| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>03D2302976 | (X3) Date Survey Completed<br>02/03/2026 |
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| **Name of Provider or Supplier**<br>El Mirage Er & Medical Center | **Street Address, City, State**<br>12000 N El Mirage Rd, El Mirage, 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 |
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| **D2005** | ENROLLMENT<br>CFR(s): 493.801(a)(4)<br><br>(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Proficiency Testing (PT) records for testing performed in the specialties of Chemistry and Hematology and interview with the Technical Consultant (TC-1) on 2/03/26 at 11:14 AM, the laboratory failed to authorize the proficiency testing program, American Proficiency Institute (API), to release all PT scores and data to HHS during 2025. Findings include: 1. The laboratory began patient testing on 11/01/24 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 10,000. 2. No evidence was presented for review during the survey to indicate the laboratory authorized API to release PT results to HHS/CMS from 1/01 /25 through the date of the survey, 2/03/26. 3. Review of the API PT records (API customer# 86852) from 2025 revealed there was no CLIA number assigned to the API account. 4. As of 2/03/26, the laboratory's PT records were unavailable in CMS's reporting database, CASPER (Certification and Survey Provider Enhanced Reports). 5. TC-1 interviewed on 2/03/26 at 11:14 AM acknowledged that the laboratory's PT results were not being reported to HHS/CMS by API from 1/01/25 through 2/03/26. |
| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of |

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| | this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Proficiency Testing (PT) records from 2025, review of the Laboratory Personnel Report (Form CMS-209) and interview with the Technical Consultant (TC-1) on 2/03/26 at 11:25 AM, the laboratory failed to include 9 out of 10 testing personnel in the testing of PT samples during 2025, for testing performed in the specialties of Hematology and Chemistry. Findings include: 1. The laboratory began patient testing in the specialties of Hematology and Chemistry on 11/01/24, with an approximate annual test volume of 10,000. 2. The CMS-209, Laboratory Personnel Report form presented for review during the survey listed 10 testing personnel. 3. The API PT attestation statements presented for review for each of the 3 testing events of 2025 for Chemistry-Core and each of the 3 testing events of 2025 for Hematology/Coagulation were signed by the same testing personnel, TP-3, as the only person performing the test. 4. TC-1 interviewed on 2/03/26 at 11:25 AM confirmed that all PT samples for each testing event listed above were tested by TP-3, and acknowledged that the remaining 9 testing personnel were not involved in the testing of PT samples during 2025. |