

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2065288	(X3) Date Survey Completed 01/24/2024
Name of Provider or Supplier Premier Biotech Labs, Llc	Street Address, City, State 723 Kasota Ave Se, Minneapolis, MN	
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>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 document review and interview with laboratory personnel, the Laboratory Director (LD) and the testing personnel (TP) failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods on 13 of 19 events reviewed in 2023. Findings are as follows: 1. The laboratory performed therapeutic drug and drugs of abuse testing which falls under the sub-specialty of Toxicology testing as confirmed by Technical Supervisor #2 (TS2) during an interview at 9:10 a.m. on January 24, 2024. 2. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 3. The LD's and TP's signature were required on the CAP Attestation Statement as the directions indicated on the form. The laboratory had typed the LD's and TP's names on the form but had failed to have them physically sign the form as indicated for 13 of 19 events in 2023. See below. OFD-D 2023 Oral Fluid for Drugs of Abuse OFD-D 2023 Oral Fluid for Drugs of Abuse ETB-B 2023 Ethanol Biomarkers DAI-B 2023 Urine Drug Adulterant SCDD-A 2023 Synthetic Cannabinoid/Designer Drug SCDD-B 2023 Synthetic Cannabinoid/Designer Drug UDC-A 2023 Forensic Urine Drug Testing, Confirmatory UDC-B 2023 Forensic Urine Drug Testing, Confirmatory UDC-C 2023 Forensic Urine Drug Testing, Confirmatory UDC-D 2023 Forensic Urine Drug Testing, Confirmatory UDS6-B 2023 Urine Drug Testing (Screen), Limited UT-B 2023 Urine Toxicology UT-A 2023 Urine Toxicology 4. In an interview at 11:35 a.m. on January 24, 2024, TS2 confirmed the above findings. .</p>
D3037	RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for one (1) of 19 events from 2023. Findings are as follows: 1. The laboratory performed therapeutic drug and drugs of abuse testing which falls under the sub-specialty of Toxicology testing as confirmed by Technical Supervisor #2 (TS2) during an interview at 9:10 a.m. on January 24, 2024. 2. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 3. The UT-A 2023 Urine Toxicology Original Evaluation PT documentation was not present in laboratory records on the date of survey, January 24, 2023. The laboratory was able to print the evaluation from the CAP website during the survey, however these results had not been reviewed by the appropriate laboratory staff. 4. In an interview on at 12:20 p.m. on January 24, 2024, TS2 confirmed the above findings. .

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results for non-regulated analytes when the PT program did not evaluate or score the results in three urine drug testing events in 2023. Findings are as follows: 1. The laboratory performed therapeutic drug and drugs of abuse testing which falls under the sub-specialty of Toxicology testing as confirmed by Technical Supervisor #2 (TS2) during an interview at 9:10 a.m. on January 24, 2024. 2. The laboratory performed PT using the College of American Pathologists (CAP) PT provider. 3. All of the results from the second 2023 Synthetic Cannabinoid/Designer Drug PT event were not graded due to them being educational challenges. The three results from Meprobamate /Carisoprod challenges in the first and second 2023 Urine Drug Testing (screen), Limited PT events were not graded due to them being educational challenges. 4. The CAP report referred the laboratory to the participant summary for evaluation of the non-graded test results. Evidence the laboratory had compared their results obtained with the CAP expected results in the participant summary could not be found. 5. The laboratory was unable to provide evaluations of the non-graded results upon request. 6. In an interview at 12:15 p.m. on January 24, 2024, TS2 confirmed the above finding.