

1. Abstract

The study was designed to evaluate the clinical performance characteristics of the HBsAg Rapid Test, a visual read lateral flow immunoassay. Samples used were both fresh collected serum or -80°C plasma samples. The clinical performance characteristics of the study device test were calculated by comparing the study device test result with the predicate devices used in the hospital diagnostic routine (Roche for plasmas and Abbott for serums). A total of 300 individuals were included in the study, of which 30% (100/300) were determined to be positive for Hepatitis B. The HBsAg Rapid Test demonstrated an overall clinical sensitivity of 99% (99/100) and a clinical specificity of 100% (200/200) when compared with predicate methods.

2. Detail Description

The HBsAg Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of hepatitis B antigens in serum or plasma specimen from individuals with suspected hepatitis infection in conjunction with clinical presentation and the results of routine hospital laboratory tests.

The study is designed to demonstrate suitability of the HBsAg Rapid Test for hepatitis detection in clinical serum or plasma specimens.

The goal of the study is to compare the antigen test results to the corresponding predicate results for overall sensitivity and specificity. Specimens are collected from patients showing hepatitis symptoms as well as asymptomatic participants. Study staff records participants' information. For each study participant, samples were collected and stored (plasma) or freshly collected and tested (serum).

3. Material and Methods

3.1 Study arms

A total of 100 positives and 200 negatives individuals were subjected to testing procedures in order to diagnose hepatitis infection.

3.2 Materials

3.1.1 Candidate Device

AllTest HBsAg Rapid Test (IHBSG-402)
Lot No.: ATHBSG22030001-T

3.1.2 Predicate Device

Device name: Cobas CV HB 6800

Brand: Roche

Lot : J04805, exp 2023-11-30

Used for plasma samples

and

Device name: Alinity s HBsAg and Alinity s HBsAg Confirmatory

Brand: Abbott

Used for serum samples

3.1.3 Clinic Sites and Personnel

The study will be carried out at professional laboratory of clinical institution by laboratory professionals for performance evaluation of Candidate test by comparison between Candidate Device and Predicate Device.

Information of clinical institution

Samples source site

Name of clinical institution: Hopital St Louis

Address: 1 avenue claude Vellefaux, 75010 Paris France

Qualification: Virology dept

Tel: [REDACTED]

Test site

Name of clinical institution : Centre de ressources Biologique, Hôpital Lariboisière

Address: 2 rue ambroise Paré, 75010 Paris France

Qualification : service hospitalier des Technologies Avancées pour la Biologie Médicale

Tel: [REDACTED]

Personnel introduction

Clinical Operator	Position/Title	Responsibility
<i>Pr Philippe Manivet</i>	Director	Head of CRB hop lariboisière, Paris
<i>Jean-Marc Josse</i>	Coordinator	Biosignis SAS

4. Study Design

4.1 Overall Design

This clinical performance study is a comparison between AllTest HBsAg Rapid Test and Predicate Device test. In case of any discrepancy between the Alltest test and the Predicate Device test, the final standard shall be the third-party test result. The evaluation will be carried out at least 1 site, however, more sites can be added if sufficient subjects/samples are applicable.

4.2 Number of Specimens

1) Estimated enrollment

<i>Items</i>	<i>Specimen Number</i>	<i>Specimen Type</i>	<i>Specimen Requirement</i>
Total number of HBsAg samples	≥300	Serum/Plasma	Specimens from outpatient, physical examination or inpatient patients

2) Special requirements of the total samples

<i>Items</i>	<i>Specimen Number</i>	<i>Specimen Requirement</i>
Positive Clinical samples	≥100	Specimens from outpatient, physical examination or inpatient patients
Negative Clinical samples	≥200	Specimens from outpatient, physical examination or inpatient patients

5. Study Method

5.1 Specimen Collection

Collect samples according to Package Inserts of Candidate Device and Predicate Device. Both fresh samples and left-over samples are acceptable if they are stored properly. The fresh samples collected specially for this study need be consented.

Serum:

Collect whole blood specimen into a collection tube without anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the serum supernatant. Don't leave samples in centrifuge after spinning.

Plasma:

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA K2, heparin sodium, citrate sodium or potassium oxalate) according to standard venous blood sampling process. Gently invert the collection tube for several times and leave to settle for 30 minutes for blood coagulation, and then spin at 1,000 to 1,200 g for 10 to 15 minutes at room temperature to obtain the plasma supernatant. Don't leave samples in centrifuge after spinning.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2 – 8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

5.2 Sample Acceptance Criterion

Inclusion criteria:

- a. Human blood of outpatient, physical examination or inpatient patients who need to be tested for HBsAg.
- b. Clear non-hemolyzed specimens can be obtained.
- c. The information of specimen from the individuals can be traceable.

Exclusion criteria:

- a. The sample size is too small to complete the whole experiment.
- b. Overdue and deteriorated samples that were not collected, processed or stored as required.
- c. Samples of patients with repeated enrolment (only valid samples of the first enrolment of the patient are retained).
- d. Other samples that can be proved not to be operated according to the requirements of the scheme.

Professional personnel will test Candidate Device in the lab environment, by reading the device instructions and performing the test.

5.3 Samples Testing

Allow the test, specimen, and buffer to reach room temperature (15-30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

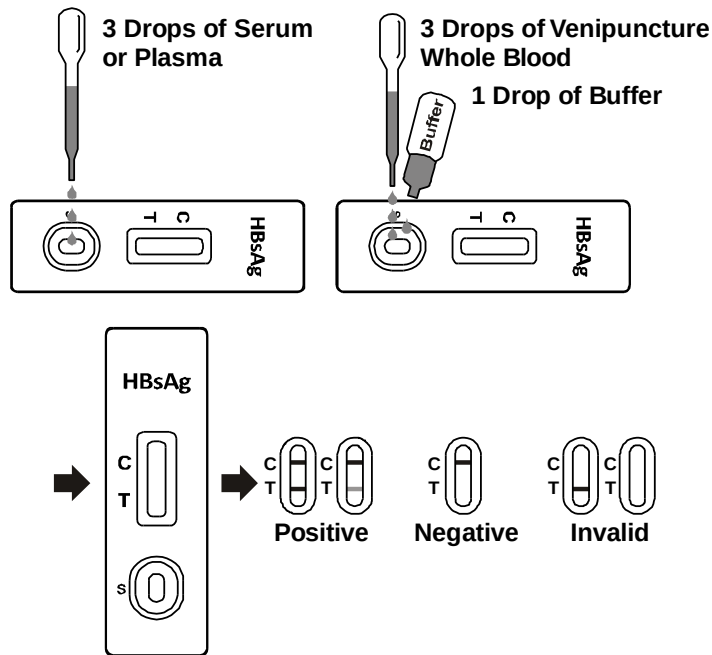
- Hold the dropper vertically and transfer **3 drops of serum or plasma** to the specimen well (S) of test cassette and start the timer. See illustration below.

For **Venous Whole Blood** specimen:

- Hold the dropper vertically and transfer **3 drops of whole blood** to the specimen well (S) of test cassette, then **add 1 drop of buffer**, and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 15~30 minutes.** Do not interpret the result after 30 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



6. Statistical Analyses

This test will adopt statistic analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:

Table: Candidate Device Results vs Predicate Device Results

		Predicate Device Testing		Total
		Positive	Negative	
Candidate Device Testing	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	a+b+c+d

$$\text{Relative Sensitivity} = [a / (a+c)] \times 100\%$$

$$\text{Relative Specificity} = [d / (b+d)] \times 100\%$$

$$\text{Overall Accuracy} = [(a+d) / (a+b+c+d)] \times 100\%$$

We'll do Kappa consistency test on the result, and when the Kappa value is between 0-1, it means better consistency between the test results of the two devices. It is normally considered consistent when the Kappa value bigger than 0.75.

$$\text{Kappa} = \frac{N(a+d) - (\gamma_1 C_1 + \gamma_2 C_2)}{N^2 - (\gamma_1 C_1 + \gamma_2 C_2)}$$

7. Data Collection

All the testing data will be listed in data sheet of attachment section (Raw data will be kept in laboratory).

8. Data Analysis and Conclusion

All test results for Candidate Device and Predicate Device will be analyzed and recorded with data sheet and the rate of concordant and accuracy shall be calculated.

9. Attachment

Data Sheet for Clinical Specimens. (Results from the AllTest HBsAg Rapid Test Form and Predicate Device Test Result Form will be transferred to this Data Sheet)

10. Result of the clinical test

Plasma samples were -80°C stored samples selected on their positive or negative status

Serum plasma were freshly collected samples, temporary stored at 4°C, waiting for the predicate result.

This strategy has given the required number of positive vs negative samples

Samples collected were tested by an operator, but the reading of the result was made by another operator blindly, to avoid any “driven” analysis of the result.

IHBSG-402 Lot: ATHBSG22030001-T

Method		Predicate Device Testing		Total
		Positive	Negative	
Candidate Device Testing	Positive	99	0	99
	Negative	1	200	201
Total		100	200	300

Relative Sensitivity= 99%

Relative Specificity=100%

Overall Accuracy=99,67%

Kappa=0.99

11. Discussion and conclusions

The HBsAg rapid test clinical verification study enrolled 300 consecutive patients with 100/300 (33%) positive. The overall accuracy compared to reference methods was 99,67% with 99 % sensitivity and 100 % specificity for the 300 cases.

In conclusion, by analyzing the test results of the product tested and the reference product, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of such systems and can be used for auxiliary diagnosis of putative Hepatitis B infection.

Name: Pr. Philippe Manivet.

Function: Head of the department Biobank Lariboisière.

Date: 09/16/2022.

Signature:



Data Sheet for Clinical Results

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
1	HBsAg	serum	M	83	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,2836	index	Alinity	Antigen detection	KP	NG	
2	HBsAg	serum	M	64	11/07/2022	positive	12/07/2022	ATHBSG22030001-T	positive	5018	index	Alinity	Antigen detection	KP	NG	
3	HBsAg	serum	M	62	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,2547	index	Alinity	Antigen detection	KP	NG	
4	HBsAg	serum	M	86	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,3603	index	Alinity	Antigen detection	KP	NG	
5	HBsAg	serum	M	71	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,3299	index	Alinity	Antigen detection	KP	NG	
6	HBsAg	serum	F	54	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,2763	index	Alinity	Antigen detection	KP	NG	
7	HBsAg	serum	M	61	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,3565	index	Alinity	Antigen detection	KP	NG	
8	HBsAg	serum	M	67	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,3565	index	Alinity	Antigen detection	KP	NG	
9	HBsAg	serum	M	31	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,4266	index	Alinity	Antigen detection	KP	NG	
10	HBsAg	serum	F	79	11/07/2022	negative	12/07/2022	ATHBSG22030001-T	negative	0,3470	index	Alinity	Antigen detection	KP	NG	
11	HBsAg	serum	M	26	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3310	index	Alinity	Antigen detection	KP	NG	
12	HBsAg	serum	F	29	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3388	index	Alinity	Antigen detection	KP	NG	
13	HBsAg	serum	F	21	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3353	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
14	HBsAg	serum	M	50	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2693	index	Alinity	Antigen detection	KP	NG	
15	HBsAg	serum	F	81	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3666	index	Alinity	Antigen detection	KP	NG	
16	HBsAg	serum	F	37	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2658	index	Alinity	Antigen detection	KP	NG	
17	HBsAg	serum	F	73	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3310	index	Alinity	Antigen detection	KP	NG	
18	HBsAg	serum	M	57	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2761	index	Alinity	Antigen detection	KP	NG	
19	HBsAg	serum	M	44	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3516	index	Alinity	Antigen detection	KP	NG	
20	HBsAg	serum	F	50	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2830	index	Alinity	Antigen detection	KP	NG	
21	HBsAg	serum	M	43	20/06/2022	positive	18/07/2022	ATHBSG22030001-T	positive	2680	index	Alinity	Antigen detection	KP	NG	
22	HBsAg	serum	M	74	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2780	index	Alinity	Antigen detection	KP	NG	
23	HBsAg	serum	F	51	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2745	index	Alinity	Antigen detection	KP	NG	
24	HBsAg	serum	M	72	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2780	index	Alinity	Antigen detection	KP	NG	
25	HBsAg	serum	M	39	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2658	index	Alinity	Antigen detection	KP	NG	
26	HBsAg	serum	F	67	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3001	index	Alinity	Antigen detection	KP	NG	
27	HBsAg	serum	M	24	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3353	index	Alinity	Antigen detection	KP	NG	
28	HBsAg	serum	M	21	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2693	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
29	HBsAg	serum	M	40	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3735	index	Alinity	Antigen detection	KP	NG	
30	HBsAg	serum	M	74	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3396	index	Alinity	Antigen detection	KP	NG	
31	HBsAg	serum	F	29	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3075	index	Alinity	Antigen detection	KP	NG	
32	HBsAg	serum	F	22	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3092	index	Alinity	Antigen detection	KP	NG	
33	HBsAg	serum	F	21	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3110	index	Alinity	Antigen detection	KP	NG	
34	HBsAg	serum	F	31	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3127	index	Alinity	Antigen detection	KP	NG	
35	HBsAg	serum	M	32	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3301	index	Alinity	Antigen detection	KP	NG	
36	HBsAg	serum	F	30	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3388	index	Alinity	Antigen detection	KP	NG	
37	HBsAg	serum	F	48	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3567	index	Alinity	Antigen detection	KP	NG	
38	HBsAg	serum	M	66	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3585	index	Alinity	Antigen detection	KP	NG	
39	HBsAg	serum	F	31	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2933	index	Alinity	Antigen detection	KP	NG	
40	HBsAg	serum	M	55	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3447	index	Alinity	Antigen detection	KP	NG	
41	HBsAg	serum	F	17	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3127	index	Alinity	Antigen detection	KP	NG	
42	HBsAg	serum	M	41	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3242	index	Alinity	Antigen detection	KP	NG	
43	HBsAg	serum	M	57	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3207	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
44	HBsAg	serum	F	49	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2796	index	Alinity	Antigen detection	KP	NG	
45	HBsAg	serum	M	33	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2884	index	Alinity	Antigen detection	KP	NG	
46	HBsAg	serum	M	53	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3457	index	Alinity	Antigen detection	KP	NG	
47	HBsAg	serum	M	37	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3197	index	Alinity	Antigen detection	KP	NG	
48	HBsAg	serum	M	42	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3911	index	Alinity	Antigen detection	KP	NG	
49	HBsAg	serum	F	37	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2881	index	Alinity	Antigen detection	KP	NG	
50	HBsAg	serum	M	47	20/06/2022	positive	18/07/2022	ATHBSG22030001-T	positive	4219	index	Alinity	Antigen detection	KP	NG	
51	HBsAg	serum	F	72	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2502	index	Alinity	Antigen detection	KP	NG	
52	HBsAg	serum	M	36	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,4039	index	Alinity	Antigen detection	KP	NG	
53	HBsAg	serum	F	24	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3631	index	Alinity	Antigen detection	KP	NG	
54	HBsAg	serum	M	20	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3023	index	Alinity	Antigen detection	KP	NG	
55	HBsAg	serum	M	42	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3388	index	Alinity	Antigen detection	KP	NG	
56	HBsAg	serum	M	33	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3040	index	Alinity	Antigen detection	KP	NG	
57	HBsAg	serum	M	26	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3110	index	Alinity	Antigen detection	KP	NG	
58	HBsAg	serum	M	31	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2832	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
59	HBsAg	serum	F	19	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3092	index	Alinity	Antigen detection	KP	NG	
60	HBsAg	serum	F	39	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3110	index	Alinity	Antigen detection	KP	NG	
61	HBsAg	serum	F	31	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3457	index	Alinity	Antigen detection	KP	NG	
62	HBsAg	serum	F	40	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2658	index	Alinity	Antigen detection	KP	NG	
63	HBsAg	serum	M	31	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3857	index	Alinity	Antigen detection	KP	NG	
64	HBsAg	serum	M	23	20/06/2022	positive	18/07/2022	ATHBSG22030001-T	positive	1966	index	Alinity	Antigen detection	KP	NG	
65	HBsAg	serum	M	35	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3284	index	Alinity	Antigen detection	KP	NG	
66	HBsAg	serum	M	60	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3509	index	Alinity	Antigen detection	KP	NG	
67	HBsAg	serum	F	56	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3718	index	Alinity	Antigen detection	KP	NG	
68	HBsAg	serum	M	65	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2658	index	Alinity	Antigen detection	KP	NG	
69	HBsAg	serum	F	54	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3345	index	Alinity	Antigen detection	KP	NG	
70	HBsAg	serum	M	65	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2899	index	Alinity	Antigen detection	KP	NG	
71	HBsAg	serum	F	34	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3036	index	Alinity	Antigen detection	KP	NG	
72	HBsAg	serum	F	45	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2796	index	Alinity	Antigen detection	KP	NG	
73	HBsAg	serum	F	29	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2830	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
74	HBsAg	serum	M	47	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3122	index	Alinity	Antigen detection	KP	NG	
75	HBsAg	serum	F	29	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3104	index	Alinity	Antigen detection	KP	NG	
76	HBsAg	serum	M	36	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2728	index	Alinity	Antigen detection	KP	NG	
77	HBsAg	serum	F	26	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3362	index	Alinity	Antigen detection	KP	NG	
78	HBsAg	serum	M	66	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3336	index	Alinity	Antigen detection	KP	NG	
79	HBsAg	serum	M	38	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3822	index	Alinity	Antigen detection	KP	NG	
80	HBsAg	serum	M	38	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2936	index	Alinity	Antigen detection	KP	NG	
81	HBsAg	serum	M	45	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3579	index	Alinity	Antigen detection	KP	NG	
82	HBsAg	serum	F	51	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3857	index	Alinity	Antigen detection	KP	NG	
83	HBsAg	serum	M	87	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3705	index	Alinity	Antigen detection	KP	NG	
84	HBsAg	serum	F	72	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2813	index	Alinity	Antigen detection	KP	NG	
85	HBsAg	serum	F	42	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3293	index	Alinity	Antigen detection	KP	NG	
86	HBsAg	serum	M	60	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3207	index	Alinity	Antigen detection	KP	NG	
87	HBsAg	serum	M	51	21/06/2022	positive	18/07/2022	ATHBSG22030001-T	positive	1367	index	Alinity	Antigen detection	KP	NG	faint band
88	HBsAg	serum	M	26	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3825	index	Alinity	Antigen detection	KP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
89	HBsAg	serum	F	54	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2241	index	Alinity	Antigen detection	KP	NG	
90	HBsAg	serum	F	36	21/06/2022	positive	18/07/2022	ATHBSG22030001-T	positive	4249	index	Alinity	Antigen detection	CP	NG	
91	HBsAg	serum	M	37	20/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2710	index	Alinity	Antigen detection	CP	NG	
92	HBsAg	serum	F	42	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3944	index	Alinity	Antigen detection	CP	NG	
93	HBsAg	serum	F	60	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2919	index	Alinity	Antigen detection	CP	NG	
94	HBsAg	serum	M	27	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3058	index	Alinity	Antigen detection	CP	NG	
95	HBsAg	serum	M	60	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3683	index	Alinity	Antigen detection	CP	NG	
96	HBsAg	serum	M	22	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3544	index	Alinity	Antigen detection	CP	NG	
97	HBsAg	serum	M	34	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3394	index	Alinity	Antigen detection	CP	NG	
98	HBsAg	serum	F	25	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3128	index	Alinity	Antigen detection	CP	NG	
99	HBsAg	serum	M	20	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3499	index	Alinity	Antigen detection	CP	NG	
100	HBsAg	serum	F	16	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,4830	index	Alinity	Antigen detection	CP	NG	
101	HBsAg	serum	M	76	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,2884	index	Alinity	Antigen detection	CP	NG	
102	HBsAg	serum	M	73	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3104	index	Alinity	Antigen detection	CP	NG	
103	HBsAg	serum	M	20	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3162	index	Alinity	Antigen detection	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
104	HBsAg	serum	F	56	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3718	index	Alinity	Antigen detection	CP	NG	
105	HBsAg	serum	M	65	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3413	index	Alinity	Antigen detection	CP	NG	
106	HBsAg	serum	M	43	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3224	index	Alinity	Antigen detection	CP	NG	
107	HBsAg	serum	M	49	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3156	index	Alinity	Antigen detection	CP	NG	
108	HBsAg	serum	F	65	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3585	index	Alinity	Antigen detection	CP	NG	
109	HBsAg	serum	M	32	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3293	index	Alinity	Antigen detection	CP	NG	
110	HBsAg	serum	M	22	21/06/2022	negative	18/07/2022	ATHBSG22030001-T	negative	0,3036	index	Alinity	Antigen detection	CP	NG	
111	HBsAg	serum	F	20	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4532	index	Alinity	Antigen detection	CP	NG	
112	HBsAg	serum	M	60	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3375	index	Alinity	Antigen detection	CP	NG	
113	HBsAg	serum	F	21	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3735	index	Alinity	Antigen detection	CP	NG	
114	HBsAg	serum	M	54	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3944	index	Alinity	Antigen detection	CP	NG	
115	HBsAg	serum	F	18	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4152	index	Alinity	Antigen detection	CP	NG	
116	HBsAg	serum	M	53	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4152	index	Alinity	Antigen detection	CP	NG	
117	HBsAg	serum	F	89	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3849	index	Alinity	Antigen detection	CP	NG	
118	HBsAg	serum	F	24	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3906	index	Alinity	Antigen detection	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
119	HBsAg	serum	M	57	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4095	index	Alinity	Antigen detection	CP	NG	
120	HBsAg	serum	M	44	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4001	index	Alinity	Antigen detection	CP	NG	
121	HBsAg	serum	M	20	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4058	index	Alinity	Antigen detection	CP	NG	
122	HBsAg	serum	M	67	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3413	index	Alinity	Antigen detection	CP	NG	
123	HBsAg	serum	F	66	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4039	index	Alinity	Antigen detection	CP	NG	
124	HBsAg	serum	M	18	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4418	index	Alinity	Antigen detection	CP	NG	
125	HBsAg	serum	M	31	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3811	index	Alinity	Antigen detection	CP	NG	
126	HBsAg	serum	M	54	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,4133	index	Alinity	Antigen detection	CP	NG	
127	HBsAg	serum	M	33	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2601	index	Alinity	Antigen detection	CP	NG	
128	HBsAg	serum	M	53	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2511	index	Alinity	Antigen detection	CP	NG	
129	HBsAg	serum	M	35	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2655	index	Alinity	Antigen detection	CP	NG	
130	HBsAg	serum	M	27	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2691	index	Alinity	Antigen detection	CP	NG	
131	HBsAg	serum	M	61	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2637	index	Alinity	Antigen detection	CP	NG	
132	HBsAg	serum	M	44	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2890	index	Alinity	Antigen detection	CP	NG	
133	HBsAg	serum	F	26	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2944	index	Alinity	Antigen detection	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
134	HBsAg	serum	F	29	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2818	index	Alinity	Antigen detection	CP	NG	
135	HBsAg	serum	F	26	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2637	index	Alinity	Antigen detection	CP	NG	
136	HBsAg	serum	M	24	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3197	index	Alinity	Antigen detection	CP	NG	
137	HBsAg	serum	F	43	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2637	index	Alinity	Antigen detection	CP	NG	
138	HBsAg	serum	F	24	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2402	index	Alinity	Antigen detection	CP	NG	
139	HBsAg	serum	M	42	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,3468	index	Alinity	Antigen detection	CP	NG	
140	HBsAg	serum	M	62	18/07/2022	negative	22/07/2022	ATHBSG22030001-T	negative	0,2890	index	Alinity	Antigen detection	CP	NG	
141	HBsAg	Plasma	F	31	09/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	KIT COBAS 6800/8800 HBV 96T IVD	CP	NG	clots in sample
142	HBsAg	Plasma	M	25	10/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	147000	UI/mL	COBAS 6800	PCR	CP	NG	clots in sample
143	HBsAg	Plasma	M	52	13/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	26100	UI/mL	COBAS 6800	PCR	CP	NG	
144	HBsAg	Plasma	F	35	13/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
145	HBsAg	Plasma	F	19	14/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
146	HBsAg	Plasma	F	26	14/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
147	HBsAg	Plasma	F	37	15/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
148	HBsAg	Plasma	F	38	14/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
149	HBsAg	Plasma	M	40	17/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	12000	UI/mL	COBAS 6800	PCR	CP	NG	
150	HBsAg	Plasma	F	32	16/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
151	HBsAg	Plasma	F	25	16/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
152	HBsAg	Plasma	F	31	20/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
153	HBsAg	Plasma	M	82	21/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	33100000	UI/mL	COBAS 6800	PCR	CP	NG	
154	HBsAg	Plasma	F	26	20/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
155	HBsAg	Plasma	M	27	21/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	27800	UI/mL	COBAS 6800	PCR	CP	NG	
156	HBsAg	Plasma	F	34	21/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
157	HBsAg	Plasma	M	35	23/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	12900	UI/mL	COBAS 6800	PCR	CP	NG	
158	HBsAg	Plasma	F	24	22/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
159	HBsAg	Plasma	M	59	24/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	281000	UI/mL	COBAS 6800	PCR	CP	NG	
160	HBsAg	Plasma	F	35	24/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
161	HBsAg	Plasma	F	28	25/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
162	HBsAg	Plasma	M	26	28/01/2020	positive	22/07/2022	ATHBSG22030001-T	positive	99600000	UI/mL	COBAS 6800	PCR	CP	NG	
163	HBsAg	Plasma	F	33	27/01/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
164	HBsAg	Plasma	F	33	04/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
165	HBsAg	Plasma	F	36	04/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
166	HBsAg	Plasma	F	42	06/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	361000	UI/mL	COBAS 6800	PCR	CP	NG	
167	HBsAg	Plasma	F	27	06/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
168	HBsAg	Plasma	F	36	22/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
169	HBsAg	Plasma	F	42	24/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	23400	UI/mL	COBAS 6800	PCR	CP	NG	
170	HBsAg	Plasma	F	26	12/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	6130000	UI/mL	COBAS 6800	PCR	CP	NG	
171	HBsAg	Plasma	F	21	12/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
172	HBsAg	Plasma	F	36	12/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
173	HBsAg	Plasma	M	33	17/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	24300	UI/mL	COBAS 6800	PCR	CP	NG	
174	HBsAg	Plasma	M	25	17/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	6110000 00	UI/mL	COBAS 6800	PCR	CP	NG	
175	HBsAg	Plasma	F	42	17/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	15500	UI/mL	COBAS 6800	PCR	CP	NG	
176	HBsAg	Plasma	F	68	19/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	20000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
177	HBsAg	Plasma	M	38	10/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	291000	UI/mL	COBAS 6800	PCR	CP	NG	
178	HBsAg	Plasma	M	30	11/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	65100	UI/mL	COBAS 6800	PCR	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
179	HBsAg	Plasma	M	60	09/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	13700	UI/mL	COBAS 6800	PCR	CP	NG	
180	HBsAg	Plasma	F	38	05/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed + clots
181	HBsAg	Plasma	F	28	07/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
182	HBsAg	Plasma	F	33	10/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
183	HBsAg	Plasma	M	36	10/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	186000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
184	HBsAg	Plasma	F	49	13/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	108000000	UI/mL	COBAS 6800	PCR	CP	NG	
185	HBsAg	Plasma	F	27	15/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
186	HBsAg	Plasma	F	40	14/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
187	HBsAg	Plasma	F	41	14/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
188	HBsAg	Plasma	F	36	13/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
189	HBsAg	Plasma	M	22	27/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	11200	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
190	HBsAg	Plasma	M	28	28/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	11500	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed + lipids
191	HBsAg	Plasma	M	24	28/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	10900	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
192	HBsAg	Plasma	M	41	02/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	23000	UI/mL	COBAS 6800	PCR	CP	NG	
193	HBsAg	Plasma	M	39	28/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	776000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
194	HBsAg	Plasma	F	32	29/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
195	HBsAg	Plasma	F	29	01/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
196	HBsAg	Plasma	F	25	02/03/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
197	HBsAg	Plasma	F	37	25/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
198	HBsAg	Plasma	F	29	25/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
199	HBsAg	Plasma	M	46	25/02/2020	positive	22/07/2022	ATHBSG22030001-T	positive	36900	UI/mL	COBAS 6800	PCR	CP	NG	
200	HBsAg	Plasma	F	22	24/02/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
201	HBsAg	Plasma	F	42	08/04/2020	positive	22/07/2022	ATHBSG22030001-T	positive	24400	UI/mL	COBAS 6800	PCR	CP	NG	
202	HBsAg	Plasma	M	69	17/04/2020	positive	22/07/2022	ATHBSG22030001-T	positive	127000	UI/mL	COBAS 6800	PCR	CP	NG	
203	HBsAg	Plasma	F	27	20/04/2020	positive	22/07/2022	ATHBSG22030001-T	positive	15400	UI/mL	COBAS 6800	PCR	CP	NG	
204	HBsAg	Plasma	M	40	19/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	1350000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed ++
205	HBsAg	Plasma	F	28	20/06/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
206	HBsAg	Plasma	M	44	22/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	2750000	UI/mL	COBAS 6800	PCR	CP	NG	
207	HBsAg	Plasma	M	32	27/04/2020	positive	22/07/2022	ATHBSG22030001-T	positive	107000	UI/mL	COBAS 6800	PCR	CP	NG	
208	HBsAg	Plasma	M	52	02/05/2020	positive	22/07/2022	ATHBSG22030001-T	positive	27100	UI/mL	COBAS 6800	PCR	CP	NG	

N°	Analyte	Matrix	Gender	Age	Sample collection time	Result Alltest Rapid Test	Test Date Rapid Test	Lot Rapid Test	Interpretation	Result	Result Unit	Instrument	Method	Operator	Reader	comments
209	HBsAg	Plasma	M	41	08/05/2020	positive	22/07/2022	ATHBSG22030001-T	positive	16400000	UI/mL	COBAS 6800	PCR	CP	NG	
210	HBsAg	Plasma	M	32	25/05/2020	positive	22/07/2022	ATHBSG22030001-T	positive	332000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
211	HBsAg	Plasma	M	26	27/05/2020	positive	22/07/2022	ATHBSG22030001-T	positive	54100000	UI/mL	COBAS 6800	PCR	CP	NG	
212	HBsAg	Plasma	M	30	29/05/2020	positive	22/07/2022	ATHBSG22030001-T	positive	16660000	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
213	HBsAg	Plasma	F	34	28/05/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<40	UI/mL	COBAS 6800	PCR	CP	NG	
214	HBsAg	Plasma	F	31	12/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	60700	UI/mL	COBAS 6800	PCR	CP	NG	
215	HBsAg	Plasma	M	31	15/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	361000	UI/mL	COBAS 6800	PCR	CP	NG	
216	HBsAg	Plasma	F	30	15/06/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
217	HBsAg	Plasma	F	35	24/06/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
218	HBsAg	Plasma	M	39	29/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	26500	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
219	HBsAg	Plasma	M	16	30/06/2020	positive	22/07/2022	ATHBSG22030001-T	positive	35400000	UI/mL	COBAS 6800	PCR	CP	NG	
220	HBsAg	Plasma	F	33	01/07/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
221	HBsAg	Plasma	M	24	03/07/2020	positive	22/07/2022	ATHBSG22030001-T	positive	167000	UI/mL	COBAS 6800	PCR	CP	NG	
222	HBsAg	Plasma	F	38	08/07/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<20	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
223	HBsAg	Plasma	M	23	21/07/2020	positive	22/07/2022	ATHBSG22030001-T	positive	759000	UI/mL	COBAS 6800	PCR	CP	NG	

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224	HBsAg	Plasma	M	31	29/07/2020	positive	22/07/2022	ATHBSG22030001-T	positive	9930000	UI/mL	COBAS 6800	PCR	CP	NG	
225	HBsAg	Plasma	F	29	28/07/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
226	HBsAg	Plasma	F	36	01/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
227	HBsAg	Plasma	F	35	07/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
228	HBsAg	Plasma	F	69	11/08/2020	negative	22/07/2022	ATHBSG22030001-T	positive	39400	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
229	HBsAg	Plasma	F	31	10/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
230	HBsAg	Plasma	F	33	12/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
231	HBsAg	Plasma	F	29	12/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
232	HBsAg	Plasma	M	51	17/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	212000	UI/mL	COBAS 6800	PCR	CP	NG	faint band
233	HBsAg	Plasma	M	28	21/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	94400	UI/mL	COBAS 6800	PCR	CP	NG	
234	HBsAg	Plasma	M	35	24/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	108000	UI/mL	COBAS 6800	PCR	CP	NG	
235	HBsAg	Plasma	M	44	26/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	48200	UI/mL	COBAS 6800	PCR	CP	NG	
236	HBsAg	Plasma	M	24	27/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	4460000 00	UI/mL	COBAS 6800	PCR	CP	NG	
237	HBsAg	Plasma	M	66	27/08/2020	positive	22/07/2022	ATHBSG22030001-T	positive	3930000 0	UI/mL	COBAS 6800	PCR	CP	NG	
238	HBsAg	Plasma	F	28	26/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	

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239	HBsAg	Plasma	F	41	27/08/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
240	HBsAg	Plasma	M	35	01/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
241	HBsAg	Plasma	M	58	25/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	6550000 0	UI/mL	COBAS 6800	PCR	CP	NG	
242	HBsAg	Plasma	F	27	26/03/2020	positive	22/07/2022	ATHBSG22030001-T	positive	39600	UI/mL	COBAS 6800	PCR	CP	NG	
243	HBsAg	Plasma	F	34	30/10/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	troubled sample
244	HBsAg	Plasma	F	33	01/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
245	HBsAg	Plasma	F	21	04/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	4030000 0	UI/mL	COBAS 6800	PCR	CP	NG	
246	HBsAg	Plasma	F	26	06/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	561000	UI/mL	COBAS 6800	PCR	CP	NG	
247	HBsAg	Plasma	M	35	09/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	89400	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
248	HBsAg	Plasma	F	27	08/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
249	HBsAg	Plasma	F	30	10/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
250	HBsAg	Plasma	M	33	16/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	3480000 00	UI/mL	COBAS 6800	PCR	CP	NG	
251	HBsAg	Plasma	F	25	14/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
252	HBsAg	Plasma	F	26	14/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
253	HBsAg	Plasma	F	26	15/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	

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254	HBsAg	Plasma	F	29	16/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
255	HBsAg	Plasma	M	62	18/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	625000	UI/mL	COBAS 6800	PCR	CP	NG	
256	HBsAg	Plasma	F	23	17/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
257	HBsAg	Plasma	F	32	18/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
258	HBsAg	Plasma	F	41	20/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	46200	UI/mL	COBAS 6800	PCR	CP	NG	
259	HBsAg	Plasma	F	34	21/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
260	HBsAg	Plasma	F	37	21/11/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
261	HBsAg	Plasma	F	36	23/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	866000	UI/mL	COBAS 6800	PCR	CP	NG	
262	HBsAg	Plasma	F	28	24/11/2020	positive	22/07/2022	ATHBSG22030001-T	positive	118000	UI/mL	COBAS 6800	PCR	CP	NG	
263	HBsAg	Plasma	M	29	03/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
264	HBsAg	Plasma	M	37	07/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	60500	UI/mL	COBAS 6800	PCR	CP	NG	
265	HBsAg	Plasma	M	41	08/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	287000	UI/mL	COBAS 6800	PCR	CP	NG	
266	HBsAg	Plasma	F	42	08/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
267	HBsAg	Plasma	F	35	09/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
268	HBsAg	Plasma	M	27	11/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	40300	UI/mL	COBAS 6800	PCR	CP	NG	

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269	HBsAg	Plasma	F	22	11/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	339000	UI/mL	COBAS 6800	PCR	CP	NG	
270	HBsAg	Plasma	F	26	16/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	45400000	UI/mL	COBAS 6800	PCR	CP	NG	
271	HBsAg	Plasma	M	35	16/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	6270000	UI/mL	COBAS 6800	PCR	CP	NG	
272	HBsAg	Plasma	M	35	16/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	431000	UI/mL	COBAS 6800	PCR	CP	NG	
273	HBsAg	Plasma	F	31	16/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
274	HBsAg	Plasma	M	43	18/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	26600000	UI/mL	COBAS 6800	PCR	CP	NG	
275	HBsAg	Plasma	F	33	20/09/2020	negative	22/07/2022	ATHBSG22030001-T	negative	<10	UI/mL	COBAS 6800	PCR	CP	NG	
278	HBsAg	Plasma	M	34	21/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	11200	UI/mL	COBAS 6800	PCR	CP	NG	
279	HBsAg	Plasma	M	27	28/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	58800000	UI/mL	COBAS 6800	PCR	CP	NG	
284	HBsAg	Plasma	M	34	30/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	301000	UI/mL	COBAS 6800	PCR	CP	NG	
285	HBsAg	Plasma	M	37	30/09/2020	positive	22/07/2022	ATHBSG22030001-T	positive	42500	UI/mL	COBAS 6800	PCR	CP	NG	
286	HBsAg	Plasma	M	44	01/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	34500	UI/mL	COBAS 6800	PCR	CP	NG	
287	HBsAg	Plasma	M	25	02/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	57700000	UI/mL	COBAS 6800	PCR	CP	NG	
291	HBsAg	Plasma	M	41	08/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	1770000	UI/mL	COBAS 6800	PCR	CP	NG	
293	HBsAg	Plasma	M	39	09/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	1690000	UI/mL	COBAS 6800	PCR	CP	NG	

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294	HBsAg	Plasma	M	23	09/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	192000	UI/mL	COBAS 6800	PCR	CP	NG	
296	HBsAg	Plasma	M	44	14/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	>1000000000	UI/mL	COBAS 6800	PCR	CP	NG	
297	HBsAg	Plasma	F	27	15/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	64500000	UI/mL	COBAS 6800	PCR	CP	NG	
300	HBsAg	Plasma	M	54	20/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	>1000000000	UI/mL	COBAS 6800	PCR	CP	NG	lipds
301	HBsAg	Plasma	F	22	21/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	23400	UI/mL	COBAS 6800	PCR	CP	NG	
302	HBsAg	Plasma	M	35	22/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	5550000	UI/mL	COBAS 6800	PCR	CP	NG	
303	HBsAg	Plasma	M	24	27/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	686000000	UI/mL	COBAS 6800	PCR	CP	NG	
305	HBsAg	Plasma	M	29	29/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	14500	UI/mL	COBAS 6800	PCR	CP	NG	hemolysed
308	HBsAg	Plasma	M	53	23/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	61000	UI/mL	COBAS 6800	PCR	CP	NG	
312	HBsAg	Plasma	M	32	26/10/2020	positive	22/07/2022	ATHBSG22030001-T	positive	182000000	UI/mL	COBAS 6800	PCR	CP	NG	
313	HBsAg	serum	F	31	27/07/2022	positive	03/08/2022	ATHBSG22030001-T	positive	4929	index	Alinity	Antigen detection	CP	TG	
314	HBsAg	serum	M	36	27/07/2022	positive	03/08/2022	ATHBSG22030001-T	positive	1988	index	Alinity	Antigen detection	CP	TG	
315	HBsAg	serum	F	61	27/07/2022	positive	03/08/2022	ATHBSG22030001-T	positive	4120	index	Alinity	Antigen detection	CP	TG	
316	HBsAg	serum	M	34	27/07/2022	positive	03/08/2022	ATHBSG22030001-T	positive	4667	index	Alinity	Antigen detection	CP	TG	
317	HBsAg	serum	M	25	01/08/2022	positive	03/08/2022	ATHBSG22030001-T	positive	3116	index	Alinity	Antigen detection	CP	TG	

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318	HBsAg	serum	F	47	22/08/2022	positive	24/08/2022	ATHBSG22030001-T	positive	3143,000 0	index	Alinity	Antigen detection	LS	CT	
319	HBsAg	serum	M	43	22/08/2022	positive	24/08/2022	ATHBSG22030001-T	positive	4802,000 0	index	Alinity	Antigen detection	LS	CT	