

# COVIDIEN

P. O. Box 1169  
Norfolk, Nebraska 68702-1169

Tel: (402) 371-9010

## Certificate of Sterility

To: *Tri-Tech Forensics*

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This is to certify that the following product meets all the sterility requirements as specified by **COVIDIEN** with a sterility assurance level of  $10^{-3}$ . The lot was gamma radiation sterilized and dosimetric released in accordance with **COVIDIEN** procedures, the AAMI recommended practice, and 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

HRI No. 8881-352796

Lot No. 734724

Sterilization Date 11/09/2017

The Sterilization Process at Covidien 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 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 Covidien.

Sterilization Manager:

*allan murphy*

Date:

12-12-2017

Quality Assurance:

*Doree M. Doherty*

Date:

12 DEC 2017



## CERTIFICATE OF COMPLIANCE

TO: *Tri-Tech Forensics*

P.O. NO. *60728*

LOT NO. *734724*

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 COVIDIEN. INDIVIDUAL INSPECTION RECORDS ARE AVAILABLE UPON REQUEST FOR SPECIFIC LOTS.

*12 DEC 2017*

DATE

BY: *Rene M. DePalma, DE*

QUALITY ASSURANCE MANAGER

EC031099

FM20013768 Rev 0

BLOOD COLLECTION LOT CONTROL  
FINAL TUBE ASSAY RELEASE

LOT NO.: 734 724	HRI NO.: 8881-352796
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TEST RESULTS

SODIUM FLUORIDE:	A4996, A5024
POTASSIUM OXALATE:	A4663, A5041

LOT # 734724  
HRI: 8881-352796  
ASSAY: POTASSIUM OXALATE  
12/8/2017  
NOTEBOOK REF: VM47PG65  
SPECIFICATION: 15.0-26.0 mg/tube

LOT # 734724  
HRI: 8881-352796  
ASSAY: SODIUM FLUORIDE  
12/8/2017  
NOTEBOOK REF: VM47PG66  
SPECIFICATION: 88.0-112.0-32.0 mg/tube

ml titer	mg/tube		mg/tube	
24.80	21.54	P	99.9	P
24.15	20.97	P	105.9	P
24.50	21.28	P	102.3	P
25.75	22.36	P	104.9	P
26.20	22.75	P	107.1	P
26.15	22.71	P	97.1	P
27.25	23.66	P	104.9	P
25.40	22.06	P	93.0	P
25.50	22.14	P	94.1	P
27.95	24.27	P	91.5	P

MEAN: 22.37  
STD DEV: 1.030

MEAN: 100.1  
STD DEV: 5.802

TESTED BY: VIOLA MCSHANNON

TESTED BY: VIOLA MCSHANNON

*Viola McShannon*  
12-08-17

RELEASED BY: <i>J. Hingst</i>	DATE: 12-8-17
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ORIGINAL

*Pharm 4-11-17*



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

Certificate of Analysis

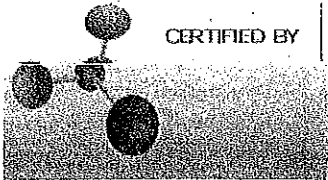
Fisher Scientific's Quality System has been found to conform to Quality Management System Standard ISO9001:2008 standard by SAI Global Certificate Number CERT - 0090918

QA APPROVED  
*AMT 4-11-17*

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. Fisher Scientific expressly disclaims all warranties, expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. Certain products (USP/FCC/NF/EP/BP/JP grades) are sold for use in food, drug, or medical device manufacturing. Fisher does not claim regulatory coverage under 21 CFR nor maintain DMF's with the FDA. The following are the actual analytical results obtained:

Catalog Number	S299	Quality Test / Release Date	11/29/2016
Lot Number	167642		
Description	SODIUM FLUORIDE, A.C.S.		
Country of Origin	India	* Suggested Retest Date	Nov-2021

Result name	Units	Specifications	Test Value
APPEARANCE		REPORT	White powder
ASSAY	%	>= 99	100.3
CHLORIDE	%	<= 0.005	<0.005
HEAVY METALS (as Pb)	%	<= 0.003	<0.0030
IDENTIFICATION	PASS/FAIL	= PASS TEST	PASS TEST
INSOLUBLE MATTER	%	<= 0.02	0.003
IRON (Fe)	%	<= 0.003	<0.0030
LOSS ON DRYING @ 105 C	%	<= 0.3	0.05
POTASSIUM (K)	%	<= 0.02	<0.020
SODIUM FLUOSILICATE	%	<= 0.1	<0.10
SULFATE (SO4)	%	<= 0.03	<0.030
SULFITE	%	<= 0.005	<0.005
TITRATABLE ACID	mEq/g	<= 0.03	<0.030
TITRATABLE BASE	mEq/g	<= 0.01	<0.010



*Jessica Bailey-Wyche*

Quality Assurance Specialist - Certificate of Analysis Fair Lawn

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

Certificate of Analysis



ORIGINAL

Certificate of Analysis

*J. Hamm* 1-5-17  
 QA APPROVED  
*V. McShane* 1-5-17

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

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Catalog Number	S299	Quality Test / Release Date	7/19/2016
Lot Number	164105		
Description	SODIUM FLUORIDE, A.C.S.		
Country of Origin	India	* Suggested Retest Date	Jul-2021

Result name	Units	Specifications	Test Value
APPEARANCE		REPORT	White powder
ASSAY	%	>= 99	99.0
CHLORIDE	%	<= 0.005	<0.005
HEAVY METALS (as Pb)	%	<= 0.003	<0.0030
IDENTIFICATION	PASS/FAIL	= PASS TEST	PASS TEST
INSOLUBLE MATTER	%	<= 0.02	0.003
IRON (Fe)	%	<= 0.003	<0.0030
LOSS ON DRYING @ 105 C	%	<= 0.3	0.02
POTASSIUM (K)	%	<= 0.02	0.010
SODIUM FLUOSILICATE	%	<= 0.1	<0.01
SULFATE (SO4)	%	<= 0.03	<0.030
SULFITE	%	<= 0.005	<0.005
TITRATABLE ACID	mEq/g	<= 0.03	<0.030
TITRATABLE BASE	mEq/g	<= 0.01	<0.010



*Jerisa Bailey-Wyche*

Quality Assurance Specialist - Certificate of Analysis Fair Lawn

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 \*Based on suggested storage condition.