



AiD™ HBsAg ELISA

*Developing Scientifically
Focusing on the Health*

Analytical Sensitivity: **<0.1 IU/ml**
Sensitivity: **100%**
Specificity: **99.92%**
Incubation time: **60'+30'+30'**
Specimen volume: **100μl**
Shelf-life: **15 months**

Analytical Sensitivity

The analytical sensitivity of the AiD™ HBsAg ELISA was determined with the second international standard for HBsAg, subtype adw2, genotype A, NIBSC code 00/588.

NIBSC 00/588 IU/ml	Mean S/CO
1	29.35
0.5	17.53
0.25	8.50
0.12	3.91
0.063	2.01
0.031	0.88
0.016	0.31
0.008	0.15
0.004	0.01

Linear Interpolation between s/co 2.01 & 0.88	
0.069	1.00

The analytical sensitivity of the AiD™ HBsAg ELISA is **0.069 IU/ml (NIBSC 00/588)**. This meets the specifications described in the Common Technical Specifications (2002/364/EC) for HBsAg tests.

Clinical Sensitivity

AiD™ HBsAg ELISA was evaluated for sensitivity on 22 HBV commercial available seroconversion panels, and on total 403 HBsAg positive samples including 146 HBsAg HBV genotyped and HBsAg subtyped samples.

HBV genotyped samples include the following numbers:

- Genotype A: 32 samples
- Genotype B: 30 samples
- Genotype C: 11 samples
- Genotype D: 30 samples
- Genotype E: 30 samples
- Genotype F: 13 samples

The samples represent the following HBsAg subtypes: adw, adw2, adw4, adr, ayw1, ayw2, ayw3 and ayw4.

Results: All positive samples detected as positive, including the HBV genotypes A-F or HBsAg subtypes. The sensitivity of AiD™ HBsAg ELISA is **100%**.

Analytical Specificity (Potential cross-reacting blood samples)

100 samples representing related infections were tested:

- anti-HIV 34 samples
- anti-HCV 33 samples
- anti-HBc 33 samples

98 out of 100 samples had negative screening results for HBsAg with the AiD™ HBsAg ELISA.

The two false positive samples (one anti-HCV reactive and one anti-HBc reactive) were negative in Abbott PRISM HBsAg Test and negative with a PCR based test.

Analytical Specificity (Hospitalized patients)

200 blood samples from patients were tested with the AiD™ HBsAg ELISA test. All samples were previously tested negative for HBsAg with the ABBOTT PRISM HBsAg test.

191 out of 200 samples were negative results for HBsAg with the AiD™ HBsAg ELISA screening test. 8 out of 9 initially positive samples repeated reactive test results.

Clinical Specificity

- European blood donors (n=5038): **99.78%**
- Chinese blood donors (n=10,820): **99.92%**



Seroconversion Panels

The 22 hepatitis B virus (HBV) seroconversion panels were chosen to determine HBsAg reactivity in adequate bleeding intervals. Sensitivity is expressed by means of the following scores:

- the number of positive bleeds divided by the total number of panels
- the sum of days since 1st bleed for the 1st positive detection for each panel divided by the total number of panels

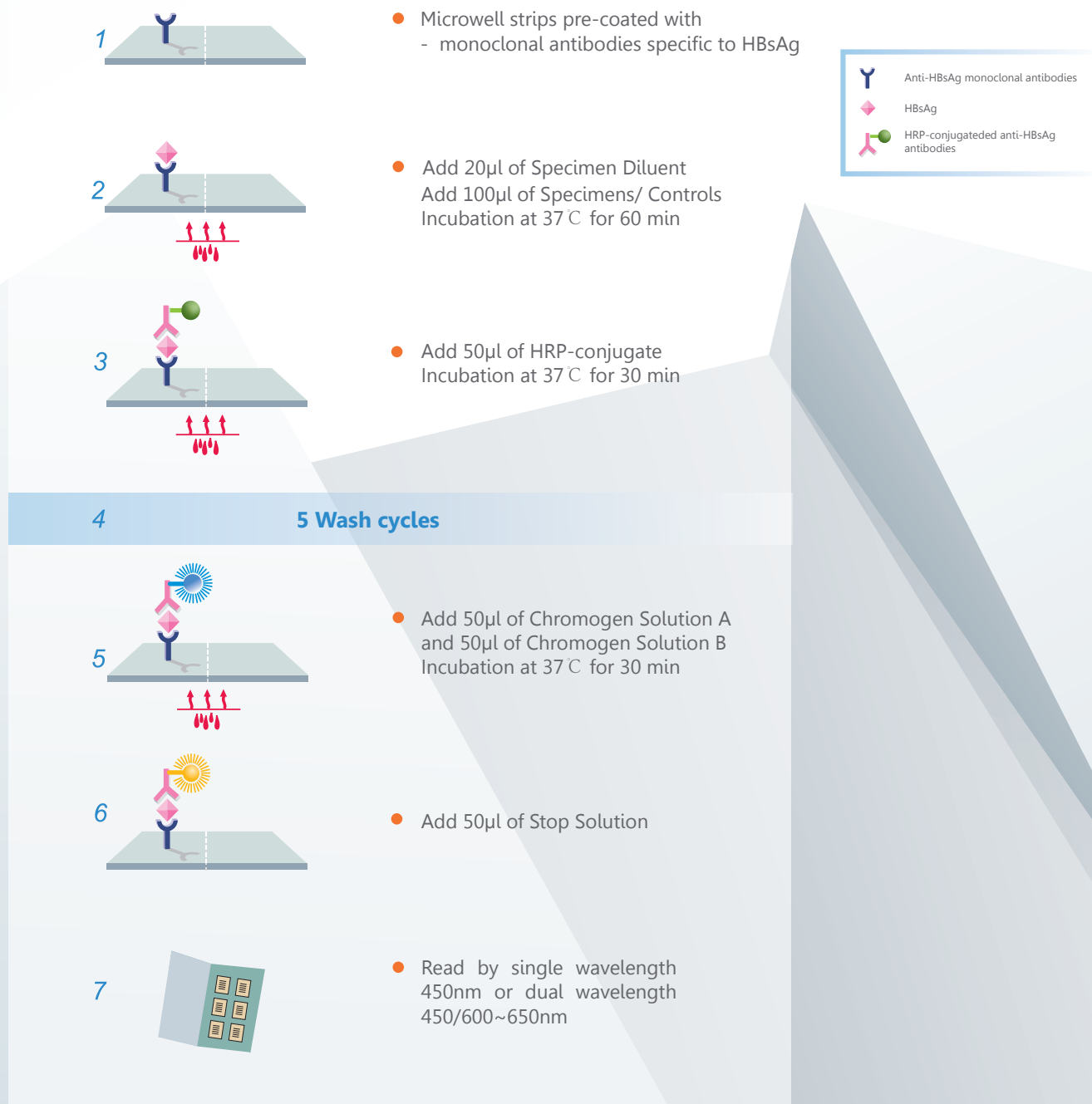
The scores of the AiD™ HBsAg ELISA were then compared with the scores of the "CE minimum standard" which is the least sensitive HBsAg CE assay within the range of CE-marked assays. The difference is calculated between the scores of the minimum standard and the AiD™ HBsAg ELISA.

Panel		CE minimum standard		AiD™ HBsAg ELISA	
		# positive samples	1 st day positive	# positive samples	1 st day positive
1	PHM 916	2	65	1	69
2	PHM 919	4	19	4	19
3	PHM 928	3	14	3	14
4	PHM 929	2	25	4	18
5	PHM 931	4	19	3	21
6	PHM 932	7	61	7	61
7	6273	2	25	2	25
8	6274	5	8	6	4
9	6275	3	22	3	22
10	6279	1	28	1	28
11	65449	1	33	4	21
12	65524	3	47	4	44
13	65556	2	35	3	9
14	65584	2	149	3	142
15	66201	4	49	4	49
16	66537	3	41	4	36
17	67303	3	79	3	79
18	67449	4	86	4	86
19	67694	4	110	3	112
20	67773	2	20	2	20
21	68541	4	30	4	30
22	68739	4	47	4	47
Sum		69	1012	76	956
Score		3.14	46	3.45	43.45

Over the total of 22 panels, the AiD™ HBsAg ELISA detected antigen in 76 samples or an average of 3.45 positive samples per panel hence AiD™ HBsAg ELISA detects overall 7 samples more than the CE minimum standard or 0.31 samples per panel.

The AiD™ HBsAg ELISA detected antigen on an average of 43.45 days after the first bleed, which is **2.55 days per panel earlier** than the CE minimum standard.

Principle and Procedures



Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WB-1296	AiD™ HBsAg ELISA	Antigen	Serum/Plasma	96T/kit
WB-12480	AiD™ HBsAg ELISA	Antigen	Serum/Plasma	480T/kit