CAPACITY/CAPABILITY ASSESSMENT

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

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

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Abbreviations

Ag	Antigen
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
ID	Individual donation
LOD	Limit of detection
MAR	Medically assisted reproduction
MP	Mini-pool
NA	Not applicable
NAT	Nucleic acid test
NFP	National focal point
NR	Not reported
PCR	Polymerase chain reaction
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 was published[i]. 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 donor-derived transmission of human immunodeficiency virus (HIV) through SoHO. To assess the donor testing landscape for HIV prior to the publication of ECDC guidelines, ECDC developed surveys to collect information on current HIV testing practices for SoHO donors across the EU/EEA.

Methods

In the first quarter of 2024, an online survey was distributed to national focal points (NFP) for blood, tissues and non-reproductive cells and medically assisted reproduction (MAR) to gather information on national donor testing strategies for HIV, including on the national donation services, testing protocols and laboratory testing methods.

Results

The number of respondents to the survey ranged between 21 for NFPs for MAR and 27 for NFPs for blood. In addition to the mandatory detection of anti-HIV-1/2, HIV nucleic acid (amplification) tests (NAT) are mandated or recommended in 85%, 60% and 35% of the participating countries for blood, tissues and non-reproductive cells, and reproductive cells, respectively. In the blood field, either by law or national recommendation, NAT is performed on individual donations (ID) in 48% of the countries; in 26% of countries, no specification regarding ID or mini-pool (MP) strategy was given. Less than 50% of the countries reported having a required limit of detection. HIV-2 NAT tests are used in 22 and 11 countries for blood and tissues and non-reproductive cells, respectively, and in six countries for reproductive cells. Antigen-antibody tests for HIV-1/2 are used instead of antibody-only tests for HIV-1/2 in 78%, 45% and 25% of responding countries for blood, tissues and non-reproductive cells, and MAR, respectively.

Conclusion

Next to the mandatory serological test with antibodies against HIV-1 and HIV-2, HIV NAT is currently included in the donor testing strategy in most participating countries for the different SoHO fields. Future assessments will allow ECDC and the relevant countries to understand the impact of ECDC guidelines on donor testing strategies for HIV in the EU/EEA.

[i] 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. Available from: http://data.europa.eu/eli/reg/2024/1938/oj

1. Background

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[ii]. This Regulation repeals the Blood Directive (2002/98/EC) and the Tissues and Cells Directive (2004/23/EC), and it will apply from 2027, three years after its publication, with an extra year for specific provisions.

The Regulation establishes 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 SoHOs from a communicable disease threat perspective. In this context, ECDC is developing guidelines for the prevention of donor-derived transmission of human immunodeficiency virus (HIV) through SoHO.

We aimed to collect qualitative information from different European Union/European Economic Area (EU/EEA) countries to describe testing requirements for HIV in the EU/EEA at the time of development of ECDC guidelines.

2. Methods

Online surveys (see Annex 1 and 2) were developed and published by ECDC in the EU Survey web application[iii]. The surveys, covering information on the national SoHO donation services, testing recommendations and laboratory test methods for HIV for blood, tissues and cells, and medically assisted reproduction (MAR), were shared with ECDC SoHO-Network national focal points (NFP) of the 30 EU/EEA countries in early February by email.

The survey responses from participating countries were extracted from the EU Survey application in May 2024 in an Excel format. The questions presented in the section are the original questions from the survey. The compiled replies to each question were summarised in tables, by frequency and proportion of responses, or represented in maps. The comments to the questions were extracted and summarised where relevant.

[ii] 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. Available from: http://data.europa.eu/eli/reg/2024/1938/oj

[iii] European Commission. EU Survey web application, Brussels. Available at: https://ec.europa.eu/eusurvey/

3. Survey results

Survey on HIV testing requirements in the EU/EEA – blood

Responses were obtained from 27 of 30 EU/EEA countries (participation rate of 90%): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Italy, Latvia, Liechtenstein, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

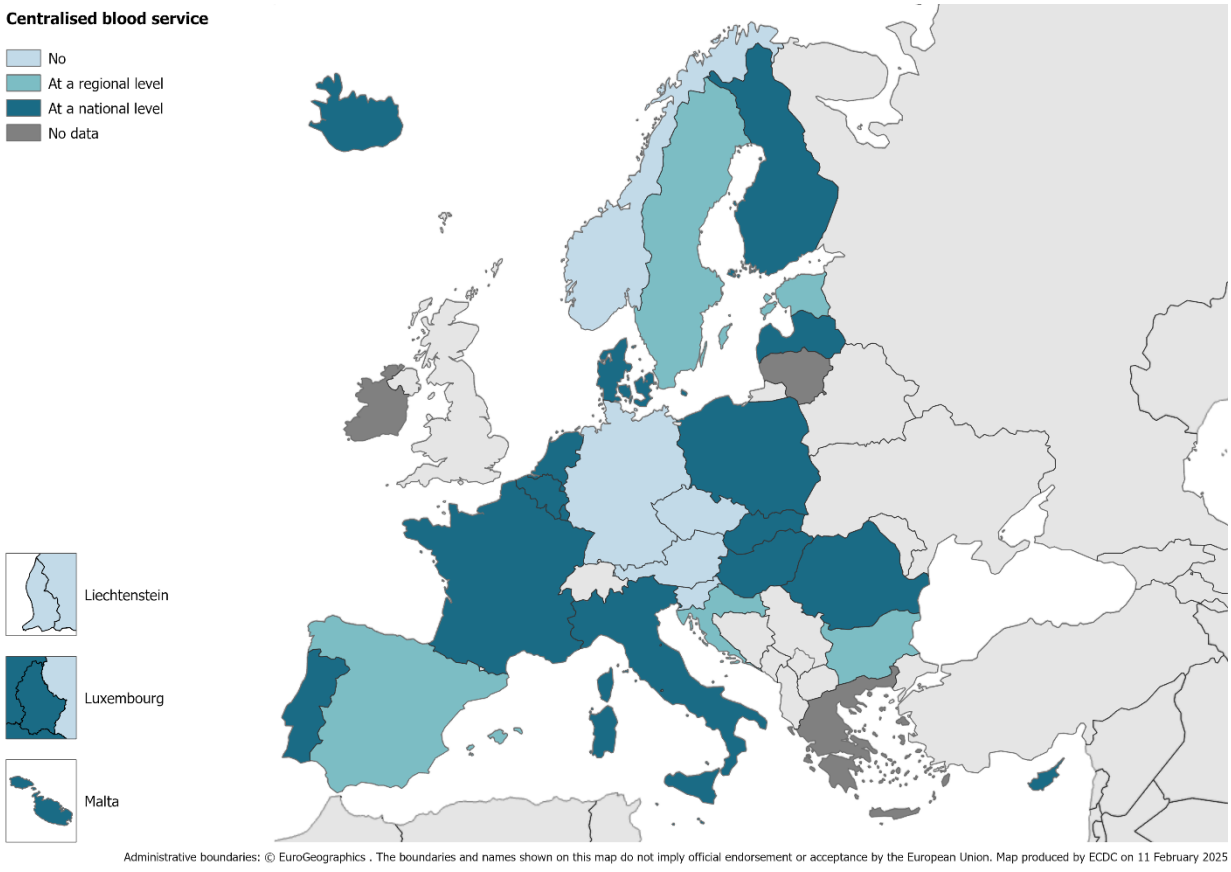
As of August 2024, no data were provided for Greece, Ireland, and Lithuania, and no results from these countries were included in the report.

Q1. Organisation of the National Transfusion Service

1.1 Is there a centralised blood service in your country?

Among the 27 responding EU/EEA countries, 15 (56%) countries reported having the blood service centralised at the national level, five (19%) had regional centralised blood services, and seven (26%) did not have a centralised blood service (Figure 1).

Figure 1. Existence of centralised blood services in the EU/EEA countries

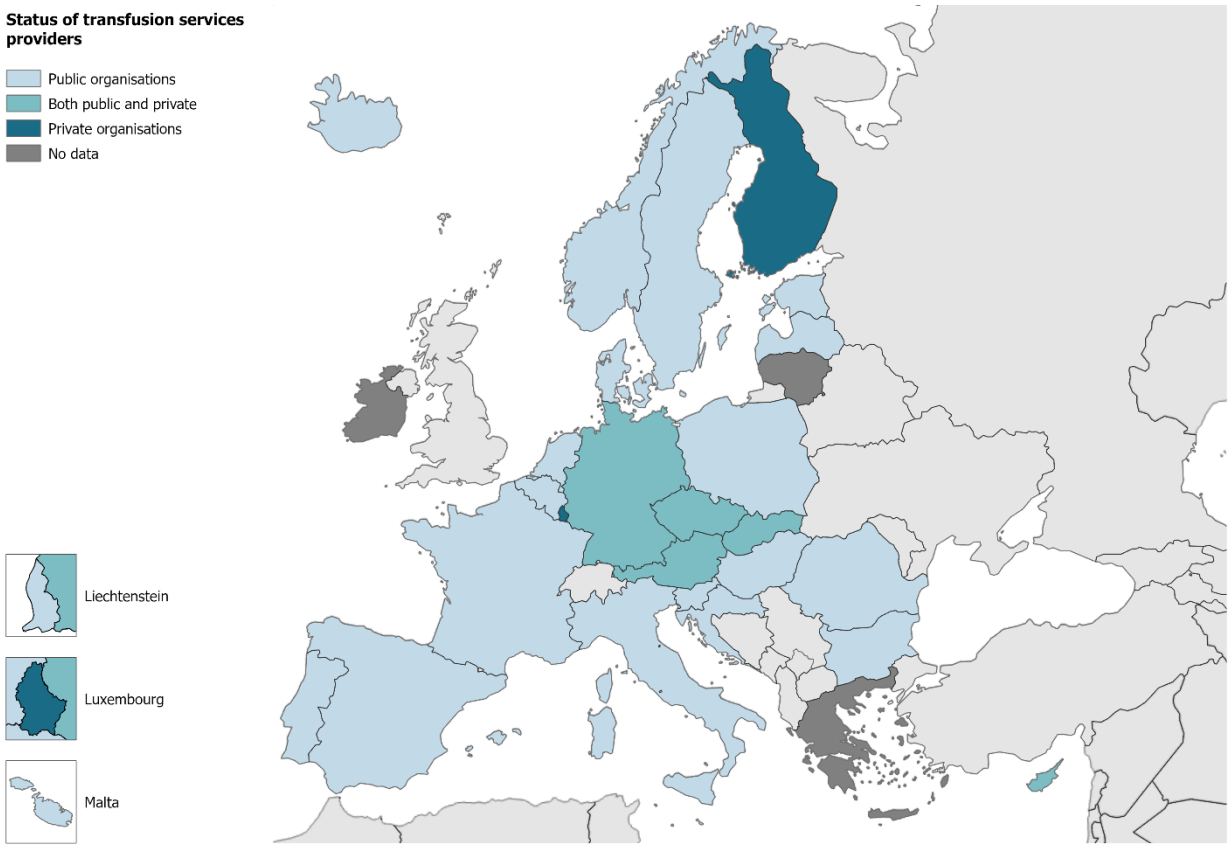


The NFP from Slovakia gave an additional note: "We have partially centralised blood service (National transfusion service – NTS, responsible for about 75% of donations), and partially decentralised (transfusion departments - some of them under the government, some of them private)".

1.2 What is the status of the providers of the transfusion service?

Twenty (70%) countries reported that transfusion services are provided by public organisations, five (19%) by both public and private organisations and two countries reported having transfusion services only provided by private organisations (Figure 2).

Figure 2. Status of transfusion services providers in the EU/EEA



Q2. What HIV testing strategies are required in your country for blood donors: are they legally binding or recommended at the national or regional level?

All 27 reporting countries provided information for this question, which is presented in Table 1. The use of HIV nucleic acid (amplification) tests (NAT) is mandatory or recommended in 23 (85%) of the participating countries, in addition to the compulsory serological testing for anti-HIV-1/2. In 13 (48%) countries, NAT is performed on individual donations (ID), while in three (11%) countries, it is performed using only mini-pools (MP). Seven (26%) countries did not specify whether they used the ID or MP strategy. Less than 50% of the countries reported having set a required limit of detection (LOD). Twenty-one (78%) countries reported performing combined antigen-antibody tests instead of antibody-only tests for HIV-1/2.

Table 1. HIV testing strategies for blood donors in the EU/EEA

Country	Anti-HIV-1/2	HIV p24Ag	HIV NAT – ID	HIV NAT - MP	HIV NAT (ID or MP not specified)	Minimum LOD for NAT (IU/ml)
Austria						NR
Belgium						NR
Bulgaria						NR
Croatia						NR
Cyprus						NR
Czechia						500
Denmark						75[a]
Estonia						10 000
Finland						NR
France						No requirement
Germany						10 000[b]
Greece						
Hungary						7
Iceland					[c]	NR
Ireland						
Italy						NR
Latvia						NR
Liechtenstein[d]						NR
Lithuania						
Luxembourg						NR
Malta						10 000
Netherlands						970[e]
Norway						NR
Poland						NR
Portugal						No requirement
Romania		[f]				NR
Slovakia						20[g]
Slovenia						No requirement
Spain		[h]				NR
Sweden						NR

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

Ag: antigen. HIV: human immunodeficiency virus. ID: individual donation. LOD: limit of detection. MP: mini-pool. NAT: nucleic acid test. NR: not reported.

[a] Note from NFP from Denmark: "The LOD reported is legally binding."

[b] Note from NFP for Germany: "For fresh frozen plasma that does not undergo quarantine storage, the HIV-1 NAT LOD must be 3300 IU/ml. The HIV-1 NAT LOD (10 000 IU/ml or 3 300 IU/ml) is legally binding in Germany."

[c] Note from NFP for Iceland: "Currently, HIV NAT testing of blood donors is neither required nor carried out at the Blood Bank in Iceland. The Ministry of Health has decided to implement NAT screening of all blood donors for HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) starting in 2025. [...] Therefore, NAT screening for HBV, HCV and HIV will be a mandatory test for every blood donor by 2025."

[d] Note from NFP from Liechtenstein: "Blood and blood products from Liechtenstein are tested and processed in Austria. Please refer to the Austrian requirements and rules."

[e] Note from NFP from the Netherlands: "Minimal LOD for NAT for our current strategy is not legally binding. The LOD (stated as 95% per individual donation ≤ 970 IU HIV-RNA/ml plasma) was calculated more than 15 years ago. Because we are testing in pools of 6, since the implementation of HBV DNA donation screening in the Netherlands, the current tests are far more sensitive".

[f] Note from NFP for Romania: "HIV serological testing is done using tests combining HIV p24Ag + Ab."

[g] Note from NFP from Slovakia: "The LOD reported is not yet legally binding. HIV NAT is tested only in the National Transfusion Service of Slovak Republic (corresponding to approximately 75% of blood donations)."

[h] Note from NFP for Spain: "Currently, all commercial tests are combined HIV p24Ag + Ab."

Q3. Practice in place

3.1. Does any blood establishment apply more stringent measures regarding HIV testing than what is legally required or recommended?

Of the 27 countries who responded to this question, eight countries (30%) reported more stringent measures beyond the mandatory or recommended ones, mainly testing for HIV p24 antigen (four countries) and/or performing HIV-2 NAT (four countries). Four (50%) countries reported on the proportion of donations that are tested with the additional tests, ranging between 70% and 100% (Table 2).

Table 2. Additional tests applied beyond mandatory/recommended HIV testing strategy and proportion of donations tested with additional methods, EU/EEA

Country	More stringent measures? (Y/N/NA)	If yes, which ones:						
		Anti-HIV-1/2 (%)	HIV p24Ag (%)	HIV-1 NAT ID or pool not specified (%)	HIV-1 NAT pool (%)	HIV-1 NAT ID (%)	HIV-2 NAT (%)	Other (%)
Austria	N							
Belgium	Y							[a]
Bulgaria	N							
Croatia	N							
Cyprus	Y		(100)			(100)	(100)	
Czechia	Y							
Denmark	Y		(100)					
Estonia	N							
Finland	N							
France	N							
Germany	Y		(>90)				(>70)	
Greece								
Hungary	Y[b]							
Iceland	N							
Ireland								
Italy	N							
Latvia[c]	NA	NA	NA	NA	NA	NA	NA	NA
Liechtenstein	N							
Lithuania								
Luxembourg	N							
Malta	N							
Netherlands	N[d]							
Norway	N							
Poland	N							
Portugal	N							
Romania	Y[e]							
Slovakia[f]	Y					(>75)	(>75)	
Slovenia	N							
Spain	N							
Sweden	N							

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

Ag: antigen. HIV: human immunodeficiency virus. ID: individual donation. N: no. NA: not applicable; NAT: nucleic acid test. Y: yes.

[a] Note from NFP for Belgium: "In case of positive serology, and if NAT ID and confirmation test are negative, blood products are discarded, and the donor is tested one month later. In case of the same results one month later, the donor is excluded (false positive). Use of combination test: Ag-p24 + Ab-HIV1/2."

[b] Note from NFP for Hungary: "The same test is used for one sample."

[C] Note from NFP for Latvia: "The use of more stringent measures is not prohibited, but we don't have information at the national level."

[d] Note from the NFP from the Netherlands: "Due to the fact a combination test (Ag-Ab) is used, Ag-p24 is tested as well, but testing for Ag-p24 is not required and is not regarded as part of the donation screening."

[e] Note from NFP for Romania: "The more stringent testing measures, represented by HIV-1 and HIV-2 NAT testing, are only implemented in one blood establishment, that is subordinated to the Ministry of Defence.

[f] Note from NFP from Slovakia: "In Slovakia, both HIV-1 and HIV-2 viruses are tested by individual NAT."

Q4. Use of HIV-1 and HIV-2 NAT combined tests

4.1. Are HIV-1 and HIV-2 NAT combined tests used in your country?

Twenty-five out of 27 countries responded to this question. NAT combined tests for HIV-1 and HIV-2 are used in 22 countries. Eighteen countries gave the rationale behind testing for both viruses, mainly reporting legal requirements (22%), local epidemiology (22%), safety of blood transfusions (17%) and technical reasons (39%) (Table 3).

Table 3. Use of HIV-1 and HIV-2 combined NAT per country, EU/EEA

Country	Use of HIV-1 and HIV-2 combined NAT	Description of the HIV-1 and HIV-2 combined NAT in use	Rationale for the use of HIV-1 and HIV-2 combined NAT
Austria	Yes	Cobas® MPX Test, Roche.	*Legally binding.*
Belgium	Yes	NR	*NR*
Bulgaria	Yes	Procleix® Ultrio Elite Assay, Grifols.	*The use of HIV-1 NAT has reduced the window period of detection by 6 to 11 days in donations tested individually.* *The residual risk for potential HIV-2 transfusion is estimated to be extremely low, but it has not been possible to confirm these estimates directly. Screening for HIV-2 RNA should reduce the risk even further.*
Croatia	Yes	Procleix® Ultrio Elite Assay, Grifols.	*Possible risk of transmission in migrant workers (for example, seafarers), travellers, and migrants.* *HIV-1/2 NAT is legally binding in Croatia.*
Cyprus	Yes	Procleix® Ultrio Elite Assay, Grifols	*Minimising the window period and having a safer technique for the transfused patients.* *To use the minimal blood sample volume for both tests.*
Czechia	No	NA	*NA*
Denmark	Yes	Procleix® Ultrio Elite Assay, Grifols (4 out of 5 regions). NAT testing from Roche (one region).	*National tender.*
Estonia	Yes	Procleix® Ultrio Elite Assay, Grifols.	*HIV-1 and HIV-2 may be discriminated by using rapid immunoassays. The residual risk for potential HIV-2 transfusion is estimated to be extremely low, but it has not been possible to confirm these estimates directly. Screening for HIV-2 RNA should reduce the risk even further.*
Finland	Yes	Cobas® MPX Test, Roche.	*MPX test is a multiplex assay which detects both HIV-1 and -2 simultaneously.*
France	Yes	Cobas® MPX Test (on Cobas® 8800 System), Roche. Procleix® UltrioPlex E Assay, Grifols. *(both CE-marked assays detect HIV-1 and HIV-2 RNA)*	*The rationale concerns the application of the COMMISSION IMPLEMENTING DECISION (EU) 2019/1244 from July 1, 2019, amending Decision 2002/364/EC as regards requirements for combined tests of HIV and HCV antigens and antibodies and with regard to the requirements applicable to nucleic acid amplification techniques as they relate to reference materials and qualitative HIV tests [notified under number C(2019) 4632].*
Germany	Yes	Procleix® Ultrio Elite Assay, Grifols; Procleix® UltrioPlex E Assay, Grifols; Cobas® MPX Test, Roche; Cobas ® TaqScreen MPX Test, Roche; PoET® HIV Test, GFE Blut mbH.	*HIV-2-NAT testing is included in the combined tests (multiplex tests), which are commercially available but are not legally binding due to a lack of epidemiological risk.*
Greece			
Hungary	Yes	Cobas® MPX Test (on Cobas® 6800 System), Roche.	*National tender.*
Iceland	No	NA	*NA*
Ireland			
Italy	Yes	*Either real-time PCR or TMA can be used, depending on local choices.*	*Improving towards avoiding HIV-1 and HIV-2 window period donations.*
Latvia	Yes	Procleix® Ultrio Elite Assay, Grifols.	*NR*

Country	Use of HIV-1 and HIV-2 combined NAT	Description of the HIV-1 and HIV-2 combined NAT in use	Rationale for the use of HIV-1 and HIV-2 combined NAT
Liechtenstein	Yes	NR	*Blood and blood products from Liechtenstein are tested and processed in Austria. Please refer to the Austrian requirements and rules.*
Lithuania			
Luxembourg			
Malta	Yes	Procleix® Ultrio Elite Assay, Grifols.	*A combined test is done based on financial and time management.*
Netherlands	Yes	Cobas® MPX Test (on Cobas® 6800/8800 System), Roche.	*Both viruses are relevant for transfusion safety.*
Norway	No	NA	*NA*
Poland	Yes	Procleix® Ultrio Elite Assay, Grifols; Cobas® MPX Test, Roche.	*Used assays can detect both forms of the virus (using such assays is not connected with the epidemiological situation).*
Portugal	Yes	Cobas® MPX Test (on Cobas® 5800/6800/8800 Systems for HIV-1 subgroup M (the most prevalent in Portugal), for HIV-1 subgroup O and HIV-2.	*Country's HIV epidemiology and demographic profile.* *HIV-2 is a concern due to the prevalence of HIV-2 within some migrant populations living in Portugal and the possibility of the virus spreading among the broader population.*
Romania	Yes	Cobas® MPX Test	*Blood establishments using NAT testing are under the Ministry of Defence; we do not have this information.*
Slovakia	Yes	Procleix® UltrioPlex E Assay, Grifols.	*NR*
Slovenia	Yes	Procleix® Ultrio Elite Assay, Grifols.	*All the major players on the market provide combined tests.*
Spain	Yes	PCR, Roche; TMA, Grifols.	*NR*
Sweden			

No data

HIV: human immunodeficiency virus. ID: individual donation. NA: not applicable. NAT: nucleic acid test. NR: not reported. PCR: polymerase chain reaction. TMA: transcription-mediated amplification.

Survey on HIV testing requirements in the EU/EEA – tissues and non-reproductive cells

Responses were obtained from 22 out of 30 EU/EEA countries (participation rate of 73%): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Iceland, Liechtenstein, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Spain, and Sweden.

Liechtenstein did not provide additional information in this survey due to the lack of transplantation service.

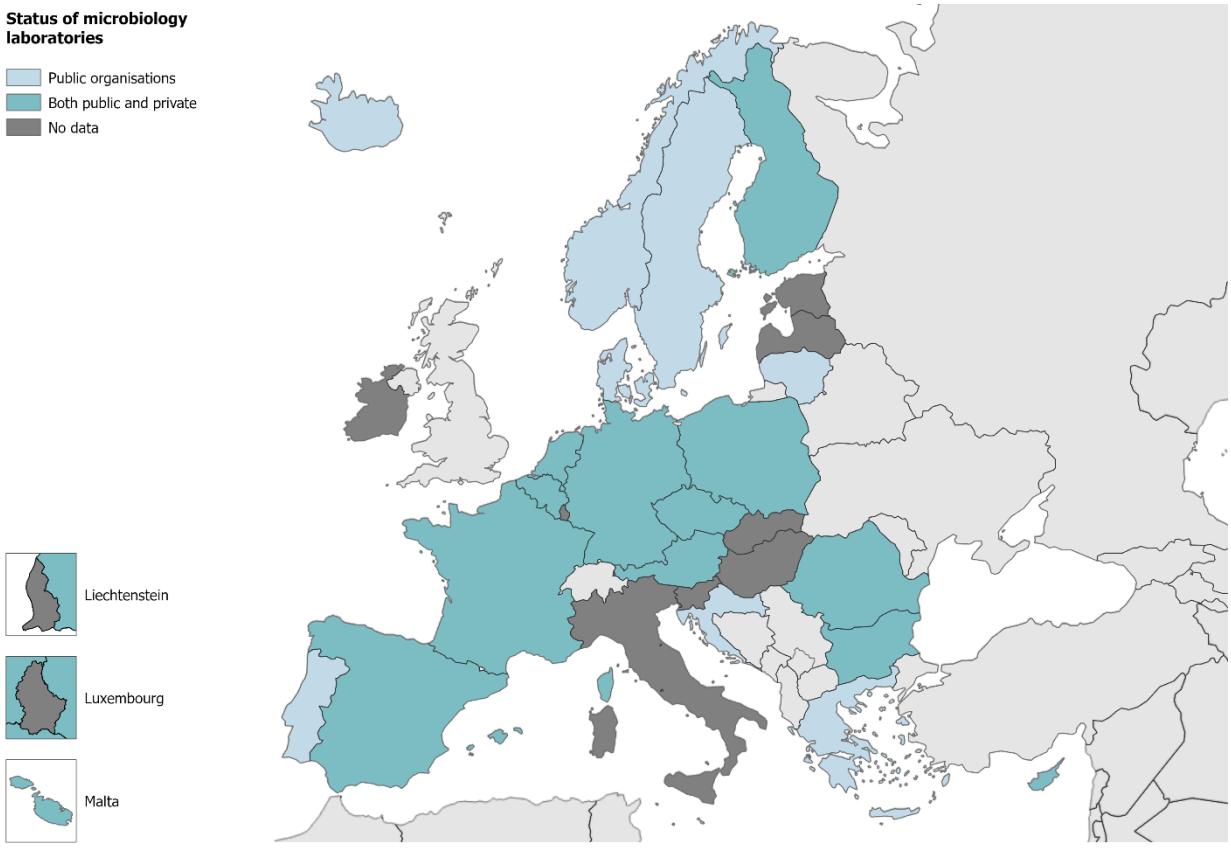
As of August 2024, no data was provided for Estonia, Hungary, Ireland, Italy, Latvia, Luxembourg, Slovakia, and Slovenia, and no results from these countries are included in the report.

Q1. Organisation of the National Transplantation Service for tissues and non-reproductive cells

1.1 What is the status of the microbiology laboratories responsible for donor testing?

Thirteen countries (62%) reported having microbiology laboratories performing donor testing integrated within public organisations, and eight (38%) in both public and private organisations (Figure 3).

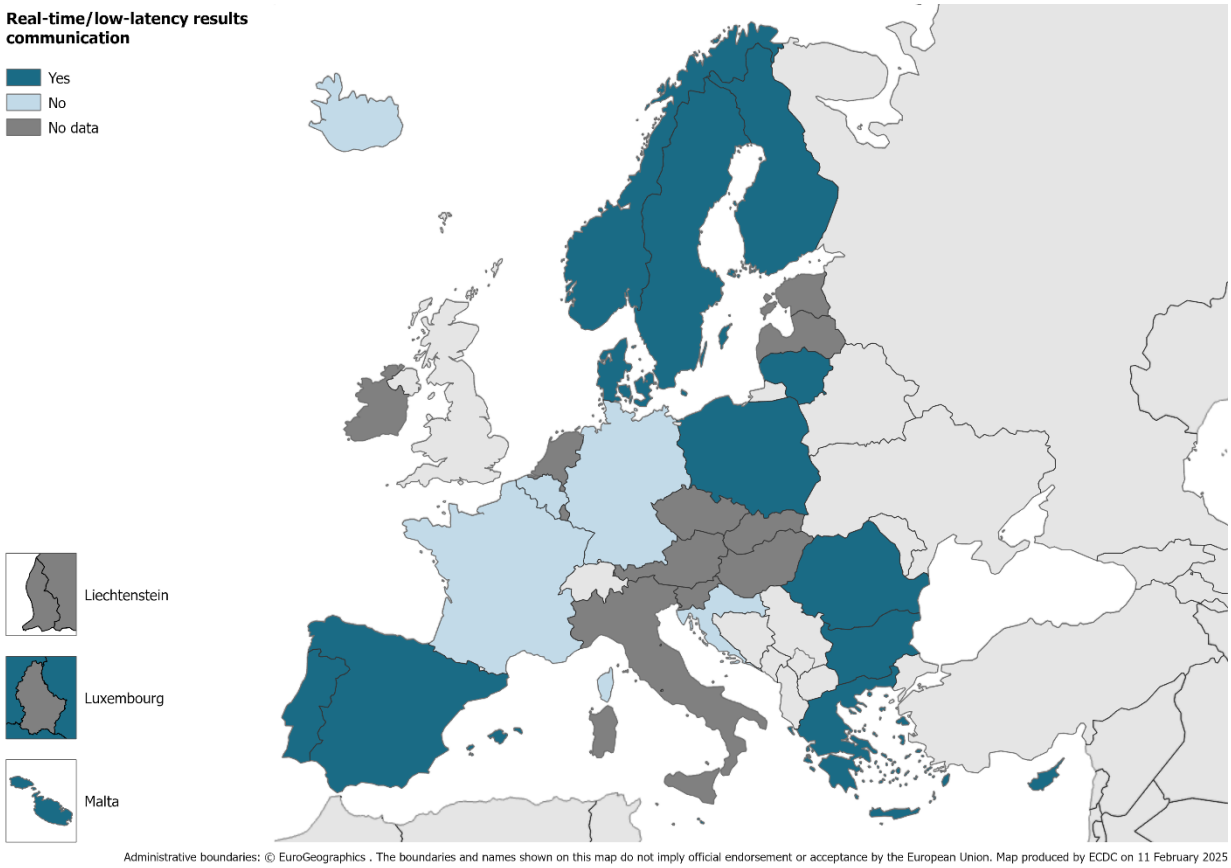
Figure 3. Status of microbiology laboratories performing donor testing in the EU/EEA



1.2 Are some of the microbiology laboratories responsible for donor testing able to provide results at any time or day?

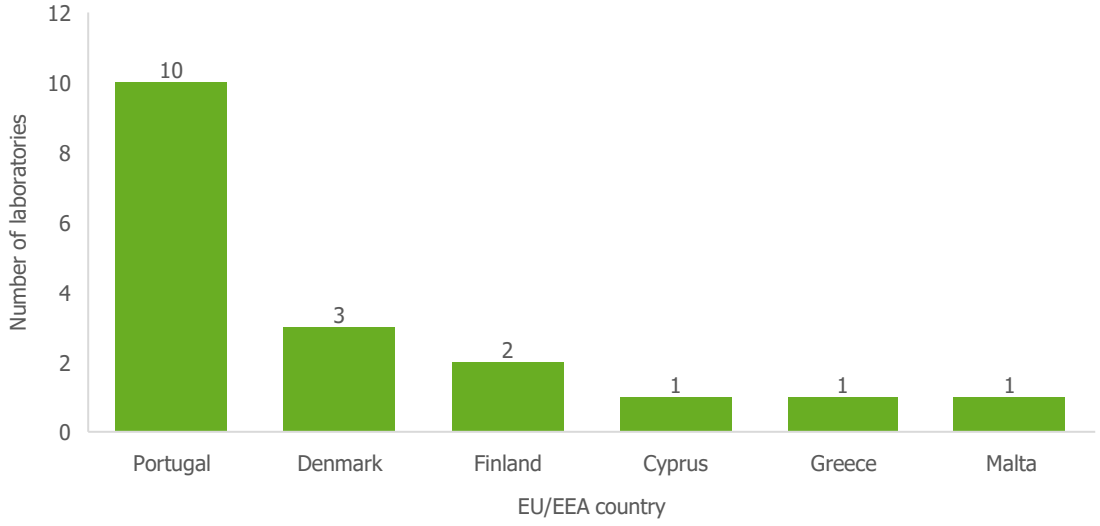
Eighteen countries responded to this question, with 13 countries describing having real-time or low-latency results communication concerning donor testing (Figure 4).

Figure 4. Microbiology laboratories reporting real-time/low-latency results concerning donor testing, EU/EEA



From the countries above, six reported the number of microbiology laboratories with the ability to report donor testing results at any time or day (Figure 5). Of those six countries, Portugal reported the largest number of laboratories (10) able to report results in real-time or with low latency; all other countries reported having three or fewer laboratories with this capability.

Figure 5. Number of microbiology laboratories reporting real-time/low-latency results concerning donor testing, EU/EEA



Q2. What HIV testing strategies are required in your country for tissues and non-reproductive cell donors: are they legally binding or recommended at the national or regional level?

Of the 21 countries eligible to provide information, 20 (95%) reported data on the HIV testing strategy for tissues and non-reproductive cell donors.

Living donors

The use of HIV NAT is mandatory or recommended in 12 (60%) of participating countries, in addition to the compulsory serological testing for anti-HIV-1/2. Eight (40%) countries reported performing combined antigen-antibody tests instead of antibody-only tests for HIV-1/2. Additional information can be found in Table 4.

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

Country	Anti-HIV-1/2	HIV p24Ag	HIV NAT
Austria			
Belgium[a]			
Bulgaria			
Croatia			
Cyprus			
Czechia			
Denmark[b]			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Italy			
Latvia			
Liechtenstein	NA	NA	NA
Lithuania[c]			
Luxembourg			
Malta			
Netherlands[d]			
Norway			
Poland			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden[e]			

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

Ag: antigen. HIV: human immunodeficiency virus. NA: not applicable. NAT: nucleic acid test.

[a] Note from NFP for Belgium: "When cells and tissues from living donors and for allogeneic use can be stored for long periods, it is necessary to take another blood sample and test for anti-HIV-1/2 after 180 days. If the tests are repeated, the donation sample can be collected within 30 days before and within seven days after the donation. When cells and tissues from living donors and for allogeneic use cannot be stored for long periods, and retest is impossible, NAT will be carried out, like those which apply to deceased donors, unless the treatment includes an inactivation step validated for the virus in question. If, in the case of a living donor, the donation sample, as defined above, is tested with HIV NAT, it is then not necessary to examine a second blood sample. Likewise, it is unnecessary to repeat the test when the transformation procedure includes an inactivation step validated for the infectious agent."

[b] Note from NFP for Denmark: "HIV NAT test is a must if donations are released without a re-test of anti-HIV-1/2 six months after donation. All laboratories use Ab-Ag combined tests for the serology testing."

[c] Note from NFP for Lithuania: "HIV NAT is not mandatory for living donors if serology tests are repeated after 180 days."

[d] Note from NFP for the Netherlands: "Legally binding: anti-HIV-1/2, for living tissue donors to be repeated 180 days after donation (second sample can be replaced by NAT testing of the donation sample)."

[e] Note from NFP for Sweden: "HIV NAT is used when tests cannot be repeated."

Deceased donors

Out of the participating countries, 12 (60%) countries reported mandatory or recommended use of HIV NAT, in addition to mandatory serological testing for anti-HIV-1/2. Nine (45%) countries reported performing combined antigen-antibody tests instead of antibody-only tests for HIV-1/2. More details can be found in Table 5.

Table 5. HIV testing strategies for deceased donors in the EU/EEA

Country	Anti-HIV-1/2	HIV p24Ag	HIV NAT
Austria			
Belgium[a]			
Bulgaria			
Croatia			
Cyprus			
Czechia			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Italy			
Latvia			
Liechtenstein	NA	NA	NA
Lithuania			
Luxembourg			
Malta			
Netherlands			
Norway			
Poland			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			

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

Ag: antigen. HIV: human immunodeficiency virus. NAT: nucleic acid test.
[a] Note from NFP for Belgium: "In deceased donors, anti-HIV-1/2 and HIV-1 NAT are carried out unless the transformation procedure includes an inactivation step that is validated for HIV."

2.1. Is molecular testing in pools authorised for tissues and non-reproductive cell donors?

HIV molecular pool testing for tissues and non-reproductive cell donors is authorised in four countries (Austria, Greece, the Netherlands and Poland). However, in the Netherlands, it is only authorised for living donors; for deceased donors, HIV NAT is performed in individual donations.

2.2. If a minimum limit of detection for HIV NAT is required, please specify:

For this question, one copy of HIV-1 RNA equals 2 IU/mL. Croatia provided estimates for minimum LOD for HIV NAT for tissues and non-reproductive cells – HIV-1 = 18 IU/ml; HIV-2 = 10.4 IU/ml. The NFPs added the following notes for the countries below:

- Cyprus: "*Limits of detection for HIV NAT are not regulated.*"
- Germany: "*There is no official definition for testing tissue donors. The specifications valid for blood donor testing (HIV-1: 10 000 IU/mL) are used as a basis.*"
- Portugal: "*There is no national legally binding or recommended minimum LOD for HIV NAT.*"

Q3. Practice in place

3.1. Does any establishment apply more stringent measures regarding HIV testing than what is legally required or recommended?

Nineteen countries responded to this question, with eight countries (38%) applying more stringent measures beyond mandatory or recommended ones. These additional tests correspond mainly to HIV p24 antigen (two countries) and/or HIV NAT, including HIV-2 NAT (Table 6).

Table 6. Additional tests applied beyond mandatory/recommended HIV testing strategy in tissues and non-reproductive cells donors testing, EU/EEA

Country	More stringent measures? (Y/N/NA)	If yes, which ones:			
		Anti-HIV-1/2	HIV p24Ag	HIV-1 NAT	HIV-2 NAT
Austria	Y				
Belgium	N				
Bulgaria	N				
Croatia	Y				
Cyprus	N				
Czechia	Y				
Denmark	Y				[a]
Estonia					
Finland	N				
France	N				
Germany	Y			[b]	
Greece	N				
Hungary					
Iceland	N				
Ireland					
Italy					
Latvia					
Liechtenstein	NA	NA	NA	NA	NA
Lithuania	N				
Luxembourg					
Malta	N				
Netherlands	Y				
Norway	N				
Poland	Y				
Portugal	N				
Romania	Y				
Slovakia					
Slovenia					
Spain					
Sweden					

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

Ag: antigen. HIV: human immunodeficiency virus. N: no. NA: not applicable. NAT: nucleic acid test. Y: yes.
[a] Note from NFP for Denmark: "4 of 5 regions use HIV1 / 2 NAT test - but HIV-2 NAT is not mandatory."
[b] Note from NFP for Germany: "For certain tissues such as cardiovascular tissues, musculoskeletal tissues and amniotic membranes (except for tissues for which a validated inactivation procedure is used)."

3.2. To the best of your knowledge, are the tests used for HIV donor testing validated for deceased donors?

Seventeen countries responded to this question. Eleven (52%) confirmed that the tests used for HIV donor testing are validated for application in deceased donors. Seven countries (41%) specified using serological tests, including combined antigen-antibody assays, validated for deceased donors. The use of validated HIV NAT was also reported by seven (41%) of the responding countries (Table 7).

Table 7. Tests used in HIV donor testing validated for deceased donors, EU/EEA

Country	HIV tests validated (Y/N/NA)	Anti-HIV-1/2	HIV p24Ag	HIV-1 NAT	HIV-2 NAT	Other
Austria	Y					
Belgium	Y					[a]
Bulgaria	N					
Croatia	Y					
Cyprus[b]	N					
Czechia	Y					
Denmark	Y					
Estonia						
Finland	N					
France	Y					
Germany	Y					
Greece						
Hungary						
Iceland	N					
Ireland						
Italy						
Latvia						
Liechtenstein	NA	NA	NA	NA	NA	NA
Lithuania	Y					
Luxembourg						
Malta						
Netherlands	Y					
Norway[c]	N					
Poland	Y					
Portugal[d]	N					
Romania	Y					
Slovakia						
Slovenia						
Spain						
Sweden	N					

	Validated test
	Not reported as a validated test
	No data

Ag: antigen. HIV: human immunodeficiency virus. N: no. NA: not applicable. NAT: nucleic acid test. Y: yes.
[a] Note from NFP for Belgium: "Samples from deceased donors must be analysed using tests validated by the producer himself or by the laboratory that performs them (in the absence of certification via the producer) for their use on postmortem samples".
[b] Note from NFP for Cyprus: "Samples from donors are collected while heart-beating, so labs use the same protocol for living donors."
[c] Note from NFP for Norway: "For recipients abroad, testing strategies for the recipient's country is applied."
[d] Note from NFP for Portugal: "To the best of your knowledge, one hospital has been performing a validation study for HIV screening on post-mortem samples."

Q4. Use of HIV-1 and HIV-2 NAT combined tests

4.1. Are HIV-1 and HIV-2 NAT combined tests used in your country?

Nineteen out of 21 countries responded to this question. NAT combined tests for HIV-1 and HIV-2 are in use in 11 countries (52%). For the seven countries testing for both viruses, the rationale provided was regarding reporting legal requirements (14%), local epidemiology (29%) and technical reasons (57%) (Table 8).

Table 8. Use of HIV-1 and HIV-2 combined NAT per country, EU/EEA

Country	Use of HIV-1 and HIV-2 combined NAT	Description of the HIV-1 and HIV-2 combined NAT in use	Rationale for the use of HIV-1 and HIV-2 combined NAT
Austria	Yes	Cobas® MPX Test, Roche.	*Legally binding.*
Belgium	No	NA	*NA*
Bulgaria	No	NA	*NA*
Croatia	Yes	NR	*Due to the frequent history of travel outside of the country in the donor population.*
Cyprus	Yes	All CE-marked reagents can be used.	*Choice of the laboratory.*
Czechia	No	NA	*NA*
Denmark	Yes	Procleix® Ultrio Elite Assay, Grifols (4 out of 5 regions)[a]	*It is used for our blood donors.*
Estonia			
Finland	No	NA	*NA*
France	Yes	The tests must be CE-marked and selected in public establishments according to the approved tenders.	*NR*
Germany	Yes	Procleix® Ultrio Elite Assay, Grifols; Cobas® MPX Test, Roche; Cobas ® TaqScreen MPX Test, Roche.	*HIV-2 NAT testing is included in the combined tests (multiplex tests), which are commercially available but are not legally binding due to a lack of epidemiological risk.*
Greece			
Hungary			
Iceland[b]	No	NA	*NA*
Ireland			
Italy			
Latvia			
Liechtenstein	No	NA	*NA*
Lithuania	No	NA	*NA*
Luxembourg			
Malta	No	NA	*NA*
Netherlands	Yes	NR	*NR*
Norway	Yes	A combined NAT-test for simultaneous detection of HIV-1 RNA and HIV-2 RNA in plasma was approved for diagnostic use: qualitative detection, not quantification.	*High-quality of test, cost-effectiveness, legal demands (recipients' country).*
Poland	No	NA	*NA*
Portugal	Yes	Cobas® MPX Test (on Cobas® 6800/8800 Systems for HIV-1 subgroup M (the most prevalent in Portugal), for HIV-1 subgroup O and HIV-2.	*Country's HIV epidemiology and demographic profile.*
Romania	Yes	NR	*NR*
Slovakia			
Slovenia			
Spain			
Sweden	Yes	*Use in some laboratories, but not all.*	*NR*

No data

HIV: human immunodeficiency virus. NA: not applicable. NAT: nucleic acid test. NR: not reported. RNA: ribonucleic acid.
[a] Note from NFP for Denmark: "One region uses NAT testing from Roche, but it does not detect HIV-2 RNA."
[b] Note from NFP for Iceland: "NAT testing is currently not required for tissue/cells donors in Iceland."

Survey on HIV testing requirements in the EU/EEA – reproductive cells

Responses were obtained from 21 countries (participation rate of 70%): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Iceland, Liechtenstein, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Spain and Sweden.

Liechtenstein did not provide additional information in this survey due to the lack of MAR service.

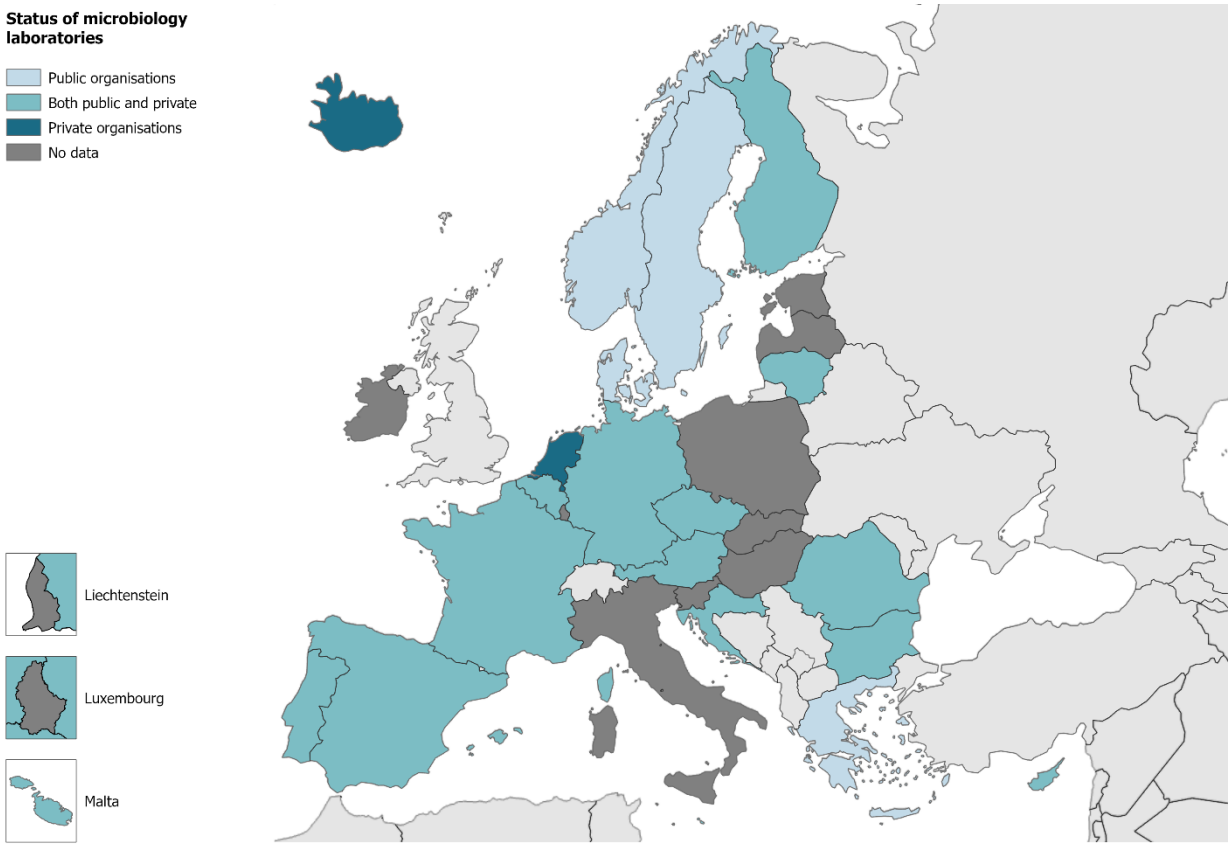
As of August 2024, no data was provided for Estonia, Hungary, Ireland, Italy, Latvia, Luxembourg, Poland, Slovakia and Slovenia, and no results from these countries are included in the report.

Q1. Organisation of the National Medically Assisted Reproductive Service

1.1 What is the status of the microbiology laboratories responsible for donor testing?

Among the 20 EU/EEA countries responding, four countries (20%) have microbiology laboratories performing donor testing integrated into public organisations, 14 countries (70%) have them integrated into both public and private organisations, and two countries (10%) have them integrated in private organisations (Figure 6).

Figure 6. Status of microbiology laboratories performing donor testing in the EU/EEA



Q2. What HIV testing strategies are required in your country for reproductive cell donors: are they legally binding or recommended on the national or regional level?

Twenty countries provided information on this question, which is presented in Table 9. HIV NAT is mandatory or recommended in seven (35%) of the participating countries, in addition to the compulsory serological testing for anti-HIV-1/2. In five (25%) countries, combined antigen-antibody tests are performed instead of antibody-only tests for HIV-1/2.

Table 9. HIV testing strategies for reproductive cells in the EU/EEA

Country	Anti-HIV-1/2	HIV p24Ag	HIV NAT
Austria			
Belgium			
Bulgaria			
Croatia			
Cyprus			
Czechia			
Denmark[a]			
Estonia			
Finland[b]			
France			[c]
Germany			
Greece			
Hungary			
Iceland[d]			
Ireland			
Italy			
Latvia			
Liechtenstein	NA	NA	NA
Lithuania[e]			
Luxembourg			
Malta			
Netherlands			
Norway			
Poland			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden[f]			

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

Ag: antigen. HIV: human immunodeficiency virus. NA: not applicable. NAT: nucleic acid test.
[a] Note from NFP for Denmark: "HIV NAT test is a must if donations are released without a re-test of anti-HIV six months after donation."
[b] Note from NFP for Finland: "Without 180-days quarantine time for sperm donors, PCR is obligatory."
[c] Note from NFP from France: "HIV NAT is used for third-party (non-partner) donation; in partner donation (direct and indirect use), it is performed only when anti-HIV-1/2 is positive".
[d] Note from NFP for Iceland: "In reproductive cells, anti-HIV-1/2 serology is required for non-spouse donors, and indirect spouse donations (cells processed and/or stored) if there is a risk of cross-contamination. However, anti-HIV-1/2 serology is NOT required for spouse donors in the case of direct use (no storage)."
[e] Note from NFP for Lithuania: "HIV NAT currently are used in third-party donation and partner donation (for indirect use). But HIV NAT is not mandatory if serological HIV tests (e.g. Anti-HIV-1/2) for those donors are repeated in 180 days."
[f] Note from NFP for Sweden: "HIV NAT is not mandatory, but when used, testing of the donor does not have to be repeated in 180 days, and the cells can be used without delay."

Q3. Practice in place

3.1. Does any establishment apply more stringent measures regarding HIV testing than what is legally required or recommended?

Seventeen countries responded to this question. Six countries (30%) apply more stringent measures beyond mandatory or recommended ones, which are mainly HIV NAT (six countries), including HIV-2 NAT (Table 10).

Table 10. Additional tests applied beyond mandatory/recommended HIV testing strategy in reproductive cells donors testing, EU/EEA

Country	More stringent measures? (Y/N/NA)	If yes, which ones:			
		Anti-HIV-1/2	HIV p24Ag	HIV-1 NAT	HIV-2 NAT
Austria	Y				
Belgium	N				
Bulgaria[a]	Y				
Croatia	N				
Cyprus	N				
Czechia	Y				
Denmark[b]	Y				
Estonia					
Finland	N				
France	N				
Germany	N				
Greece	N				
Hungary					
Iceland[c]	Y				
Ireland					
Italy					
Latvia					
Liechtenstein	NA	NA	NA	NA	NA
Lithuania	N				
Luxembourg					
Malta	N				
Netherlands					
Norway	N				
Poland					
Portugal	N				
Romania	Y				
Slovakia					
Slovenia					
Spain					
Sweden					

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

Ag: antigen. HIV: human immunodeficiency virus. N: no. NA: not applicable. NAT: nucleic acid test. Y: yes.
[a] Note from NFP for Bulgaria: "HIV-1 and HIV-2 NAT testing is performed in some living sperm donors."
[b] Note from NFP for Denmark: "Four of five regions use HIV-1/2 NAT test - but HIV-2 NAT is not mandatory."
[c] Note from NFP for Iceland: "LIVIO organises HIV-1/2 NAT testing for some reproductive donor cells (non-spouse donors) before releasing stored cells from quarantine."

4. Conclusion

According to the Blood Directive (2002/98/EC) and the Tissues and Cells Directive (2004/23/EC), all SoHO donors must be tested with serological testing for antibodies against HIV-1 and HIV-2 (anti-HIV-1/2). This report provides an overview of the current testing strategies for HIV in blood, and tissues and cells at the EU/EEA level. It shows that, in addition to the mandatory requirements of the Directives, the majority of the participating EU/EEA countries also apply molecular techniques (i.e. NAT) as part of their current testing strategy in the different SoHOs. NAT may be legally required or recommended within the country and is sometimes applied as an additional safety measure. The choice between NAT testing in individual donations or mini-pool testing differs among countries. It also depends on the type of SoHO and the characteristics of the screened donor. Mini-pools are used more frequently in blood testing.

HIV-2 NAT is also used by several countries. This is often related to the type of commercial tests available and requirements in the In Vitro Diagnostics Regulation and its implementing acts[iv], and not to a substantial risk based on the country's epidemiological profile for the virus.

This report provides information on the status of transfusion, transplantation, and MAR services within the EU/EEA and highlights the heterogeneity of donor testing strategies between countries. These data serve as a baseline for current testing practices of SoHO donors. ECDC will periodically monitor the progress of SoHO donor testing strategies in EU/EEA countries after the entry into force of ECDC guidelines for the prevention of donor-derived transmission of HIV in the EU/EEA.

[iv] European Commission (EC). Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council. Final text available in https://eur-lex.europa.eu/eli/reg_impl/2022/1107/oj.

Annex 1. Survey on HIV testing requirements in the EU/EEA – blood

EU blood donor HIV testing monitoring
Blood and blood components

Fields marked with * are mandatory.

***Please select your EU/EEA country:**

- AT - Austria
- BE - Belgium
- BG - Bulgaria
- HR - Croatia
- CY - Cyprus
- CZ - Czechia
- DK - Denmark
- EE - Estonia
- FI - Finland
- FR - France
- DE - Germany
- EL - Greece
- HU - Hungary
- IS - Iceland
- IE - Ireland
- IT - Italy
- LV - Latvia
- LI - Liechtenstein
- LT - Lithuania
- LU - Luxembourg
- MT - Malta
- NL - Netherlands
- NO - Norway
- PL - Poland
- PT - Portugal
- RO - Romania
- SK - Slovak Republic
- SI - Slovenia
- ES - Spain
- SE - Sweden

1. Organisation of the national transfusion service

1.1. Is there a centralised blood service in your country?

- Yes, at a national level
- Yes, at a regional level
- No

1.2. What is the status of the providers of the transfusion service?

- Public domain
- Private organisations
- Both

1.3. Please add any additional comment if needed.

2. What are the HIV testing strategies required in your country for blood donors: legally binding or recommended on the national or regional level?

	Applicable	If applicable please specify: universal testing	If applicable please specify: donors at risk only
Legally binding	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)
National recommendations	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)
Regional recommendations	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 antigen ☐ HIV NAT ID ☐ HIV NAT pool ☐ HIV NAT ID or pool not specified ☐ Other (please specify below)
If you selected "Other" please specify here:			

2.1. If a minimum limit of detection for HIV NAT is required, please specify:

(consider 1 copy HIV-1 = 2 IU/mL)

IU/mL

2.2. Please add any additional comment if needed. Where several tests are legally binding or recommended, please clarify if the requirement is to use any of these tests *(e.g., either HIV NAT **or** anti-HIV-1/2)*

3. Practice in place

3.1. Does any blood establishment apply more stringent measures regarding HIV testing from what is legally required or recommended?

- Yes
- No

3.2. Please add any additional comment if needed.

4. Use of HIV-1 and HIV-2 NAT combined tests

4.1. Are HIV-1 and HIV-2 NAT combined test in use in your country?

- Yes
- No

4.2. Please add any additional comment if needed.

Annex 2. Survey on HIV testing requirements in the EU/EEA – tissues and cells

EU TC donor HIV testing monitoring
Tissues and cells

Fields marked with * are mandatory.

***Please select your EU/EEA country:**

- AT - Austria
- BE - Belgium
- BG - Bulgaria
- HR - Croatia
- CY - Cyprus
- CZ - Czechia
- DK - Denmark
- EE - Estonia
- FI - Finland
- FR - France
- DE - Germany
- EL - Greece
- HU - Hungary
- IS - Iceland
- IE - Ireland
- IT - Italy
- LV - Latvia
- LI - Liechtenstein
- LT - Lithuania
- LU - Luxembourg
- MT - Malta
- NL - Netherlands
- No - Norway
- PL - Poland
- PT - Portugal
- RO - Romania
- SK - Slovak Republic
- SI - Slovenia
- ES - Spain
- SE - Sweden

1. Organisation of the national transplantation service for tissues and cells

1.1. What is the status of the microbiological laboratories responsible for donor screening?

- ○ Public domain
- ○ Private organisations
- ○ Both

1.2. How many microbiological laboratories perform donor screening nationally?

1.3. Are some of the microbiological laboratories responsible for donor screening able to provide results at any time or day (i.e., 24/7)?

- ○ Yes
- ○ No

1.4. Please add any additional comment if needed, including any differences between SoHOs (tissues and cells) or deceased/living donors

2. What are the HIV testing strategies required in your country for tissues and cells donors: legally binding or recommended on the national or regional level?

	Applicable?	Living donors: tissues and non-reproductive cells	Living donors: reproductive cells	Deceased donors
Legally binding	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)
National recommendations	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)
Regional recommendations	○ Yes ○ No	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)	☐ Serology: anti-HIV-1/2 ☐ Serology: HIV p24 Ag ☐ HIV NAT ☐ Other (specify below)
If you selected "Other" please specify here:				

2.2. Is molecular testing in pool authorised for tissues and cells donors?

- Yes
- No

2.3. If a minimum limit of detection for HIV NAT is required, please specify:
(consider 1 copy HIV-1 = 2 IU/mL)

IU/mL

2.4. Please add any additional comment if needed. Where several tests are legally binding or recommended, please clarify if the requirement is to use any of these tests *(e.g., either HIV NAT **or** anti-HIV-1/2)*

3. Practice in place

3.1 Does any establishment apply more stringent measures regarding HIV testing from what is legally required or recommended?

- Yes
- No

3.2 To the best of your knowledge, are the tests used for HIV screening validated for deceased donors?

- Yes
- No

3.3. Please add any additional comment if needed.

4. Use of HIV-1 and HIV-2 NAT combined tests

4.1. Are HIV-1 and HIV-2 NAT combined test in use in your country?

- Yes

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