GBC General Biologicals Corporation

Reveal. Better Life.

GB HIV Ag-Ab COMB

Earlier Detection

Detect Both Antigen / Antibody

New Method

Increase the sensitivity and decrease the risk of false negative results

Reliable Quality

manufactured under ISO 13485:2003

CE 0344 TFDA 007587

GB HIV Ag-Ab COMB Kit is a 4 generation assay, developed and evaluated in compliance with the new Common Technical Specifications 2009/886/EC (CTS) as required by the article 5 of the IVD Directive 98/79/EC.

GBC Elisa System

GB Wato™ Microplate Washer	S00346
GB Rito™ Microplate Reader	S00345
Dynex DS2®	S00337
Dynex DSX®	S00338

Ag - Subtype Detection

NIBSC reference samples	NIBSC Code	OD 450/650nm	CO	OD/CO	Result
NIBSC BWS for anti HIV-1	99/750	1.989	0.268	7.4	POS
NIBSC 1 in 5 BWS for anti HIV	99/710	1.204	0.268	4.5	POS
NIBSC Monitor Sample for anti HIV-2	99/674	3.596	0.268	13.3	POS
NIBSC, ref panel 02/210, HIV-1/subt A	02/210	3.727	0.228	16.4	POS
NIBSC, ref panel 02/210, HIV-1/subt B	02/210	3.718	0.228	16.3	POS
NIBSC, ref panel 02/210, HIV-1/subt C	02/210	3.97	0.228	17.5	POS
NIBSC, ref panel 02/210, HIV-1/subt E	02/210	4	0.228	17.6	POS
NIBSC, ref panel 02/210, HIV-1/group O	02/210	3.898	0.228	17.1	POS
NIBSC, ref panel 02/210, anti HIV-2	02/210	3.808	0.228	16.7	POS
NIBSC, ref panel 02/210, diluent control	02/210	0.049	0.228	0.2	NEG

Commercial samples from NIBSC were tested for immune-reactivity.All samples are detected with the GB HIV Ag-Ab COMB kit.

Ab/Ag -Diagnostic Sensitivity

HIV Ag/Ab positive samples were tested for sensitivity using GB HIV Ag-Ab COMB Kit. The number of specimen tested were: HIV-1 Ab positive specimen (n=310), HIV-1 Ab positive specimen, non-B subtype (n=44), HIV Ab/Ag positive specimen (n=50), HIV-2 Ab positive specimen (n=60).

Specimen Type	Reactive	Non-Reactive	Sensitivity
HIV-1 Ab Positive Specimen	310	0	100%
HIV-1 Ab Positive Specimen,non-B subtype	44	0	100%
HIV Ab/Ag Positive Specimen	50	0	100%
HIV-2 Ab Positive Specimen	100	0	100%
Total	504	0	100%

The Diagnostic Sensitivity for anti-HIV antibody detection, calculated on 504 positive samples,is 100%.

Ag - Analytical Sensitivity

Conc. IU/ml NIBSC 90/636	GB HIV Ag-Ab COMB S/co	Other HIV Ag-Ab S/co
3.125	5.64	2.03
1.563	3.17	1.1
0.781	1.73	0.74
0.391	1.12	0.61
0.195	0.88	0.47
0.098	0.53	NT

The analytical sensitivity for HIV-1 p24 antigen using GB HIV Ag-Ab COMB kit was assessed by testing commercially available NIBSC International Standard for HIV-1 p24 antigen, Cat#90/636).
The tables show that GB HIV Ag-Ab COMB kit can detect 0.391 IU/mL.

Diagnostic Specificity (Normal Human Sera)

Specificity has been evaluated by testing 2 types of specimen samples:
Type 1: Blood Donor Samples
Type 2: Hospitalized Patient Samples
The results are shown in the following table:

Type#	#Samples Tested	Initially Reactive	Repeated Reactive	%Specificity
1	5126	7	5	99.9%
2	208	2	2	99.04%
Total	5334	9	7	99.9%

SPECIFICATION:

Diagnostic Sensitivity	100.00%
Diagnostic Specificity	≥ 99.7%
Substrate	TMB
New Method	4th generation assay
Sample Type	serum/plasma

ORDERING INFORMATION:

Catalogue No.	Product
4EAIC11	GB HIV Ag-Ab COMB - 96T
4EAIC13	GB HIV Ag-Ab COMB - 480T

Due to continuous development, specifications are subject to change without prior notice.

Authorised Distributor

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