

Product Information

Product Name:	Blank Whole Blood
Product Number:	44600-WB(F)
Date of Manufacture:	12/22
Lot Number:	D2523
Expiration Date:	2024-12-31
Intended Use:	In vitro diagnostic
Homogeneity:	Sufficiently homogeneous for analytical testing

Precautions

Matrix:	Whole Blood
Form:	Frozen
Anticoagulant:	Potassium Oxalate
Preservative:	Sodium Chloride
Preservative:	Sodium Fluoride
pH:	6-7
Virology:	Non-reactive for HBsAg, HCV, and HIV
Microbial Growth:	<100 colony-forming units per milliliter

Storage and Stability

Storage Condition:	-10°C (14°F)
Open Vial Stability:	30 days*
Vial Volume:	250 ML

*The matrix may be thawed, aliquoted, and refrozen; although, this product should not be exposed to multiple freeze/thaw cycles.

ELISA Raw Material Screen

UTAK Laboratories, Whole Blood Pool TC124265-22MCTA4371

Analyte	Qualitative Value	Cutoff Value	Unit
d-Amphetamine	Negative	5	ng/mL
d-Methamphetamine	Negative	5	ng/mL
Benzoyllecgonine (BE)	Negative	5	ng/mL
Dextromethorphan	Negative	10	ng/mL
Diphenhydramine	Negative	10	ng/mL
Ethanol	Negative	20	mg/dL
Morphine	Negative	5	ng/mL
Oxazepam	Negative	10	ng/mL
Phencyclidine (PCP)	Negative	2	ng/mL
Secobarbital	Negative	5	ng/mL
(l)-9-Carboxy-11-nor-Delta-9-THC (THC-COOH)	Negative	1	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

