



Maxim Biomedical, Inc.

Certificate of Analysis

Cambridge Biotech HIV-1 Serum Western Blot Kit

Part Number: 98002

Kit Expiration:

Kit Lot:

Kit Component Summary:

<u>Component</u>	<u>Lot No.</u>	<u>Expiration Date</u>
Master Strip Lot		
Second Strip Lot		
Third-Forth Strip Lot		
Fifth-Sixth Strip Lot		
Wash Buffer		
Blotting Buffer		
Blotting Powder		
Conjugate 1		
Conjugate 2		
Substrate A		
Substrate B		
Non-Reactive Control		
Weakly Reactive Control		
Strongly Reactive Control		

Testing Results

<u>Test Methods</u>	<u>Specification</u>	<u>Result</u>
Physical Inspection:	Kit contains all components with correct labeling and dating	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 Results

<u>Components</u>	<u>Specification</u>	<u>Result</u>
Strips	No observable growth beyond 10 ⁻³ 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: _____

Date: _____