Cardinal Health 1222 Sherwood Road Norfolk, NE 68701 402.371.9010 main



cardinalhealth.com

### **CERTIFICATE OF COMPLIANCE**

TO: Tri Tech Forensics

P.O. NO. 90155

LOT NO. 219292

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.

DUNINADBA

DATE

ÓLIALITY ASSURANCE

FM20013768 Rev 2

Cardinal Health 1222 Sherwood Road Norfolk, NE 68701 402.371.9010 main



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# ERTIFICATE OF STERILITY Blood Collection

This is to certify that the product meets all the sterility requirements as specified by Cardinal Health with a sterility assurance level of 10<sup>-3</sup>. 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. 219292

HRI No. 8881352796

Sterilization Date: 6/16/2022

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.

Sterilization

Quality Assurance

DATE: 30/11/2022

### **BLOOD COLLECTION LOT CONTROL** FINAL TUBE ASSAY RELEASE

GS10001646

LOT NO.:

HRI NO.:

TEST RESULTS

Sodium Fluoride:

A5414-1, A5483

Potassium Oxalate:

A5506

LOT# 219292

HRI: 8881-352796

Assay: Potassium Oxalate

6/21/2022

Notebook Reference: Tube Assay #01

Specification: 15.0-26.0 mg/tube

LOT# 219292 HRI: 8881-352796

Assay: Sodium Fluoride

6/29/2022

Notebook Reference: Tube Assay #01

mg/tube 97.8

98.7

99.0 98.0 99.2

108.0

96.5 95.7

95.1

101.0

P

Ρ

Ρ

P

Ρ

Ρ

Specification: 88.0 - 112.0 mg/tube

ml titer	mg/tube
23.40	20.84 P
23.70	21.10 P
23.10	20.57 P
22.75	20.26 P
23,35	20.79 P
22.30	19.86 P
23.05	20.52 P
23.00	20.48 P
24.30	21.64 P
24.10	21.46 P

MEAN: STD DEV: 20.75

0.540

MEAN:

98.9

STD DEV:

3.649

Tested By: Staci Hingst

Tested By:

S. Hingst

A71,000 22

Denu M. De Balu

RELEASED BY:

FM20008183 Rev 3



### **ORIGINAL**

# Certificate of Analysis Approved Approved Approved Approved Approved

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	06/01/2021	
Lot Number	212959			
Description	SODIUM FLUORIDE, A.C.S.			
Country of Origin	India	Suggested Retest Date	Nov/2023	

N/A				
Result Name	Units	Specifications	Test Value	
APPEARANCE		REPORT	WHITE POWDER	
ASSAY	%	>= 99	100	
CHLORIDE	. %	<= 0.005	<0.005	
HEAVY METALS (as Pb)	%	<= 0.003	<0.003	
IDENTIFICATION	PASS/FAIL	= PASS TEST	PASS TEST	
INSOLUBLE MATTER	%	<= 0.02	<0.02	
IRON (Fe)	%	<= 0.003	<0.003	
LOSS ON DRYING @ 105 C	%	<= 0.3	<0.3	
POTASSIUM (K)	%	<= 0.02	<0.02	
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

### ORIGINAL

### Certificate of Analysis Thermo Fisher 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 22/22/2021
Lot Number	210107	\$15.254U.M
Description	SODIUM FLUORIDE, A.C.S.	
Country of Origin	India	Suggested Retest Date: Nov/2023

N/A				
Result Name	Units - 17	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

Potassium Oxalate, Monohydrate, Crystal BAKER ANALYZED® A.C.S. Reagent





Material No.: 3212-05

Batch No.: 22D2561018 Manufactured Date: 2021-12-02

Retest Date: 2028-11-30

Revision No.: 0

## Certificate of Analysis

Meets ACS Reagent Chemical Requirements.

Test	Specification	Result
ACS - Assay (KzC2O++H2O)	98.5 - 101.0 %	99.2 %
ACS – Insoluble Matter	< 0.01 %	< 0.01 %
ACS - Neutrality	Passes Test	Passes Test
ACS - pH of 5% Solution at 25°C	7.0 ~ 8.5	8.2
ACS - Chloride (CI)	≤ 0.002 %	< 0.002 %
ACS - Sulfate (SO <sub>4</sub> )	≤ 0.01 %	< 0.01 %
ACS - Ammonium (NH <sub>4</sub> )	≤ 0.002 %	< 0.002 %
ACS - Heavy Metals (as Pb)	≤ 0.002 %	< 0.002 %
ACS - Iron (Fe)	≤ 0.001 %	< 0.001 %
ACS - Sodium (Na)	≤ 0.02 %	< 0.02 %
ACS – Substances Darkened by Hot H≥SO4	Passes Test	Passes Test

For Laboratory, Research, or Manufacturing Use

Country of Origin: USA Packaging Site: Paris Mfg Ctr & DC





#### **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 Barton Vice President

Esia a. Borton



September 23rd, 2022

Washington State Patrol Toxicology Laboratory Division 2203 Airport Way S Seattle WA, 98134

RE: Washington State Blood Alcohol Collection Kits

Blood Alcohol Collection Kits Reorder Number: BA-2WA

TTF Lot No.	Kit Serial No.	Kit Exp.	Tube Lot No.	Tube Exp.	Prep Pad Exp.
68601	N/A	5/31/2024	219292	5/31/2024	N/A

RECEIVED

JUL 19 2024

WSP TOX LAB