BLOOD COLLECTION LOT CONTROL
FINAL TUBE ASSAY RELEASE
GS10001646

LOT NO.: 131977	HRI NO: 8881-352796

TEST RESULTS

UN

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SODIUM FLUORIDE:	A5400,A5400-1
POTASSIUM OXALATE:	A5410

LOT # 131977
HRI: 8881-352796
ASSAY: POTASSIUM OXALATE
Tested : 12/6/2021
NOTEBOOK REF: Tube Assay BK #01
SPECIFICATION: 15.0 - 26.0mg/tube

ml titer	mg/tube	
22.20	19.41	P
22.90	20.03	P
24.45	21.38	P
23.57	20.61	P
23.31	20.38	P
23.15	20.24	P
25.70	22.47	P
22.65	19.81	P
20.45	17.88	P
25.00	21.86	P

MEAN: 20.41
STD DEV: 1.303

TESTED BY: Staci Hingst

Lot: 131977
HRI: 8881-352796
ASSAY: SODIUM FLUORIDE
Tested: 12/9/2021
NOTEBOOK REF: Tube Assay BK#01
SPECIFICATION: 88.0 -112.0 mg/tube

mg/tube	
108.9	P
109.8	P
105.3	P
102.9	P
105.6	P
100.2	P
100.1	P
106.2	P
95.7	P
95.1	P

MEAN: 103.0
STD DEV: 5.116

TESTED BY: Staci Hingst

12921

RELEASED BY: Renee M. DeLaCruz	DATE: 09 DEC 2021

FM20008183 Rev 3

CERTIFICATE OF ANALYSIS

Printed: 6/17/2021

Customer No : 30248 **Customer :** VWR INTERNATIONAL **Customer PO :** 4612973665

Order Number : 3372806 **Delivery # :** 121345329

Catalog : P1355 Potassium Oxalate, Monohydrate, Crystal, Reagent, ACS **Lot :** 2JF0287

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6-22-21

Chemical Formula : $(COOK)_2.H_2O$ **Formula Weight :** 184.23

CAS# : 6487-48-5

QA APPROVED 8-3-21

ORIGINAL

Test	Limit Min.	Limit Max.	Results
ASSAY ($K_2C_2O_4.H_2O$)	98.5	101.0 %	99.7 %
NEUTRALITY	-- TO PASS TEST		PASSES TEST
SUBSTANCES DARKENED BY HOT H_2SO_4	-- TO PASS TEST		PASSES TEST
INSOLUBLE MATTER	--	0.01 %	0.002 %
CHLORIDE (Cl)	--	0.002 %	0.001 %
SULFATES (SO_4)	--	0.01 %	0.004 %
AMMONIUM (NH_4)	--	0.002 %	0.001 %
HEAVY METALS (as Pb)	--	0.002 %	0.0005 %
IRON (Fe)	--	0.001 %	0.0006 %
SODIUM (Na)	--	0.02 %	0.0044 %
EXPIRATION DATE			31-AUG-2023
DATE OF MANUFACTURE			01-AUG-2019
APPEARANCE			WHITE CRYSTALLINE POWDER

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia at time of release.

Read and understand label and MSDS/SDS before handling any chemical. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective equipment before handling our chemicals.

Certificate of Analysis Results Certified By:

Jigisha Patel

spectrum® CHEMICAL MFG CORP Trusted Since 1971
AN ISO 9001:2015 REGISTERED COMPANY

Corporate Office:
755-769 Jersey Ave.
New Brunswick, NJ 08901
(732) 214-1300
Fax: (732) 246-7132

West Coast Plant:
14422 S. San Pedro St.
Gardena, CA 90248
(310) 516-8000
Fax: (310) 516-9843

Jigisha Patel
VP Regulatory Compliance & Technical Services, Regulatory
New Brunswick, NJ 08901

ORIGINAL

8-10-21

QA APPROVED 8/12/21

UNCONTROLLED COPY

Certificate of Analysis

ThermoFisher SCIENTIFIC

Certificate of Analysis

1 Reagent Lane
Fair Lawn, NJ 07410
201.796.7100 tel
201.796.1329 fax

Thermo Fisher Scientific's Quality System has been found to conform to Quality Management System Standard ISO9001:2015 by SAI Global Certificate Number CERT – 0120632

This is to certify that units of the lot number below were tested and found to comply with the specifications of the grade listed. Certain data have been supplied by third parties. Thermo Fisher Scientific expressly disclaims all warranties, expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. Products are for research use or further manufacturing. Not for direct administration to humans or animals. It is the responsibility of the final formulator and end user to determine suitability based upon the intended use of the end product. Products are tested to meet the analytical requirements of the noted grade. The following information is the actual analytical results obtained.

Catalog Number	S299	Quality Test / Release Date	09/29/2020
Lot Number	204187		
Description	SODIUM FLUORIDE, A.C.S.		
Country of Origin	India	Suggested Retest Date	Sep/2025

N/A

Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	White powder
ASSAY	%	>= 99	101
CHLORIDE	%	<= 0.005	<0.005
HEAVY METALS (as Pb)	%	<= 0.003	<0.003
IDENTIFICATION	PASS/FAIL	= PASS TEST	PASS TEST
INSOLUBLE MATTER	%	<= 0.02	0.01
IRON (Fe)	%	<= 0.003	<0.003
LOSS ON DRYING @ 105 C	%	<= 0.3	0.02
POTASSIUM (K)	%	<= 0.02	0.001
SODIUM FLUOSILICATE	%	<= 0.1	<0.1
SULFATE (SO4)	%	<= 0.03	<0.03
SULFITE	%	<= 0.005	<0.005
TITRATABLE ACID	MEQ/G	<= 0.03	<0.03
TITRATABLE BASE	MEQ/G	<= 0.01	<0.01

Julian Burton

Julian Burton - Quality Control Manager – Fair Lawn

Note: The data listed is valid for all package sizes of this lot of this product, expressed as an extension of this catalog number listed above.
If there are any questions with this certificate, please call at (800) 227-6701.
*Based on suggested storage condition.

Cardinal Health
1222 Sherwood Road
Norfolk, NE 68701
402.371.9010 main

cardinalhealth.com

CardinalHealth

CERTIFICATE OF COMPLIANCE

TO: TK Tech Forensics Inc

P.O. NO. 85645

LOT NO. 131977

ITEM 8881352796

QUANTITY 100,000

DRAWING NO. NA

CUSTOMER PART NO. NA

THIS IS TO CERTIFY THAT THE MATERIAL SHIPPED ON THE NOTED PURCHASE ORDER WAS MADE IN ACCORDANCE TO BLUEPRINTS, SPECIFICATIONS AND PERTINENT REQUIREMENTS AS SPECIFIED BY CARDINALHEALTH. INDIVIDUAL INSPECTION RECORDS ARE AVAILABLE UPON REQUEST FOR SPECIFIC LOTS.

10DEC2021
DATE

BY: Amanda Emerson Sr Quality Engineer
QUALITY ASSURANCE MANAGER

Cardinal Health
1222 Sherwood Road
Norfolk, NE 68701
402.371.9010 main

CardinalHealth

cardinalhealth.com

CERTIFICATE OF STERILITY
Blood Collection

To: _____

This is to certify that the product meets all the sterility requirements as specified by Cardinal Health with a sterility assurance level of 10^{-3}. The lot was Gamma radiation sterilized and dosimetric released in accordance with Cardinal Health procedures, the AAMI recommended practice and the Quality System Regulation (QSR). All dosimetry requirements were satisfied and the dosimetry is traceable to a recognized standard.

Item: DRY ADD LOT NO: 131977

HRI No. 8881352796 Sterilization Date:11/23/2021

The Sterilization Process at Cardinal Health has been established and validated in accordance with ISO 11137, Sterilization of Healthcare Products. All established dosage requirements are traceable to this nationally recognized standard.
Products to be sterilized are separated into product families based on product characteristics. Validation is conducted for each product family. Periodic monitoring is conducted via dose audits and bio-burden testing. The frequency of testing is based on the requirements of ISO 11137.
The Sterility Assurance Level (SAL) for the sterilized products is established in accordance with ANSI/AAMI ST67:2011, Sterilization of health care products-Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"
All validation data and individual protocols are maintained at Cardinal Health.

By: Curt Hawker DATE: 11-24-21
Sterilization

By: Amanda Ewson Sr Quality Engineer DATE: 10 DEC 2021
Quality Assurance Manager

Reference Document No:
GS10000229

DC00074376 Rev 0

TRITECHFORENSICS
identify. collect. preserve.

TUG10 OEM Statement

The Tri-Tech Forensics, Inc. (TTF) gray stoppered 10ml blood tubes, product number TUG10 are made under TTF FDA 510(K) number K922342. These tubes are privately labeled and manufactured by Cardinal Health solely for Tri-Tech Forensics and are Cardinal Health product number 8881352796.

Tube Specifications
10ml – 16x100 mm
Potassium Oxalate = 15.0 - 26.0 mg/tube
Sodium Fluoride = 88.0 – 112.0 mg/tube

Sincerely

Eric A. Barton

Eric Barton
Vice President

3811 INTERNATIONAL BOULIVARD STE 100 • LELAND, NORTH CAROLINA 28451
TRITECHFORENSICS.COM • TRITECH@TRITECHUSA.COM • 910.457.6600 • 800.438.7884 • (FAX) 910.457.0094

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