| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D2103284 | 09/20/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Us Lab Inc | 3194-A Airport Loop Dr, Ste A, Costa Mesa, CA | |

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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory records, CAP (College of American Pathologists) proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory, at least twice annually, failed to verify the accuracy of drug confirmations it performed that are not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performs urine drug screen and reported drug confirmation with its quantities by LC/MS/MS for 59 drugs which including but not limited to Naloxone, N-Desmethyltapentadol, Amitriptyline, Nortriptyline is not listed in subpart I of 42 CFR part 493. b. The laboratory elected to enroll with CAP's DMPM (Drug Monitoring for Pain Management) PT programs to ensure accuracy of the test results. c. The CAP's DMPM PT program consists of 50 drugs which does not cover all the drugs listed in the laboratory's A and C testing panels. |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory records, CAP (College of American Pathologists) proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure the establishment and |

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| | maintenance of acceptable levels of analytical performance for drug confirmation by LC/MS/MS system. The findings included: a. The laboratory performs urine drug screen and reported drug confirmation with its quantities by LC/MS/MS for 59 drugs which including but not limited to Naloxone, N-Desmethyltapentadol, Amitriptyline, Nortriptyline is not listed in subpart I of 42 CFR part 493. b. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for LC/MS/MS at least twice annually performing a split sample with other CLIA certified laboratory (see D-5217) in 2021 and 2022. |