

Product Information

Product Name:	Certified Drug Free Urine
Product Number:	88121-CDF(L)
Date of Manufacture:	09/25
Lot Number:	D7611
Expiration Date:	2026-11-30
Intended Use:	In vitro diagnostic
Homogeneity:	Sufficiently homogeneous for analytical testing
COA Rev.	00

Precautions

Matrix:	Urine
Form:	Liquid
Anticoagulant:	N/A
Preservative:	Sodium Azide (0.01%)
pH:	4.5-8
Virology:	Non-reactive for HBsAg, HCV, and HIV
Microbial Growth:	<100 colony-forming units per milliliter

Storage and Stability

Storage Condition:	2-8°C (35-46°F)
Open Vial Stability:	Up to Expiration Date
Vial Volume:	1 Gallon

ELISA Raw Material Screen

UTAK Laboratories, Urine Pool 2425-3525

Analyte	Qualitative Value	Cutoff Value	Unit
d-Amphetamine	Negative	10	ng/mL
d-Methamphetamine	Negative	5	ng/mL
Benzoylcegonine (BE)	Negative	8	ng/mL
Cotinine	Negative	10	ng/mL
Morphine	Negative	5	ng/mL
Oxazepam	Negative	10	ng/mL
(l)-9-Carboxy-11-nor-Delta-9-THC (THC-COOH)	Negative	8	ng/mL



Certification and Compliance Statements

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the below mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. Additional product information is available on the device labeling.

Approved by: Andrew Hartmann
Quality Assurance

