

Certificate of Analysis for NR-36492

Mycobacterium tuberculosis, Strain East African Indian 91_0079, Gamma-Irradiated Whole Cells

Catalog No. NR-36492

This reagent is the tangible property of the U.S. Government.

Product Description: *Mycobacterium tuberculosis* (*M. tuberculosis*), strain East African Indian 91_0079 was grown to late-log phase in glycerol-alanine-salts medium and inactivated by exposure to 2.4 mRads of ionizing gamma irradiation using a ¹³⁷Cs source. Confirmation of inactivation was performed by Alamar Blue assay. A dose of 2.4 mRads of gamma irradiation kills *M. tuberculosis* to a 10²⁰ degree of certainty while maintaining 93% to 95% of the biological activity of the enzymes. The bacilli are harvested by filtration and washed with PBS pH 7.4.

Lot: 61391647 Manufacturing Date: 12AUG2013

Production and QC testing were performed by Colorado State University under the TB Vaccine Testing and Research Materials Contract (NIH). The Colorado State University documentation for bulk lot 13.EAI.7.16.7.WCg is attached. This lot was aliquoted at Colorado State University and each vial contains approximately 10 g of *Mycobacterium tuberculosis*, strain East African Indian 91_0079 gamma-irradiated whole cells.

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WORK SHEET FOR γ-IRRADIATED CELLS

General Information Lot Number: 13.EAI.7.16.7.WCg

Species: M. tuberculosis
Strain: East African Indian 91 0079

Growth Conditions: Medium: GAS

of Fernbachs: <u>16</u> # of Roller bottles: <u>0</u>
Inoculation Date: <u>7.16.13</u> Harvest Date: <u>7.30.13</u>
SOP # used for Harvest: <u>PP003.3 1/11/13 version</u>

Wet Weight: 52.4g

Date irradiated: 8.12.13 By: IC

Alamar Blue QC Information

Date Started: 8.28.13 Date Checked: 8.30.13

Positive Control: Positive X Negative

OD = .1 change: 0.0392

Sample: Positive_____ Negative__X____

OD=.1 change: 0.0014

Aliquot Information

(Research Associate)

1 x 52.4g in 230ml falcon tube

(Laboratory Supervisor)

(date)

	0.73	0.75	0.75	0.74		OD.0001	-0.02	-0.01	0.00	-0.01		OD.0001	-0.01
	0.73	0.75	0.75	0.75		OD.001 OD.0001	-0.02	00.00	0.00	0.01		100. do	-0.01
009/	0.74	0.75	0.76	0.93	48hr Minus Blank	10. do	-0.01	00.00	0.01	0.18	48hr Average	10. do	00'0
48 hr 570/600	0.80	0.81	0.82	2.59	48hr	1. 00	0.05	90.0	0.07	1.84	48h	1. do	90.0
	8-30-13.							Sample		Pos. Cont.			Sample
	62.0	0.80	62.0	0.92		01	-0.14	-0.04	-0.03	-0.01		01	-0.07
						00.00						OD:0001	
	0.76	0.78	0.77	06.0	¥	OD .001	-0.17	-0.15	-0.16	40.04		0D .001	-0.16
009/	0.76	0.78	0.76	0.92	24hr Minus Blank	OD.01 OD.001 OD.0001	-0.17	-0.15	-0.17	-0.02	24hr Average	0D.00	-0.17
24hr 570/600	0.77	0.77	0.76	1.12	24hr	0D.1	-0.17	-0.16	-0.18	0.18	24	00.1	-0.17
A 100 C	8-29-13.							Sample		Pos. Cont.			Sample
	76.0	0.94	96.0	0.94	Г	OD.0001	0.00	0.00	0.01	-0.02	Г	OD.0001	0.01
	66.0	0.93	0.95	0.94			0.02	-0.04	-0.01	-0.03			-0.01
	96.0	0.94	0.95	0.93	Blank	1 OD .001	-0.01	-0.03	-0.02	0.04	age	1 OD .001	-0.02
- 570/600					Initial Minus Blank	10. do				W	Initial Average	10. do	
Initial 0 hr 570/600	0.97	0.95	0.95	0.93	Init	00.1	00.0	-0.02	-0.0	-0.04	1	0D.1	-0.01
	8-28-13.	13.EAI.7.16.7.WCg						Sample	8	Pos. Cont.			Sample

Sample .1 Sample .01 Pos .1 Pos .01

