

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2012555	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Mizzou Urgent Care - Mexico	Street Address, City, State 3626 South Clark Street Suite C, Mexico, MO	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual on May 21, 2025 and interview with the technical consultant, the laboratory failed to ensure the procedure manual include reference intervals (normal values) for the troponin-I analyte. Findings: 1. Review of the procedure manual revealed the manual did not include reference intervals (normal values) for troponin-I. 2. Interview with the technical consultant on May 21, 2025 at 1: 00 PM confirmed the laboratory failed to ensure the procedure manual include reference intervals (normal values) for troponin-I testing.</p>

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records for 2024 and 2025 and interview with the technical consultant, the laboratory director failed to ensure three of three PT testing events were reviewed by appropriate staff to evaluate and identify problems requiring corrective action. PT records showed the laboratory is enrolled and received reports from the PT provider for second event and third event of 2024 and first event of 2025 in the specialty of chemistry and hematology to include the following analytes; carbon dioxide, chloride, creatinine, glucose, potassium, sodium, troponin-I, blood urea nitrogen, hematocrit and hemoglobin Findings: 1. Review of the second PT testing event of 2024 the laboratory did not have documentation to show the testing reports received were reviewed and evaluated by appropriate staff and identify an unacceptable test result for one of five hemoglobin challenges. 2. Review of the third PT testing event of 2024 the laboratory did not have documentation to show testing reports received were reviewed and evaluated by appropriate staff. 3. Review of the first PT testing event of 2025 the laboratory did not have documentation to show testing reports received were reviewed and evaluated by appropriate staff and identify a failure to submit results for urea nitrogen analyte PT specimens IB-01, IB-02, IB-03, IB-04 and IB-05. 4. Interview with the technical consultant on May 21, 2025 at 1:00 PM confirmed the laboratory director failed to ensure appropriate staff review, evaluate and identify problems requiring corrective action for all PT results received.

D8103

BASIC INSPECTION REQUIREMENTS

CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of I-stat analytic records on May 21, 2025 and interview with the technical consultant, the laboratory failed to ensure all calibration verification records

for 2024 were accessible and retrievable within a reasonable timeframe during the inspection process. Findings: 1. Review of calibration verification records showed the laboratory performed I-stat calibration verification procedures on June 28, 2024. Requested calibration verification records due six months after June 28, 2024 were not accessible and retrievable during the course of inspection. 2. Interview with the technical consultant on May 21, 2025 at 1:00 PM confirmed, the requested calibration verification records were not available for review.