



# Maxim Biomedical, Inc.

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## CAMBRIDGE BIOTECH HIV-1 SERUM WESTERN BLOT KIT

Part Number: 98002

Master Kit Lot: A0122

### Certificate of Analysis

KIT EXPIRATION: 04/22/10

KIT COMPONENTS	Lot No.	Exp. Date
Master Strip Lot	91261	08/06/10
Wash Buffer	WB367	04/22/10
Blotting Buffer	BB340	09/08/10
Blotting Powder	BP272	05/24/10
Conjugate 1	BG450	05/26/10
Conjugate 2	AH304	06/10/10
Substrate A	SA302	08/14/10
Substrate B	SB304	08/04/10
Non-Reactive Control	NC530	08/26/10
Weakly Reactive Control	WP334	10/30/10
Strongly Reactive Control	SP338	09/19/10

#### TESTING RESULTS

TEST	SPECIFICATION	
Physical Inspection	Kit must contain all components and evidence correct labeling and product insert	PASS
HIV-1 Western Blot Kit Response against Reference Panel & CBER	Must be equivalent to designations when in both the overnight and one-day assay format.	PASS
Infectivity of Lysed Antigen	Negative	PASS
Function Assay: consistency	Antigen profile must exhibit reactivity to p17, p24, p31, gp41, p51, p55, p66, and gp160.	PASS
Function Assay: specificity	Reference weak positive must exhibit reactivity to p24 and gp160	PASS

#### BIOBURDEN TESTING COMPONENT

COMPONENT	SPECIFICATION	
Strips	No observable growth beyond 10 <sup>-3</sup> dilution	PASS
Wash Buffer	≤9 CFU / sample	PASS
Blotting Buffer	≤9 CFU / sample	PASS
Blotting Powder	≤9 CFU / gram	PASS
Conjugate 1	≤9 CFU / sample	PASS
Conjugate 2	≤9 CFU / sample	PASS
Substrate A	≤9 CFU / sample	PASS
Substrate B	≤9 CFU / sample	PASS
Non -Reactive Control	≤9 CFU / sample	PASS
Weakly Reactive Control	≤9 CFU / sample	PASS
Strongly Reactive Control	≤9 CFU / sample	PASS

Comments: All testing conducted and reported on this protocol passed all required specifications.

Released By: Jason Hoff 08/17/09