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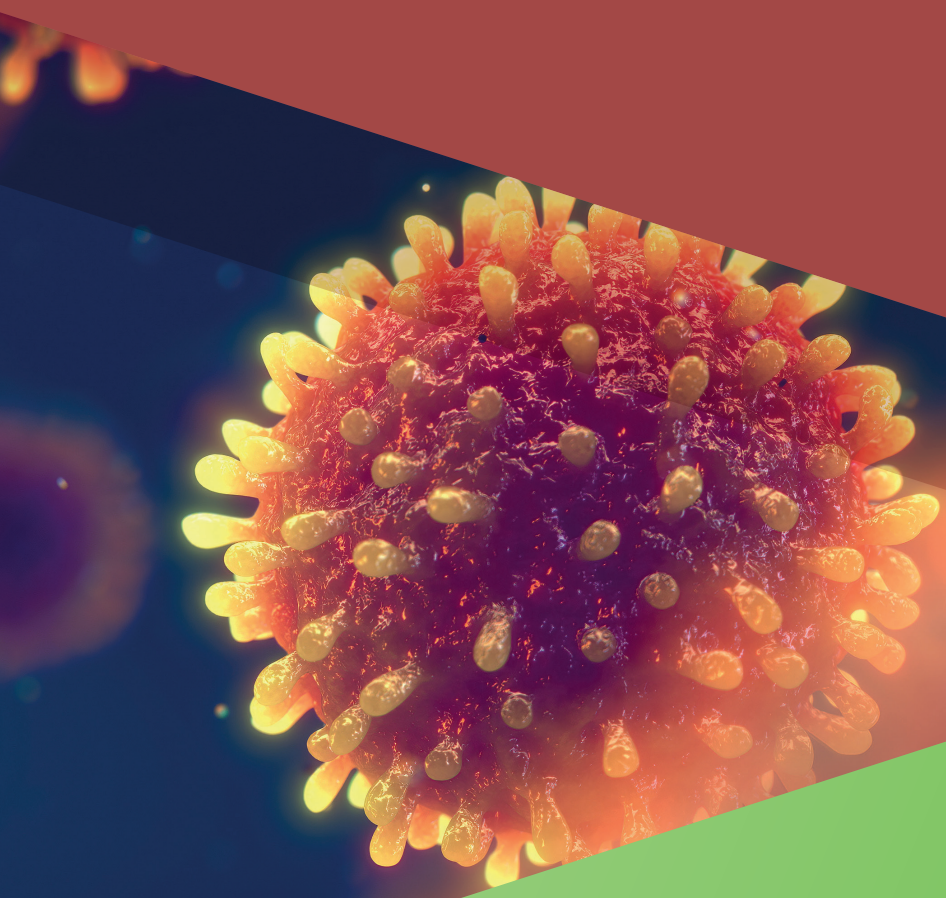

ASSESSMENT

Survey on testing strategies for hepatitis B virus in blood, and tissues and cell donors within the EU/EEA

ECDC ASSESSMENT

Survey on testing strategies for hepatitis B virus in blood, and tissues and cell donors within the EU/EEA

This report was developed in the context of an assessment of microbial safety measures for Substances of Human Origin (SoHO) at the European Union/European Economic Area (EU/EEA) level by the European Centre for Disease Prevention and Control (ECDC).

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Abbreviations

Ag	Antigen
DNA	Deoxyribonucleic acid
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HPC	Haematopoietic progenitor cells
ID	Individual donation
IU	International unit
IVDR	In vitro Diagnostics Regulation
LOD	Limit of detection
MAR	Medically assisted reproduction
MP	Minipools
NA	Not applicable
NAT	Nucleic acid (amplification) test
NFP	National focal point
NR	Not reported
PCR	Polymerase chain reaction
RR	Repeatedly reactive
SoHO	Substances of human origin
TMA	Transcription-mediated amplification

Executive summary

Background

On 13 June 2024, the new Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application (EU) 2024/1938 was published. The European Centre for Disease Prevention and Control (ECDC) was designated as the expert institution for the communicable diseases field and assigned to draft guidelines on the prevention of transmission of hepatitis B virus (HBV) through SoHO. On 1 June 2026, ECDC published 'Guidelines on the prevention of hepatitis B virus transmission through substances of human origin', covering blood and blood components, tissues and non-reproductive cells, and reproductive cells. To assess the donor testing landscape for HBV prior to the publication of the guidelines, ECDC developed surveys to collect information on current HBV testing practice for SoHO donors across the European Union/European Economic Area (EU/EEA). The results of these surveys are shared in this report.

Methods

In the third quarter of 2024, an online survey was distributed to national focal points (NFP) for blood, tissues and non-reproductive cells, and reproductive cells, to gather information on the national donor testing strategies for HBV, including testing algorithms and laboratory testing methods.

Results

The number of countries responding to the survey ranged from 19 countries for tissues and non-reproductive cells and reproductive cells to 25 countries for blood. In addition to the serological tests mandated by the Directive 2002/98/EC and the Directive 2004/23/EC, HBV DNA nucleic acid amplification tests (NAT) are mandatory or recommended in 88%, 58% and 37% of the participating countries for donors of blood and blood components, tissues and non-reproductive cells, and reproductive cells, respectively.

In the blood field, either by law or national recommendation, HBV DNA NAT is performed on individual donations in 52% of countries. Less than 50% of countries reported having a required limit of detection. About half (52%) of the countries perform additional anti-HBc testing for blood donors, either at each donation or only in new donors. When considering the use of HBV DNA NAT as an additional measure to enable the quarantine of donations to be waived, the proportion of countries applying NAT increases to 89% for the tissues and non-reproductive cells and 68% for reproductive cells.

Conclusion

Next to the mandatory serological tests, HBV DNA NAT is currently included in, or complements the SoHO donor testing strategy in most participating countries, for the different SoHO. The survey showed considerable heterogeneity among EU/EEA countries regarding testing SoHO donors for HBV. Future assessments will allow ECDC and EU/EEA countries to understand the impact of the ECDC guidelines on the donor testing strategies for HBV in the EU/EEA.

Introduction

On 13 June 2024, the new Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application was published [1]. This Regulation repeals Directive 2002/98/EC [2] and Directive 2004/23/EC [3], concerning blood and tissues and cells respectively, and it will apply from 2027, three years after its publication, with an extra year for specific provisions.

The Regulation established the European Centre for Disease Prevention and Control (ECDC) as an expert body for developing and updating technical guidelines on the safety and quality of SoHO from a communicable disease threat perspective. In this context, ECDC developed guidelines for the prevention of transmission of the hepatitis B virus (HBV) through SoHO [4]. The guidelines provide requirements and recommendations on laboratory testing methods for screening donors for HBV, and requirements and recommendations on testing strategies for HBV.

This survey report aims to describe the testing requirements for HBV in different European Union/European Economic Area (EU/EEA) countries at the time the ECDC guidelines were developed. It also provides baseline information to EU/EEA countries about the testing landscape before the publication of ECDC guidelines.

A prior mapping exercise was performed by the Directorate-General for Health and Food Safety in 2015, which provided information on more stringent testing requirements adopted by Member States for blood [5] and tissues and cells [6] donors, than what was required in the Directives.

Methods

Study design

An online survey (see Annex 1) was developed and published by ECDC in the EU Survey web application [7]. The survey covered information on the national testing recommendations and laboratory test methods for HBV. The survey was shared with ECDC SoHO-Network national focal points (NFP) of the 30 EU/EEA countries for blood and blood components, tissues and cells, and medically assisted reproduction (MAR).

Data collection

The survey included predominantly closed-ended questions. It was shared with the SoHO-Net NFPs in July 2024 for them to complete by September 2024. Additional data were collected during the data validation period, which occurred between May and June 2025, and between October 2025 and December 2025.

Separate surveys were developed for each SoHO (blood and blood components, tissues and non-reproductive cells, and reproductive cells). The data collected in each survey included information on the required and/or recommended laboratory tests used to screen SoHO donors for HBV in the country, the testing algorithm applied, and the proportion of establishments performing each test.

Data analysis

The survey responses from participating countries were extracted from the EU Survey application in April 2025. We performed a descriptive analysis per SoHO and summarised the results by frequency and proportion of responses. When relevant, the results were summarised in tables or presented in maps. The comments provided by the participating countries were extracted and summarised where relevant.

Data validation

A draft report containing preliminary data was shared with SoHO-Net NFPs in May 2025. The NFPs were asked to validate their data, make changes and provide additional information where needed. The data collected in the data validation period were added to this draft report.

Non-responding countries

No results were included for non-responding countries.

Survey results

Blood and blood components

Twenty-five EU/EEA countries responded to the survey (participation rate of 83%). As of January 2026, no data were provided for Hungary, Ireland, Liechtenstein, Lithuania, and Romania.

National HBV testing strategies for donors

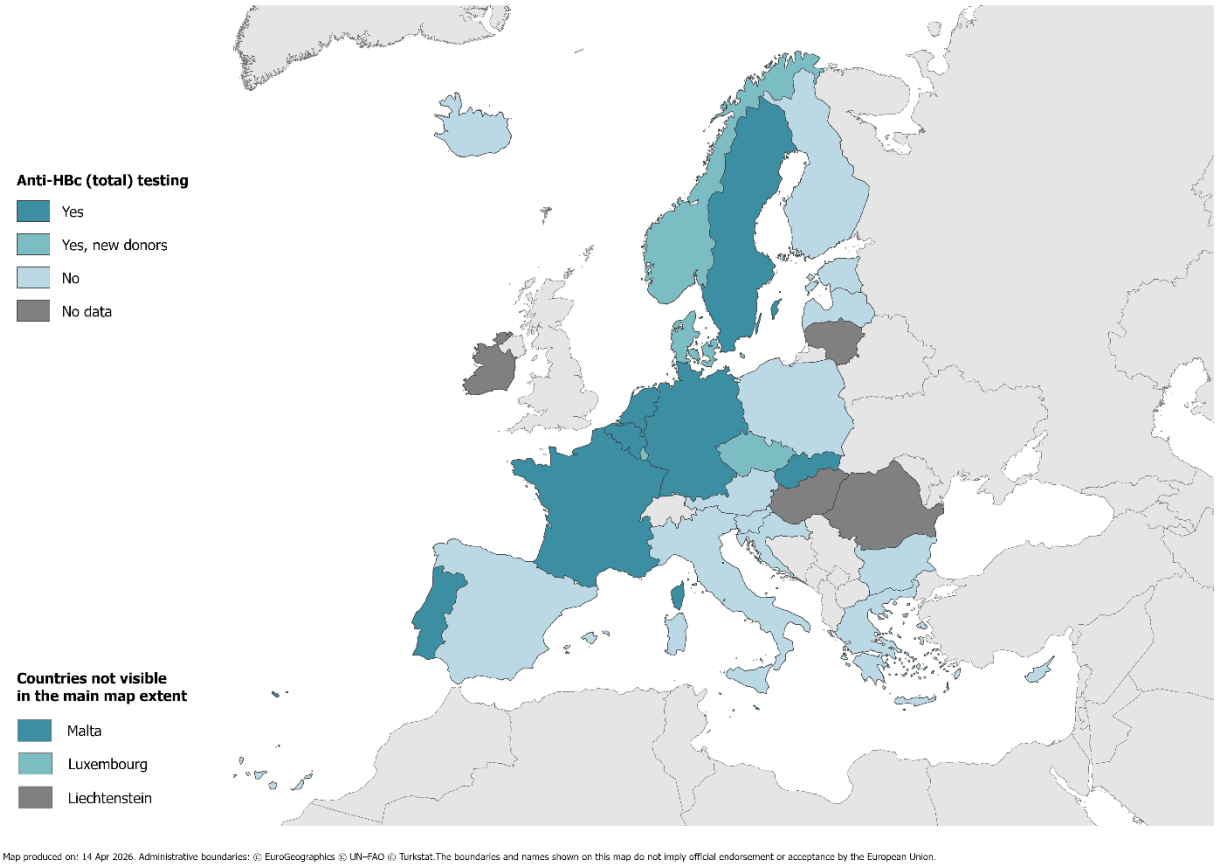
All 25 reporting countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden) provided information on the legally binding and recommended HBV testing strategies at national and/or regional level.

The use of the HBV deoxyribonucleic acid (DNA) nucleic acid (amplification) test (NAT) is mandatory or recommended in 22 (88%) of the participating countries, in addition to the mandatory serological testing for Hepatitis B surface antigen (HBsAg).

In 13 of these countries (59%), HBV DNA NAT is performed on individual donations (ID), while nine (41%) countries did not specify whether they test in ID or in minipools (MP). Less than half of the countries reported a required limit of detection (LOD) for HBV DNA NAT [range: 1.0–1000.0 international units (IU) per ml].

Twelve (48%) countries reported performing anti-HBc (total) detection in addition to HBsAg (see Figure 1). Additional information can be found in Table 1.

Figure 1. Inclusion of anti-HBc (total) in the HBV testing strategy for blood donors, EU/EEA



HBV: hepatitis B virus.

Table 1. HBV testing strategies for blood donors in the EU/EEA, 2025

Country	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT - ID	HBV DNA NAT - MP	HBV DNA NAT (not specified)	Minimum 95% LOD NAT (IU/mL)
Austria[a]							
Belgium							
Bulgaria							
Croatia							5.0
Cyprus							4.3
Czechia							35
Denmark[b]							
Estonia[c]							100.0
Finland							
France[d]							
Germany							900.0
Greece							
Hungary							
Iceland							
Ireland							
Italy							
Latvia[e]							4.3
Liechtenstein							
Lithuania							
Luxembourg[f]							1000.0
Malta							3.0
Netherlands[g]							
Norway[h]							
Poland[i]							24.0
Portugal							Not required
Romania							
Slovakia[j]							
Slovenia							
Spain[k]							1.0
Sweden[l]							

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. ID: individual donation. IU: international unit. LOD: limit of detection. mL: millilitre. MP: minipools. NAT: nucleic acid test.

Comments from the countries:

[a] **Austria -** *(…) A NAT test for HBV DNA may be legally required in addition to HBsAg testing; however, only if a donation facility intends to apply the reduced exclusion periods after risks of exposure to HBV. The type of NAT testing (ID or MP) is not explicitly specified by law.*
[b] **Denmark** *- Anti-HBc (total) is measured only in new donors.*
[c] **Estonia** *- NAT MP testing is allowed by the law, but blood entities opt for multiplex NAT ID.*
[d] **France** *- Pool of 96 for plasma for fractionation, according to the specifications of the fractionation laboratory.*
[e] **Latvia** *- In Latvia, all blood donors' samples for HBV testing are centralised and performed by one laboratory.*
[f] **Luxembourg** *- Anti-HBc (total) test is performed only for new donors or if the donor hasn't come in the last three years.*
[g] **Netherlands** *- HBV DNA NAT is performed in minipools of six donations.*
[h] **Norway** *- For new donors, there is a national recommendation for performing anti-HBc (total).*
[i] **Poland** *- In the case of HBV DNA NAT performed in mini pools, it is performed in four [transcription-mediated amplification (TMA)] or six [polymerase chain reaction (PCR)].*
[j] **Slovakia** *- The National Transfusion Service, which accounts for 75% of all donations, also performs NAT ID, but it is not yet in the national regulation.*
[k] **Spain** *- HBV DNA NAT is performed in minipools of four or six donations.*
[l] **Sweden –** *NAT is legally required if available in the regions. One region is currently performing HBV DNA NAT. Sweden will, by 2027, have legally binding testing with HBsAg, anti-HBc and HBV DNA ID NAT in place in all establishments. There is the aim to introduce MP-NAT at a later stage.*

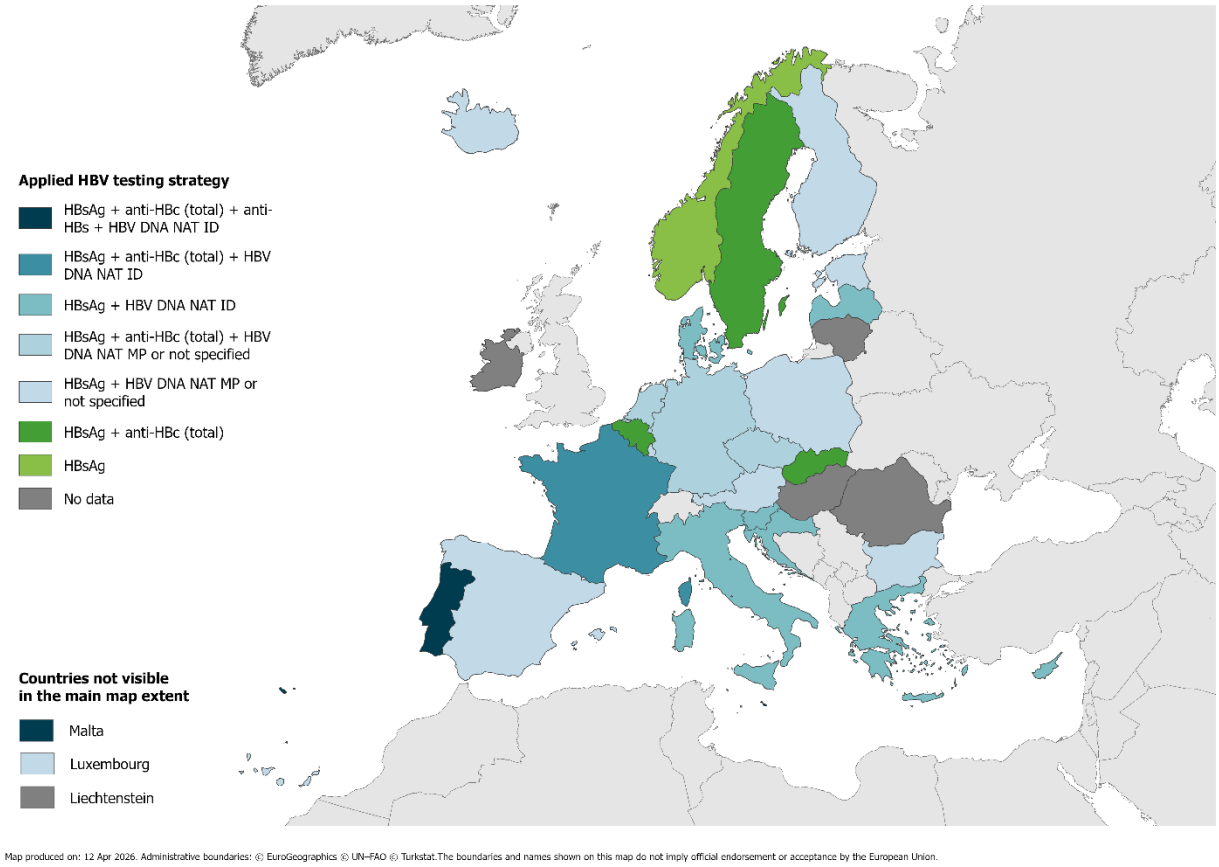
	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Practice in place

Testing algorithms

Most responding countries provided information regarding the currently used testing algorithm. Seven different main combinations of tests are applied within EU/EEA countries regarding testing strategies for HBV, as represented in Figure 2.

Figure 2. HBV main testing strategies (legally binding and/or recommended at the national level) in blood donors, EU/EEA, 2025



Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. ID: individual donation. MP: minipools. NAT: nucleic acid test.

Twenty countries (80%) reported performing the tests included in the main testing strategy simultaneously, with two countries (8%) reporting stepwise approaches to HBV testing. Eight countries (32%) reported performing additional serological tests to guide the decision on the release of donation for clinical use (antibodies against HBsAg (anti-HBs)) or to determine the true status of the donor (anti-HBc, and/or Hepatitis B e antigen (HBeAg) and antibodies against HBeAg (anti-HBe)). Additional information is available in Table 2.

Table 2. Description of algorithms for blood donor testing for HBV, EU/EEA, 2025

Country	Main testing strategy	Test performance	Details of the algorithm
Austria	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	*Serology testing is legally binding for every blood component. Additionally, for blood products collected for direct transfusion without virus inactivation procedures, human immunodeficiency virus (HIV), HBV and hepatitis C virus (HCV) NAT must be performed.*
Belgium	HBsAg + anti-HBc (total)	NR	*No testing algorithm is specified.*
Bulgaria	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	No additional information provided.
Croatia	HBsAg + HBV DNA NAT ID	Simultaneous	*If the result of HBsAg and/or HBV DNA NAT ID is reactive, alternative HBsAg and anti-HBc, anti-HBs, anti-HBe, and HBeAg are performed.*
Cyprus	HBsAg + HBV DNA NAT ID	Simultaneous	*All donations in the Cyprus Blood Establishment are tested individually with two different methods: - Serology: HIV Ag/Ab, HBsAg, syphilis IgG/IgM, and anti-HCV; - NAT (multiplex) detecting HIV RNA/HCV RNA/HBV DNA. (…) Repeatedly reactive samples for HBsAg, HBV DNA NAT or both of them are also tested in the reference laboratory for HBsAg, anti-HBs, anti-HBc IgG and IgM, anti-HBe, and HBeAg to confirm the status of the donor.*
Czechia	HBsAg + anti-HBc (total) + HBV DNA NAT MP or not specified	Simultaneous	*HBsAg and HBV DNA NAT MP on all donations. Anti-HBc (total) on new donors.*
Denmark	HBsAg + HBV DNA NAT ID	Simultaneous	*HBsAg and ID HBV DNA NAT on all donations. Anti-HBc (total) on new donors.*
Estonia	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	*According to the law, reactive HBV DNA NAT MP is followed by HBV DNA NAT ID. If the multiplex ID NAT (HIV, HBV and HCV) is used instead of MP, and it is positive, the next test will be discriminatory ID NAT.*
Finland	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	*HBV DNA NAT initially reactive or repeatedly reactive HBsAg results will lead to testing for anti-HBc and anti-HBs.*
France	HBsAg + anti-HBc (total) + HBV DNA NAT ID	Simultaneous	*Testing strategy performed for each blood donation. Screening for anti-HBs is carried out (…) when the result of anti-HBc is positive, and the result of HBsAg screening is negative.*
Germany	HBsAg + anti-HBc (total) + HBV DNA NAT MP or not specified	Stepwise	*HBsAg and anti-HBc testing must be performed simultaneously for each donation. An additional HBV DNA NAT is only mandatory if the quarantine storage of plasma is waived.*
Greece	HBsAg + HBV DNA NAT ID	Simultaneous	*In the case of a donor positive only for HBsAg and with negative HBV DNA NAT, the donor is tested for anti-HBc and anti-HBs. A second sample is requested in order to repeat the tests.*
Hungary			
Iceland	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	*HBV DNA NAT implemented from and including July 1, 2025, according to Regulation Nr. 1091 September 12th, 2024, on the (7th) amendment to Regulation No. 441/2006 on the collection, processing, preservation, and distribution of blood.*
Ireland			
Italy	HBsAg + HBV DNA NAT ID	Simultaneous	No additional information.
Latvia	HBsAg + HBV DNA NAT ID	Simultaneous	No additional information.
Liechtenstein			
Lithuania			
Luxembourg	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	*Anti-HBc is performed only for new donors or if the donor has not donated in the last three years.*
Malta	HBsAg + anti-HBc (total) + anti-HBs + HBV DNA NAT ID	Simultaneous	*If HBsAg is repeatedly reactive from initial donation and fresh sample, a confirmatory test is performed. If multiplex NAT is reactive, a discriminatory test for HBV is performed. If anti-HBc is repeatedly reactive, the donation is tested for anti-HBs; if the latter is negative, the donation is discarded, but if positive >100 mIU/mL, the donation is released.*

Country	Main testing strategy	Test performance	Details of the algorithm
Netherlands	HBsAg + anti-HBc (total) + HBV DNA NAT MP or not specified	Simultaneous	*If anti-HBc positive, the donor/donation is tested for anti-HBs. If anti-HBs is ≥200 mIU/mL, the donor/donation is accepted.*
Norway	HBsAg	NA	*At every donation: HBsAg.* *New donors: additional anti-HBc (total).*
Poland	HBsAg + HBV DNA NAT MP or not specified	Stepwise or simultaneous	*Algorithm I is performed in sequential order: HBsAg-negative donations are screened for HBV DNA.* *Algorithm II is also allowed, in which HBsAg and HBV DNA NAT are performed simultaneously.* *In case HBsAg and/or HBV DNA NAT are repeatedly reactive, the sample will be referred for HBV DNA testing or/and neutralisation test.*
Portugal	HBsAg + anti-HBc (total) + anti-HBs + HBV DNA NAT ID	NR	No additional information.
Romania			
Slovakia	HBsAg + anti-HBc (total) ± HBV DNA NAT ID	Simultaneous	*In the National Transfusion Service (responsible for 75% of all donations in Slovakia): HBsAg + anti-HBc (total) + HBV DNA NAT are performed simultaneously. Reactive results are sent to the national reference laboratory for confirmation.*
Slovenia	HBsAg + HBV DNA NAT ID	Simultaneous	*Each of the two assays is performed from its own sample: HBsAg and multiplex NAT ID (HCV RNA/HBV DNA/HIV RNA).* *In the case of reactive or grey-zone results for HBsAg, tests are repeated in duplicates; in the case of repeatedly reactive or repeatedly grey-zone HBsAg result: confirmatory HBsAg assay (neutralisation assay).* *In the case of reactive results for multiplex NAT, tests are repeated in duplicate, performing discriminatory NAT tests (HCV RNA, HBV DNA, HIV RNA) and anti-HBc.* *In the case of confirmed infection, other HBV markers are tested.* *Anti-HBc reactive donors are permanently deferred.*
Spain	HBsAg + HBV DNA NAT MP or not specified	Simultaneous	No additional information.
Sweden	HBsAg + anti-HBc (total)	Simultaneous	*In the regions where HBV DNA NAT is available, it is performed simultaneously (in individual donations).*

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. HCV: hepatitis C virus. HIV: human immunodeficiency virus. ID: individual donation. LOD: limit of detection. MP: minipools. NA: not applicable. NAT: nucleic acid test. NR: not reported. RNA: ribonucleic acid.
Note: the text in italics corresponds to verbatims of the replies provided by the countries.

No data

Additional measures

Of the 25 responding countries, nine (43%) reported more stringent measures beyond the mandatory or recommended ones at the national level. These were mainly testing for anti-HBc and/or performing HBV DNA NAT.

Table 3. Additional measures applied beyond mandatory/recommended HBV testing strategy in blood donors, EU/EEA, 2025

Country	More stringent measures? (Yes/No)	If yes, which ones:					
		Anti-HBc (total)	Anti-HBs	HBV DNA NAT - ID	HBV DNA NAT - MP	HBV DNA NAT (ID or MP not specified)	Other
Austria[a]	Yes						
Belgium	Yes						
Bulgaria	No						
Croatia	No						
Cyprus[b]	Yes						
Czechia	No						
Denmark	No						
Estonia	Yes						
Finland	No						
France	No						
Germany	Yes						
Greece	No						
Hungary							
Iceland	No						
Ireland							
Italy	Yes						
Latvia	No						
Liechtenstein							
Lithuania							
Luxembourg	No						
Malta	No						
Netherlands	No						
Norway	No						
Poland							
Portugal	No						
Romania							
Slovakia[c]	Yes						
Slovenia[d]	Yes						
Spain	Yes						
Sweden	No						

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. ID: individual donation. MP: minipools. NAT: nucleic acid test.

Comments from the countries:

[a] **Austria** – *The marked tests are used as confirmatory testing in case of a reactive HBsAg in screening.*

[b] **Cyprus –** *The additional tests are performed only for repeatedly reactive samples, in the reference laboratory.*

[c] **Slovakia –** *The National Transfusion Service, responsible for 75% of all donations, performs HBV DNA NAT ID testing as a more stringent measure.*

[d] **Slovenia** – *In the case of HBV DNA NAT reactive result, anti-HBc is tested. In the case of confirmed infection, other HBV serological markers are tested - anti-HBs, HBeAg, anti-HBe, and anti-HBc IgM.*

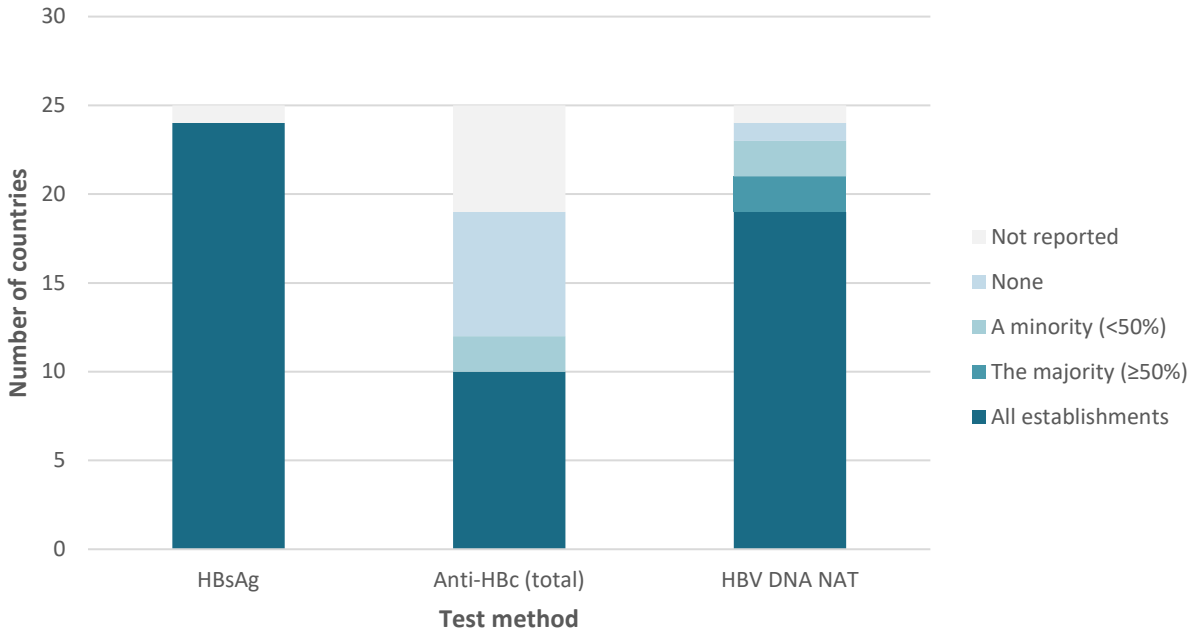
	Reported as an additional test
	Not reported as an additional test
	No data

Implementation of test methods in SoHO establishments

Twenty-four countries provided information regarding the proportion of establishments performing different test methods for HBV screening. In 21 countries (84%), the majority of, or all blood establishments are currently performing HBV DNA NAT (Figure 3). The response rate concerning anti-HBc (total) was lower (76%), with ten countries reporting that all establishments are performing the test, including countries where anti-HBc is performed only in first-time donors.

In addition, two countries (Finland and Latvia) reported that all blood donations are tested in one establishment, while in Slovenia, HBV DNA NAT is centralised in one centre, while serological testing is performed in three centres.

Figure 3. Proportion of SoHO establishments performing HBV screening test methods, EU/EEA, 2025



Ag: antigen. DNA: deoxyribonucleic acid. HbsAg: Hepatitis B surface antigen. HBV: hepatitis B virus. NAT: nucleic acid test.

Tissues and non-reproductive cells

Nineteen EU/EEA countries responded to the survey (participation rate of 63%). As of January 2026, no data were provided for Greece, Hungary, Ireland, Latvia, Liechtenstein, Luxembourg, Netherlands, Norway, Poland, Romania and Slovakia.

National HBV testing strategies for donors

All 19 reporting countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Iceland, Italy, Lithuania, Malta, Portugal, Slovenia, Spain, and Sweden) provided information on the HBV testing strategies for tissues and non-reproductive cell donors (living and deceased) at the national and/or regional level.

Living donors

The use of HBV DNA NAT is mandatory or recommended in eleven (58%) of the participating countries, in addition to the mandatory serological testing for HBsAg and anti-HBc (total). Eight (42%) countries reported that anti-HBs is performed in line with the legal requirements of national/regional recommendations. Additional information can be found in Table 4.

Table 4. HBV testing strategies for living donors of tissues and non-reproductive cells in the EU/EEA, 2025

Country	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT
Austria[a]				
Belgium[b]				
Bulgaria				
Croatia				
Cyprus				
Czechia				
Denmark				
Estonia				
Finland				
France				
Germany[c]				
Greece				
Hungary				
Iceland				
Ireland				
Italy				
Latvia				
Liechtenstein				
Lithuania[d]				
Luxembourg				
Malta				
Netherlands				
Norway				
Poland				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden[e]				

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. NAT: nucleic acid test.

Comments from the countries:

[a] **Austria** – *If the donation sample of a living donor (excluding donors of bone marrow stem cells and peripheral blood stem cells) is additionally tested for HIV, HBV and HCV using NAT, the test of a repeat blood sample may be omitted, if storage has been for longer than six months. The repeat test may also be omitted if the processing includes an inactivation step that has been validated for the viruses in question. (…) Further examinations are legally required for the determination of clinical usability if anti-HBc testing is positive and HBsAg testing is negative.*

[b] **Belgium** – *Quarantine of 180 days or HBV NAT at time of donation.*

[c] **Germany** – *For screening allogenic hematopoietic progenitor cells (HPC) donors, HBV DNA NAT is performed in addition to the serological tests.*

[d] **Lithuania** – *HBV DNA NAT is not mandatory if the serology test is repeated after an interval of 180 days.*

[e] **Sweden** – *The additional donor requirements in regional recommendations differ per tissue and cell type, with anti-HBs and HBV DNA NAT recommended for some types but not others.*

	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Deceased donors

Twelve out of the 19 participating countries (63%) reported mandatory or recommended use of HBV DNA NAT, mostly in addition to the mandatory serological testing for HBsAg and anti-HBc (total). Eight (42%) countries reported performing anti-HBs in line with the legal requirements or national/regional recommendations. Additional details can be found in Table 5.

Table 5. HBV testing strategies for deceased donors of tissues and non-reproductive cells in the EU/EEA, 2025

Country	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT
Austria				
Belgium				
Bulgaria				
Croatia				
Cyprus				
Czechia				
Denmark				
Estonia				
Finland				
France				
Germany				
Greece				
Hungary				
Iceland				
Ireland				
Italy				
Latvia				
Liechtenstein				
Lithuania				
Luxembourg				
Malta				
Netherlands				
Norway				
Poland				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden[a]				

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. NAT: nucleic acid test.

Comments from the countries:

[a] **Sweden** – *The additional donor requirements in regional recommendations differ per tissue and cell type, with anti-HBs and HBV DNA NAT recommended for some types but not others.*

	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Molecular testing in pools

Five countries (Austria, Belgium, Cyprus, Lithuania, and Sweden) have authorised HBV molecular testing (i.e. NAT) in pools for tissues and non-reproductive cell donors. The number of pooled samples applied was not specified.

Minimum limit of detection requirements for HBV DNA NAT

For this question, the countries were asked to consider that 5.3 copies of HBV DNA equal 1 IU/mL. Estimates for the minimum LOD for HBV DNA NAT for tissues and non-reproductive cells were provided by the following countries:

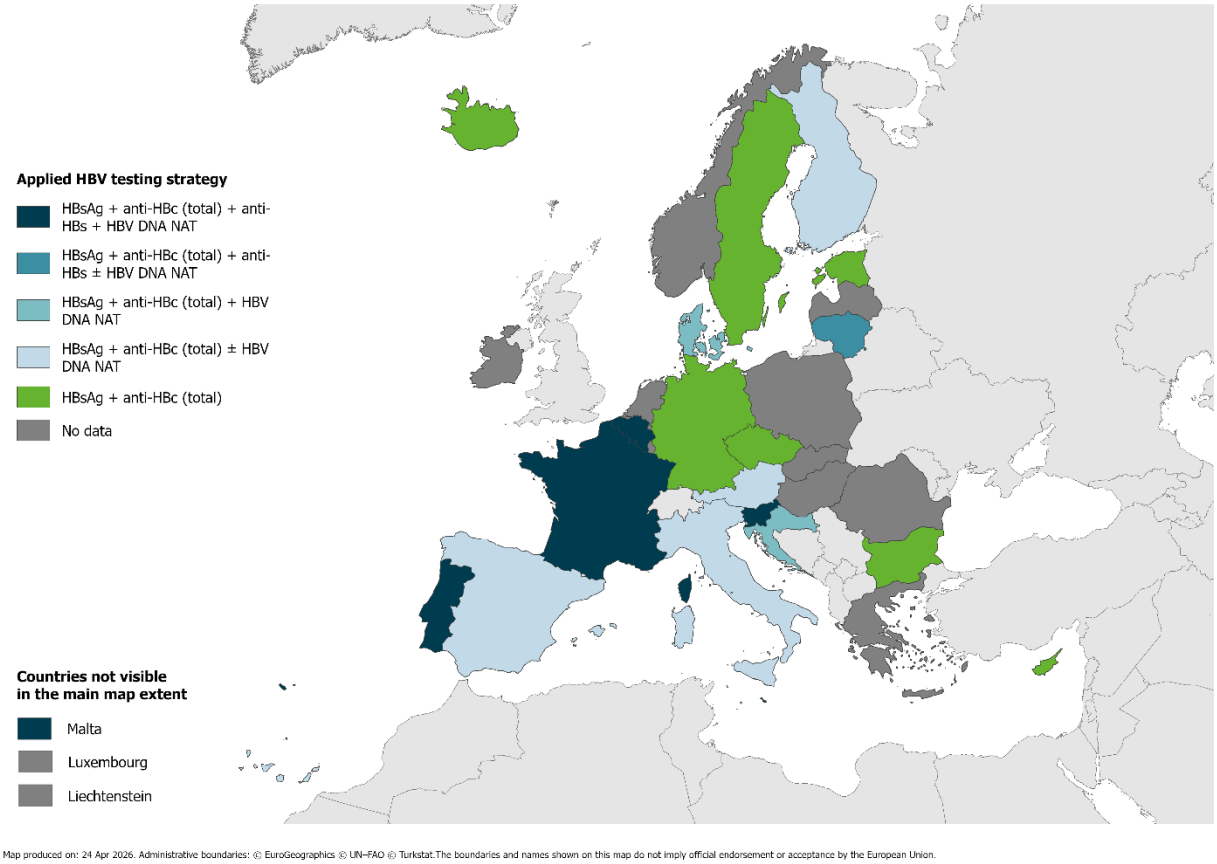
- Croatia – 4 IU/mL
- Denmark – 20 IU/mL
- Germany – 900 IU/mL; in case of haematopoietic progenitor cells (HPC), the LOD is <50IU/mL
- Slovenia – 4 IU/mL
- Spain – 30 IU/mL.

Practice in place

Testing algorithms

Seventeen countries (89%) provided detailed information regarding the testing algorithm used. There is variability in HBV testing strategies applied by countries regarding testing in tissues and non-reproductive cells donors, as represented in Figure 4.

Figure 4. HBV applied testing strategies (legally binding and/or recommended at the national level) in tissue and non-reproductive cell donors, EU/EEA, 2025



Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. ID: individual donation. MP: minipools. NAT: nucleic acid test.

Sixteen countries (84%) reported performing the tests included in the main testing strategy simultaneously, with one country (5%) reporting a stepwise approach to HBV testing. Four countries (21%) report the possibility of skipping HBV DNA NAT testing if donations are quarantined and serological tests are repeated after 180 days. Additional information is available in Table 6.

Table 6. Description of algorithms for HBV screening tests in tissues and non-reproductive cell donors, EU/EEA, 2025

Country	Main testing strategy	Details of the algorithm
Austria	HBsAg + anti-HBc (total) ± HBV DNA NAT	*Serological tests are performed simultaneously. HBV DNA NAT is performed if no quarantine is applied.*
Belgium	HBsAg + anti-HBc (total) + anti-HBs + HBV DNA NAT	*No testing algorithm specified.*
Bulgaria	HBsAg + anti-HBc (total)	*Tests performed simultaneously.*
Croatia	HBsAg + anti-HBc (total) + HBV DNA NAT	*All tests are performed simultaneously.*
Cyprus	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc are performed simultaneously. If anti-HBc is positive, further investigation is done.*
Czechia	HBsAg + anti-HBc (total)	*Tests are performed simultaneously.*
Denmark	HBsAg + anti-HBc (total) + HBV DNA NAT	*All tests are performed simultaneously.*
Estonia	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc are performed simultaneously. If anti-HBc is reactive and anti-HBs negative, further analysis and risk analysis*

Country	Main testing strategy	Details of the algorithm
		are taken into action to verify whether cells or tissues meet clinical standards.
Finland	HBsAg + anti-HBc (total) ± HBV DNA NAT	*HBV DNA NAT mandatory only for deceased donors. All tests are performed simultaneously. No testing algorithm specified.*
France	HBsAg + anti-HBc (total) + anti-HBs + HBV DNA NAT	*All tests are performed simultaneously.*
Germany	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc are performed simultaneously.* *HBV DNA NAT is performed for certain tissues such as cardiovascular tissues, musculoskeletal tissues and amniotic membranes (except for tissues for which a validated inactivation procedure is used).*
Greece		
Hungary		
Iceland	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc are performed simultaneously. If the result is positive, additional testing is required for confirmation. This applies to autologous hematopoietic stem cell donors.*
Ireland		
Italy	HBsAg + anti-HBc (total) ± HBV DNA NAT	<u>Living donor (HPC):</u> *HBsAg and HBV DNA NAT are performed simultaneously.* <u>Living donor (tissues):</u> *HBsAg and anti-HBc, followed by quarantine of 180 days. If not quarantined, it is necessary to perform HBV DNA NAT.* <u>Deceased donors:</u> *HBsAg and anti -HBc are performed simultaneously. If anti-HBc is reactive, HBV DNA NAT is performed sequentially.*
Latvia		
Liechtenstein		
Lithuania	HBsAg + anti-HBc (total) + anti-HBs ± HBV DNA NAT	*All tests are performed simultaneously. HBV DNA NAT is not performed if serological tests are repeated after an interval of 180 days.*
Luxembourg		
Malta	HBsAg + anti-HBc + anti-HBs + HBV DNA NAT	*HBsAg, anti-HBc and HBV DNA NAT are performed simultaneously.*
Netherlands		
Norway		
Poland		
Portugal	HBsAg + anti-HBc + anti-HBs + HBV DNA NAT	No additional information provided.
Romania		
Slovakia		
Slovenia	HBsAg + anti-HBc + anti-HBs + HBV DNA NAT	*Tests are performed sequentially: first HBsAg, followed by anti-HBc and anti-HBs in double samples, and HBV DNA NAT.*
Spain	HBsAg + anti-HBc (total) ± HBV DNA NAT	*When the anti-HBc test is reactive, and HBsAg is negative, additional testing will be necessary to determine whether the tissues and/or non-reproductive cells can be used or should be discarded.* *If HBV DNA NAT is used, a second test will not be required. It will also not be necessary if a validated viral inactivation process is included during the tissue and/or cell group processing phase.*
Sweden	HBsAg + anti-HBc (total)	*All tests are performed simultaneously.*

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. HPC: hematopoietic progenitor cells. NAT: nucleic acid test. "±" as applied in the case HBV DNA NAT can be performed to waive quarantine.
Note: the text in italics corresponds to verbatims of the replies provided by the countries.

No data

Additional measures

Eighteen countries responded to this question. Eight countries (44%) apply more stringent measures beyond mandatory or recommended ones at national level. These additional tests correspond mainly to anti-HBs and/or HBV DNA NAT (Table 7).

Table 7. Additional measures applied beyond the mandatory/recommended HBV testing strategy in tissues and non-reproductive cell donors screening, EU/EEA, 2025

Country	More stringent measures? (Yes/No)	If yes, which ones:	
		Anti-HBs	HBV DNA NAT
Austria[1]	Yes		
Belgium	No		
Bulgaria	Yes		
Croatia	No		
Cyprus	Yes		
Czechia	Yes		
Denmark	No		
Estonia	Yes		
Finland			
France	No		
Germany[a]	Yes		
Greece			
Hungary			
Iceland[b]	No		
Ireland			
Italy	No		
Latvia			
Liechtenstein			
Lithuania	No		
Luxembourg			
Malta	No		
Netherlands			
Norway			
Poland			
Portugal	No		
Romania			
Slovakia			
Slovenia	No		
Spain	Yes		
Sweden	Yes		

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. NAT: nucleic acid test.
[1]Note: in Austria, HBsAg and anti-HBc apply as more stringent measures in deceased donors.
Comments from the countries:
[a] **Germany –** *HBV DNA NAT is performed for certain tissues such as cardiovascular tissues, musculoskeletal tissues and amniotic membranes (except for tissues for which a validated inactivation procedure is used).*
[b] **Iceland** *– Only one autologous hematopoietic stem cell transplantation centre in Iceland (therefore no other centre with more stringent measures).*

	Reported as an additional test
	Not reported as an additional test
	No data

Validation of tests for deceased donors

Among the 17 responding countries, 13 (76%) confirmed that the tests used for HBV screening are validated for application in deceased donors. Additional information is available in Table 8.

Table 8. HBV screening test validated for deceased donors, EU/EEA, 2025

Country	Screening tests validated (Yes/No)	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT	Other
Austria	Yes					
Belgium[a]	Yes					
Bulgaria						
Croatia	Yes					
Cyprus	No					
Czechia	Yes					
Denmark	Yes					
Estonia	Yes					
Finland						
France[b]	Yes					
Germany	Yes					
Greece						
Hungary						
Iceland	No					
Ireland						
Italy[c]	Yes					
Latvia						
Liechtenstein						
Lithuania	No					
Luxembourg						
Malta	Yes					
Netherlands						
Norway						
Poland						
Portugal[d]	No					
Romania						
Slovakia						
Slovenia	Yes					
Spain[e]	Yes					
Sweden[f]	Yes					

Ag: antigen. HBV: hepatitis B virus. NA: not applicable. NAT: nucleic acid test.

Comments from the countries:

[a] **Belgium –** *Testing must be carried out by an approved laboratory using CE marked test kits where applicable. The type of testing carried out must be validated for this purpose based on current scientific knowledge. Additional validation for deceased donors is verified upon inspection.*

[b] **France –** *Laboratories must use the tests with the best sensitivity on the market, and for deceased donors, the tests validated for these kinds of donors.*

[c] **Italy –** *These tests are only validated in some regions.*

[d] **Portugal** – *To the best of our knowledge, there isn't any validation study for HBV screening on postmortem samples.*

[e] **Spain –** *Not all the tests are validated for HBV screening with samples from deceased donors. SOHO establishments only use validated tests or require pre-mortem samples for screening.*

[f] **Sweden –** *Legal mandates require these to be validated.*

	Validated screening test
	Not reported as a validated screening test
	No data

Reproductive cells

Nineteen EU/EEA countries responded to the survey (participation rate of 63%). As of January 2026, no data were provided for Hungary, Ireland, Latvia, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, and Slovakia.

National HBV testing strategies for donors

All 19 reporting countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Italy, Lithuania, Netherlands, Slovenia, Spain and Sweden) provided information on the HBV testing strategy for reproductive cells (third-party donation and within relationship use) at national and/or regional level.

Third-party donation

The use of HBV DNA NAT is mandatory or recommended in seven (37%) of the participating countries, in addition to the mandatory serological testing for HBsAg and anti-HBc (total). Four (21%) of the countries reported that anti-HBs is performed in line with the legal requirements or national/regional recommendations. Additional information can be found in Table 9.

Table 9. HBV testing strategies for reproductive cells, third-party donation in the EU/EEA, 2025

Country	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT
Austria[a]				
Belgium				
Bulgaria				
Croatia				
Cyprus				
Czechia				
Denmark				
Estonia				
Finland				
France				
Germany				
Greece				
Hungary				
Iceland				
Ireland				
Italy				
Latvia				
Liechtenstein				
Lithuania				
Luxembourg				
Malta				
Netherlands				
Norway				
Poland				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. NAT: nucleic acid test.

Comments from the countries:

[a] **Austria** – *If the donation sample of a donor (..) is additionally tested for HIV, HBV and HCV using NAT, the test of a repeat blood sample may be omitted if the storage is longer than six months. The repeat test may also be omitted if the processing includes an inactivation step that has been validated for the viruses in question.*

	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Within relationship use

Five out of the 19 participating countries (26%) reported mandatory or recommended use of HBV DNA NAT, mostly in addition to the serological testing for HBsAg and anti-HBc (total). Four (21%) of the countries reported that anti-HBs is performed in line with the legal requirements or national/regional recommendations. Additional information can be found in Table 10.

Table 10. HBV testing strategies for reproductive cells, within-relationship use in the EU/EEA, 2025

Country	HBsAg	Anti-HBc (total)	Anti-HBs	HBV DNA NAT
Austria				
Belgium				
Bulgaria				
Croatia				
Cyprus				
Czechia				
Denmark				
Estonia				
Finland				
France				
Germany				
Greece				
Hungary				
Iceland[a]				
Ireland				
Italy				
Latvia				
Liechtenstein				
Lithuania[b]				
Luxembourg				
Malta				
Netherlands				
Norway				
Poland				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden[d]				

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. NAT: nucleic acid test.
Comments from the countries:
[a] **Iceland** – *Donation from a partner for direct use: It is not necessary to apply donor selection criteria or laboratory testing if the donation involves reproductive cells from a partner intended for direct use.*
[b] **Lithuania** – *HbsAg, anti-HBc and NAT tests are not mandatory for direct use.*

	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Molecular testing in pools

HBV molecular testing in pools for reproductive cell donors is authorised in five countries (Austria, Belgium, Cyprus, Slovenia, and Sweden). The number of pooled samples applied was not specified.

Minimum limit of detection requirements for HBV DNA NAT

For this question, the countries were informed to consider that 5.3 copies of HBV DNA equal 1 IU/mL. Ten countries provided information on minimum LOD requirements for HBV DNA NAT. Estimates for the minimum LOD required for HBV DNA NAT for reproductive cells were provided by Bulgaria (9 IU/mL), Lithuania (10 IU/mL) and Slovenia (4 IU/mL); these minimum LOD values apply to both third-party donation and within relationship use. Seven countries reported that no minimum LOD for HBV DNA NAT is defined in legislation and/or recommendations.

Practice in place

Testing algorithms

Eighteen out of 19 countries (95%) provided information regarding the testing algorithm. Four countries specified that different algorithms applied for third-party donation and within-relationship use. Eight countries reported that in case HBV DNA NAT is performed at screening, quarantine of reproductive cells can be waived. Further information is available in Table 11.

Table 11. Description of algorithms for HBV screening tests in reproductive cell donation, EU/EEA, 2025

Country	Main testing strategy	Details of the algorithm
Austria	HBsAg + anti-HBc (total)	*Serological tests are performed simultaneously. HBV DNA NAT can be performed in a third-party donation, if no quarantine is applied.*
Belgium	HBsAg + anti-HBc (total) ± anti-HBs ± HBV DNA NAT	Third-party donation: *Donors are tested at each donation. HBsAg and anti-HBc (total) are performed. If positive, the donor is excluded. If negative, a six-month quarantine may apply, with retesting before use. The use of NAT is especially applicable when one wants to avoid retesting after six months of quarantine.* Within relationship use: *Testing three months before the first donation and repeated every two years. HBsAg and anti-HBc (total) are performed. If one or two positive: donation may occur, but further tests are done to determine more precisely the infection status.*
Bulgaria	HBsAg + anti-HBc (total) or HBV DNA NAT	*HBsAg and anti-HBc (total) are done simultaneously, or only HBV DNA NAT is done. If HBsAg or anti-HBc (total) are positive, further testing with HBV DNA NAT is also performed.*
Croatia	HBsAg + anti-HBc (total)	*All required tests are performed simultaneously.*
Cyprus	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc (total) are performed simultaneously. If anti-HBc is positive, further investigation will take place.*
Czechia	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc (total) are performed simultaneously.*
Denmark	HBsAg + anti-HBc (total) + HBV DNA NAT	*All tests are performed simultaneously.*
Estonia	HBsAg + anti-HBc (total)	No additional information provided.
Finland	HBsAg + anti-HBc (total)	Third party donations: *HBsAg and anti-HBc simultaneously. Sperm donor quarantine for 180 days and subsequent testing of the donor prior to release. No quarantine needed if HBV DNA NAT is performed.* Within relationship use: *Initial simultaneous testing for HBsAg and anti-HBc, additional testing only if treatment exceeds 24 months. Sperm collected for within-relationship use may be used even if HBV-serology is positive under the discretion of the physician and in agreement with the parties involved, but the sperm must be stored separately.*
France	HBsAg + anti-HBc (total) + anti-HBs ± HBV DNA NAT	Third-party donation: *Initial assessment for donation: HBsAg, Anti-HBc, and anti-HBs are performed; if any of these tests are positive, the donor will not be selected.* *At the time of donation or at last collection, serological tests and HBV DNA NAT are repeated. If NAT is not performed, serological markers are repeated six months after the donation or the last collection (…)* *For sperm donation, sperm straws are distributed when test results are known. For oocyte donation, the testing is performed from the first day of the stimulation, and the oocytes are distributed when the test results are known.* Within relationship use: *Tests are performed within the 6 months preceding the first collection or removal of gametes or germ tissue, the first insemination, the first embryo transfer from a donor or the first use of gametes/germ tissue stored as part of fertility preservation.* *Screening is repeated if a risk is identified between two attempts.*
Germany	HBsAg + anti-HBc (total)	Third-party donations: *HBsAg and anti-HBc are simultaneously at every donation, quarantine for 180 days and subsequent testing of the donor prior to release. No quarantine needed if HBV DNA NAT is performed (no defined LOD), or if the processing of the donation includes a virus inactivation step which has proven to be effective.*

Country	Main testing strategy	Details of the algorithm
		Within relationship use: *Initial simultaneous testing for HBV serology (HBsAg and anti-HBc), additional testing only if treatment exceeds 24 months. Donations may be used even if HBV serology is positive, but must be stored separately.*
Greece	HBsAg + anti-HBc (total) + anti-HBs	*HBsAg, anti-HBc and anti-HBs performed before enrolment in any MAR and every six months, for both third-party donation and within relationship use.*
Hungary		
Iceland	HBsAg + anti-HBc (total)	*According to one of the MAR clinics in Iceland (private sector):* *Oocyte donation:* *Preliminary tests (as part of donor screening) - HBsAg and anti-HBc* *Continuously test (after egg donor approval, prior to egg collection and/or egg release) - HBsAg and anti-HBc* *Sperm donation:* *Initial test (part of the sperm donor screening): should always be by both NAT and serology for HBV (HBsAg + anti-HBc (total)).* *Tests for release of donations or in case of risk habits: both NAT and serology for HBV (HBsAg + anti-HBc (total)).*
Ireland		
Italy	HBsAg + anti-HBc (total) ± HBV DNA NAT	Third-party donation: *HBsAg and anti-HBc (quarantine of 180 days). If no quarantine, it is necessary to perform HBV DNA NAT.*
Latvia		
Liechtenstein		
Lithuania	HBsAg + anti-HBc (total) ± HBV DNA NAT	*All tests are performed simultaneously. HBV DNA NAT is not performed if serology tests are repeated after an interval of 180 days.*
Luxembourg		
Malta		
Netherlands	HBsAg + anti-HBc (total)	*HBsAg and anti-HBc are both needed; if one is positive, further testing should be done.*
Norway		
Poland		
Portugal		
Romania		
Slovakia		
Slovenia	HBsAg + anti-HBc (total) + anti-HBs + HBV DNA NAT	*Tests are performed sequentially: first HBsAg, followed by anti-HBc and anti-HBs in double samples (confirmatory), and HBV DNA NAT.*
Spain	HBsAg + anti-HBc (total)	*Serological tests are performed simultaneously.* *Donors with positive HBsAg are rejected. In case of isolated positive anti-HBc, HBV DNA NAT will be requested to rule out low-level viral replication.* *If HBV DNA NAT is negative, donation is accepted.*
Sweden	HBsAg + anti-HBc (total)	*Tests are performed simultaneously at donation, with a retest at day 180 after storage unless HBV DNA NAT is used.*

Ag: antigen. DNA: deoxyribonucleic acid. HBV: hepatitis B virus. LOD: limit of detection. NAT: nucleic acid test.
Note: the text in italics corresponds to verbatims of the replies provided by the countries.

No data

Additional measures

Seventeen out of 19 countries responded to this question. Nine (42%) countries apply more stringent measures beyond the mandatory or recommended ones at national level. These additional tests mainly correspond to anti-HBs and/or HBV DNA NAT (Table 12).

Table 12. Supplementary measures applied in addition to the mandatory/recommended HBV testing strategy in reproductive cell donor screening, EU/EEA, 2025

Country	More stringent measures? (Yes/No)	If yes, which ones:	
		Anti-HBs	HBV DNA NAT
Austria	Yes		
Belgium[a]	Yes		
Bulgaria[b]	Yes		
Croatia	Yes		
Cyprus	Yes		
Czechia	No		
Denmark	No		
Estonia	Yes		
Finland			
France	No		
Germany[c]	Yes		
Greece	Yes		
Hungary			
Iceland[d]	Yes		
Ireland			
Italy	No		
Latvia			
Liechtenstein			
Lithuania	No		
Luxembourg			
Malta			
Netherlands	No		
Norway			
Poland			
Portugal			
Romania			
Slovakia			
Slovenia	No		
Spain			
Sweden	No		

Ag: antigen. DNA: deoxyribonucleic acid. HBV: human immunodeficiency virus. NAT: nucleic acid test.

Comments from the countries:

[a] **Belgium –** *Some establishments require HBsAg and Anti-HBc for every donation for within relationship use.*

[b] **Bulgaria** – *When the non-partner sperm sample taken at the time of donation is tested by NAT for HBV after the quarantine period, these tests do not need to be repeated and no quarantine is performed after a negative HBV DNA NAT.*

[c] **Germany** – *NAT can be performed to avoid 180-day quarantine.*

[d] **Iceland** – *Applicable for sperm donors (see "Details of the algorithm" above).*

	Reported as an additional test
	Not reported as an additional test
	No data

Conclusion

According to the Blood Directive (2002/98/EC) and the Tissues and Cells Directive (2004/23/EC), blood and tissue and cells donors must be tested for hepatitis B infection. Serological testing for the detection of HBsAg is mandatory for blood donors, and the detection of HBsAg and anti-HBc for tissue and cell donors.

Countries across the EU/EEA have been updating their testing strategies in the last two decades. Several countries reported having introduced molecular techniques (i.e. HBV DNA NAT) in their donor screening process in the Directorate-General for Health and Food Safety mapping exercise in 2015 [5,6].

As of January 2026, the majority of responding countries reported including HBV DNA NAT as part of their current testing strategy for SoHO donor screening. The blood and blood components field has the highest proportion of responding countries where HBV DNA NAT is legally required or recommended within the country (22/25), followed by the tissues and non-reproductive cells field (11/19). Whether HBV DNA NAT is performed in individual donations or in minipools varies depending on the type of SoHO, with testing in minipools being more frequent in the blood field.

In the tissues and non-reproductive cells, and reproductive cells fields, HBV DNA NAT is used as an additional measure to allow waiving the quarantine of donations and the need for repeating serological testing of donors to release donations from quarantine. When considering such use, the number of countries where HBV DNA NAT is applied increases to 17 (out of 19) for tissues and non-reproductive cells and 13 (out of 19) for reproductive cells.

The survey showed substantial variability in HBV testing strategies adopted by the countries. This is particularly prominent in the blood field, mainly linked to whether anti-HBc is included in the blood donor strategy, and whether it is applied at every donation or only for first-time donors.

A key point of this survey is the heterogeneity of donor testing strategies for HBV in the EU/EEA. The overall aim of the SoHO regulation is the harmonisation of practices in the SoHO field among EU/EEA countries. The ECDC guidelines contribute to this goal, focusing on the prevention of transmission of communicable diseases. These data serve as a baseline for current testing practices; ECDC will assess the progress of SoHO donor testing strategies in EU/EEA countries after the publication of the ECDC guidelines for the prevention of transmission of HBV through SoHO in the EU/EEA and entry into force of the SoHO regulation.

References

1. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance). Brussels: EC. 2024. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32024R1938
2. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. Off J Eur Union. 2003;33:30-40. Available at: http://data.europa.eu/eli/dir/2002/98/oj
3. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. 2004;102:48-58. Available at: http://data.europa.eu/eli/dir/2004/23/oj
4. European Centre for Disease Prevention and Control (ECDC). Guidelines on the prevention of hepatitis B virus transmission through substances of human origin. Stockholm: ECDC; 2026. Available at: https://www.ecdc.europa.eu/en/publications-data/guidelines-prevention-hepatitis-c-virus-transmission-through-substances-human
5. European Commission (EC). Mapping of More Stringent Blood Donor Testing Requirements - Mapping Exercise 2015. EC: Brussels. 2016. Available at: https://health.ec.europa.eu/publications/mapping-more-stringent-blood-donor-testing-requirements-mapping-exercise-2015_en
6. European Commission (EC). Mapping of More Stringent Tissues and Cells Donor Testing Requirements - Mapping Exercise 2015. EC: Brussels. 2016. Available at: https://health.ec.europa.eu/latest-updates/mapping-more-stringent-tissues-and-cells-donor-testing-requirements-mapping-exercise-2015-2016-07-06_en
7. European Commission (EC). EU Survey web application, Brussels. Available at: https://ec.europa.eu/eusurvey/

Annex 1. Survey on HBV testing strategies for SoHO donors in the EU/EEA – 2024

Blood and blood components

1. National HBV testing strategies for donors

1.1. Which HBV testing strategies are legally binding or recommended on a national or regional level? If applicable, which testing strategy (or combination of tests) is used for screening in each case (legally binding, national recommendation, regional recommendation)? Please select all the tests that apply.

	Applicable?	If applicable, please specify:
Legally binding	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ID ☐ HBV DNA NAT MP (please specify below the number of mini pools) ☐ HBV DNA NAT ID or MP not specified ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ID ☐ HBV DNA NAT MP (please specify below the number of mini pools) ☐ HBV DNA NAT ID or MP not specified ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ID ☐ HBV DNA NAT MP (please specify below the number of mini pools) ☐ HBV DNA NAT ID or MP not specified ☐ Other (please specify)
If you selected "HBV DNA NAT MP", please specify the number of pooled samples here:		Answer:
If you selected "Other", please specify here:		Answer:

1.2. If a minimum limit of detection for HBV DNA NAT is required, please specify:
(please consider 1 IU = 5.3 HBV DNA copies)
IU/ml

2. Practice in place

2.1. Based on the tests selected in question 1.1, please clarify the currently used testing algorithm, detailing which tests are performed simultaneously and which are performed in a sequential order:

Answer:

2.2. Does any blood establishment apply more stringent measures regarding HBV testing than what is legally binding or recommended (answer provided in question 1.1)?

	Applicable?	If applicable, please specify:
More stringent measures	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ID ☐ HBV DNA NAT MP (please specify below the number of mini pools) ☐ HBV DNA NAT ID or MP not specified ☐ Other (please specify)
If you selected "HBV DNA NAT MP", please specify the number of pooled samples here:		Answer:
If you selected "Other", please specify here:		Answer:

2.3. To the best of your knowledge, what is the proportion of establishments where donations are tested with:

	Proportion of establishments testing donations with (test method):
Serology: HBsAg	Answer:
Serology: anti-HBc (total)	Answer:
Serology: anti-HBs	Answer:
HBV DNA NAT (ID and/or MP)	Answer:
Other (please specify)	Answer:

2.4. Please add any additional comments if needed:

Tissues and non-reproductive cells

1. National HBV testing strategies for donors

1.1. Which HBV testing strategies are legally binding or recommended on a national or regional level? If applicable, which testing strategy (or combination of tests) is used for screening in each case (legally binding, national recommendation, regional recommendation)? Please select all the tests that apply.

	Applicable?	Living donors: tissues and non-reproductive cells	Deceased donors: tissues
Legally binding	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
If you selected "Other", please specify here:		Answer:	Answer:

1.2. Is molecular testing in pool authorised for tissues or non-reproductive cells donors? Please select the appropriate option for your country's setting.

- ○ Yes, in tissue donors
- ○ Yes, in non-reproductive cells donors
- ○ Yes, in both
- ○ No

1.3. If a minimum limit of detection for HBV DNA NAT in tissues and non-reproductive cells donors is required, please specify:

(please consider 1 IU = 5.3 HBV DNA copies)

_____ IU/ml

2. Practice in place

2.1. Based on the tests selected in question 1.1, please clarify the currently used testing algorithm, detailing which tests are performed simultaneously and which are performed in a sequential order:

2.2. Does any tissue/non-reproductive cell establishment apply more stringent measures regarding HBV testing than what is legally binding or recommended (in addition to answer provided in question 1.1)?

	Applicable?	If applicable, please specify:
More stringent measures	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
If you selected "Other", please specify here:		Answer:

2.3. To the best of your knowledge, are the tests used for HBV screening validated for deceased donors?

○ Yes
○ No

2.4. Please add any additional comments if needed:

Medically Assisted Reproduction (MAR)

1. National HBV testing strategies for donors

1.1. Which HBV testing strategies are legally binding or recommended on a national or regional level? If applicable, which testing strategy (or combination of tests) is used for screening in each case (legally binding, national recommendation, regional recommendation)? Please select all the tests that apply.

	Applicable?	Third-party donation	Within relationship use
Legally binding	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
If you selected "Other", please specify here:		Answer:	Answer:

1.2. Is molecular testing in pool authorised for reproductive cells donors?

○ Yes
○ No

1.3. Is a minimum limit of detection for HBV DNA NAT required for:

☐ Third-party donation?
☐ Within relationship use?

1.4. Please add any additional comments if needed:

2. Practice in place

2.1. Based on the tests selected in question 1.1, please clarify the currently used testing algorithm, detailing which tests are performed simultaneously and which are performed in a sequential order:

2.2. Does any MAR establishment apply more stringent measures regarding HBV testing than what is legally binding or recommended (in addition to answer provided in question 1.1)?

	Applicable?	If applicable, please specify:
More stringent measures	Answer: ○ Yes ○ No	Answer: ☐ Serology: HBsAg ☐ Serology: anti-HBc (total) ☐ Serology: anti-HBs ☐ HBV DNA NAT ☐ Other (please specify)
If you selected "Other", please specify here:		Answer:

2.3. Please add any additional comments if needed:

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