



Cardinal Health  
1222 Sherwood Road  
Norfolk, NE 68701  
402.371.9010 main

cardinalhealth.com

## CERTIFICATE OF COMPLIANCE

TO: *Tri Tech Forensics*

P.O. NO. *85645*

LOT NO. *129138*

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.

*17 SEP 2021*

DATE

BY: *Rene M. DeLuiz, QA Supervisor*  
QUALITY ASSURANCE MANAGER

Cardinal Health  
1222 Sherwood Road  
Norfolk, NE 68701  
402.371.9010 main



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**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: TT-BCS GRA 16X100 10ML P.O.-F

LOT NO: 129138

HRI No. 8881-352796

Sterilization Date: 9-12-2021

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: *C. Hines*  
Sterilization Manager

DATE: Sept 17, 2021

By: *Rene M. DeAlvarez, QA Supervisor*  
Quality Assurance Manager

DATE: 17 SEP 2021

*Julian Burton* 8-18-20  
 QA APPROVED  
*U Me Shum* 9-1-20

**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	02/26/2020
Lot Number	199130		
Description	SODIUM FLUORIDE, A.C.S.		
Country of Origin	India	Suggested Retest Date	Mar/2022

N/A			
Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	White powder
ASSAY	%	>= 99	99.8
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	0.2
POTASSIUM (K)	%	<= 0.02	0.003
SODIUM FLUOSILICATE	%	<= 0.1	0.05
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.



# CERTIFICATE OF ANALYSIS

Printed: 6/7/2021

Page 1 of 1

Customer No : 30248

Customer : VWR  
INTERNATIONAL

Customer PO : 4512717751

Order Number : 3353297

Delivery # : 120378851

Catalog : P1355

Potassium Oxalate, Monohydrate, Crystal,  
Reagent, ACS

Lot : 1KD0550

**ORIGINAL**

Chemical Formula :  $C_2O_4K_2.H_2O$

CAS# : 6487-48-5

Formula Weight : 184.23

*J. Prunty 6-11-21*

QA APPROVED  
*A. Singh 7-6-21*

## Test

Limit  
Min. Max.

## Results

Test	Limit Min. 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

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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  
Gardena, CA 90248



### **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

A handwritten signature in blue ink that reads "Eric A. Barton".

Eric Barton  
Vice President

