Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2130713	03/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Peak Recovery Llc	2922 E Cleveland Blvd St 500, Caldwell, ID	

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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on direct observations at the time of the complaint survey on 3/16/2022, a review of test analytes using the FDA CLIA categorization database and a telephone interview with the laboratory director on 3/16/2022, the laboratory failed to obtain a certificate of compliance before reporting patient results for urine toxicology tests not categorized as waived. The findings include: 1. A direct observation on 3/16/2022 identified that the laboratory was using the Siemens V-twin analyzer for testing the following analytes: methamphetamine by Lin-Zhi and ethyl glucuronide by HEIA and opiates, cannabinoid, amphetamines, 6-acetylmorphine, benzodiazepine, cocaine metabolite and creatinine all from Siemens. 2. A review of the above analytes using the FDA CLIA categorization database identified that the laboratory failed to perform patient tests that are categorized as waived. 3. A telephone interview with the laboratory director on 3/16/2022 at 11:48 am confirmed that the laboratory was

	performing patient testing that is categorized as moderate and high complexity testing. 4. The laboratory reports performing 4000 tests annually.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on direct observations at the time of the complaint survey on 3/16/2022, a review of laboratory documents, a review of analytes tested using the FDA CLIA categorization database and a telephone interview with the laboratory director on 3/16 /2022, the laboratory failed to perform testing within the scope of their certificate and within the regulations for the complexity of urine toxicology testing performed on patient samples. See D8201
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on direct observations at the time of the complaint survey on 3/16/2022, a review of analytes tested using the FDA CLIA categorization database, a review of laboratory documents and a telephone interview with the laboratory director on 3/16 /2022, the laboratory failed to perform testing within the scope of their certificate and within the regulations for the urine toxicology testing being performed. The findings include: 1. A direct observation on 3/16/22 at 11:03 am identified that the laboratory was using the Siemens V-Twin analyzer. An observation at 11:23 am identified rapid ethylglucuronide test strips by 12 Panel Now in the laboratory cabinet. An observation in the laboratory refrigerator at 11:26 am identified reagents for methamphetamine assay by Lin-Zhi and HEIA, ethyl glucuronide assay by HEIA and opiates assay, cannabinoid assay, amphetamines assay, 6-acetylmorphine assay, benzodiazepine assay, cocaine metabolite assay and creatinine assay all from Siemens. 2. A review of the above analytes using the FDA CLIA categorization database identified that the laboratory failed to only perform patient tests that are categorized as waived. 3. A direct observation of methamphetamine immunoassay reagent kit by Lin-Zhi lot 1802106 expiration 2019-8-21, ethyl glucuronide reagent kit by HEIA lot EK19212 expiration 2021-11-30, opiate Emit II Plus reagent kit lot N2 expiration 2021-09-24, Emit II Plus cannabinoid assay kit lot N3 expiration 2021-12-04 and a

	methamphetamine urine kit by HEIA lot EK16480 expiration 2020-05-31 identified that the laboratory failed to discontinue the use of expired reagents. 4. A review of laboratory documents identified that the laboratory failed to have documentation for the validation of performance for the analytes, methamphetamine, 6-acetylmorphine and ethyl glucuronide, that are not FDA approved for performance on the Siemens V-Twin. 5. A telephone interview with the laboratory director on 3/16/2022 at 11:48 am confirmed that the laboratory was performing patient testing that is categorized as moderate and high complexity testing. 6. The laboratory reports performing 4000 tests annually.