



# Maxim Biomedical, Inc.

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## CAMBRIDGE BIOTECH HIV-1 SERUM WESTERN BLOT KIT

Part Number: 98002

Master Kit Lot: B0216

### Certificate of Analysis

**KIT EXPIRATION:** 08/04/10

**KIT COMPONENTS**

	Lot No.	Exp. Date
Master Strip Lot	91491	08/29/10
Wash Buffer	WB370	12/09/10
Blotting Buffer	BB341	12/09/10
Blotting Powder	BP273	03/17/11
Conjugate 1	BG452	12/09/10
Conjugate 2	AH305	09/11/10
Substrate A	SA302	08/14/10
Substrate B	SB304	08/04/10
Non-Reactive Control	NC532	12/14/10
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	<b>PASS</b>
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.	<b>PASS</b>
Infectivity of Lysed Antigen	Negative	<b>PASS</b>
Function Assay: consistency	Antigen profile must exhibit reactivity to p17, p24, p31, gp41, p51, p55, p66, and gp160.	<b>PASS</b>
Function Assay: specificity	Reference weak positive must exhibit reactivity to p24 and gp160	<b>PASS</b>

**BIOBURDEN TESTING**

**COMPONENT**

**SPECIFICATION**

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

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

Released By: AMardine 10/01/09