b>Name of Provider or Supplier</b>  Yuma Regional Medical Center Health Campus	<b>Street Address, City, State</b>  11351 E South Frontage Rd, Yuma, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2024 for CK-MB and Troponin testing and interview with the facility personnel, the laboratory failed to monitor, assess, and, when indicated, correct problems in the general laboratory systems requirements specific to PT enrollment. Findings include: 1. The laboratory began patient testing in the specialties of Microbiology, Chemistry and Hematology on 7/24/23 under CLIA# 03D2283558 (Yuma Regional Medical Center Health Campus), with a reported annual test volume of 47,566. The laboratory is enrolled with American Proficiency Institute (API) for proficiency testing. 2. The laboratory's API records reviewed during the survey for each PT event of 2024 for CK-MB and Troponin listed the CLIA# as 03D0531581 (Yuma Regional Medical Center). The PT forms indicated, "Method: i-STAT Serial#/Location: 431326." 3. Direct observation of the i-STAT analyzers used by the laboratory indicated the serial numbers as 431326 and 430984. 4. The facility personnel interviewed on 2/13/25 at 2:00 PM stated that the laboratory under CLIA# 03D0531581 does not have or utilize i-STAT's for any testing. 5. The laboratory's QA processes for general laboratory systems failed to identify and correct the problem of using the wrong CLIA number to report CK-MB and Troponin PT results for each of the three PT events of 2024. 6. The facility personnel interviewed on 2/13/25 at 2:05 PM acknowledged that the laboratory failed to monitor, identify and correct PT enrollment problems found with CK-MB and Troponin during 2024.</p>

**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 established humidity criteria defined by the laboratory, review of the manufacturer's environmental specifications for the Ortho Vitros chemistry analyzer and interview with the facility personnel, the laboratory's established humidity range failed to be consistent with the manufacturer's required humidity range for operation of the analyzer. Findings include: 1. The laboratory began patient testing on 7/24/23 in the specialties of Microbiology, Chemistry and Hematology. The laboratory's reported test volume for Chemistry is 27,300. 2. The manufacturer's environmental specifications reviewed during the survey for the Ortho Vitros analyzer listed the operating relative humidity range as 15-75%. 3. Review of laboratory humidity records from July 2023 through February 13, 2025 indicated the laboratory's established humidity range as 5-80%. 4. The facility personnel interviewed on 2/13/25 at 4:55 PM confirmed the laboratory's established humidity range failed to be consistent with the manufacturer's operating humidity range for the Ortho Vitros analyzer.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

(b)(9) 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 performance evaluation documentation from 2024 and interview with the facility personnel, 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 documentation was presented for review for one out of one testing personnel (TP-11) who began patient testing in July 2023. 2. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel (TP-1) who began patient testing in January 2024. 3. The facility personnel interviewed on 2/13/25 at 1:40 PM confirmed the technical consultant failed to perform and document a semiannual competency evaluation for the two testing personnel indicated above. 4. The laboratory reports 47,566 tests annually in the specialties of Microbiology, Chemistry and Hematology.