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ASSESSMENT

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

ECDC ASSESSMENT

Survey on testing strategies for hepatitis C 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).

Authors

Flávia Cunha, François-Xavier Lamy, Jenny Mohseni Skoglund.

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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
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) testing
NFP	National focal point
NR	Not reported
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
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 [1]. The European Centre for Disease Prevention and Control (ECDC) was designated as the expert institution for this field of communicable diseases and assigned to draft guidelines on the prevention of hepatitis C virus (HCV) transmission through SoHO. On 1 June 2026, ECDC published 'Guidelines on the prevention of hepatitis C 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 HCV prior to the publication of ECDC guidelines, ECDC developed surveys to collect information on current HCV testing practices 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 HCV, including testing algorithms and laboratory testing methods.

Results

The number of countries that responded to the survey ranged from 18 countries for 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, HCV ribonucleic acid (RNA) nucleic acid amplification tests (NAT) are mandatory or recommended in 96%, 58% and 50% of the participating countries for donors of blood, tissues and non-reproductive cells, and reproductive cells, respectively.

In the blood field, either by law or national recommendation, HCV RNA NATs are performed on individual donations in 52% of the countries. Less than 50% of countries reported having a required limit of detection. When considering the use of HCV RNA NAT as an additional measure to enable the quarantine of donations to be waived, the proportion of countries applying NAT increases to 66% of responding countries in the reproductive cells field. The use of HCV antigen (Ag) testing is infrequent in the different SoHO fields and no countries reported using anti-HCV/HCV Ag tests.

Conclusion

In addition to the mandatory serological test, HCV RNA NAT is currently included in, or serves as a complement to the SoHO donor testing strategy in most participating countries, for the various SoHO. The survey showed limited heterogeneity among EU/EEA countries regarding the testing of SoHO donors for HCV. Future assessments will allow ECDC and the EU/EEA countries to understand the impact of ECDC guidelines on the donor testing strategies for HCV 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, (EU) 2024/1938, was published [1]. This Regulation repeals the Directive 2002/98/EC [2] and the 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 establishes the European Centre for Disease Prevention and Control (ECDC) as the expert body developing and updating technical guidelines on the safety and quality of SoHO from a communicable disease threat perspective. In this context, ECDC has developed guidelines for the prevention of hepatitis C virus (HCV) transmission through SoHO [4]. The guidelines provide requirements and recommendations on laboratory testing methods for the screening of donors for HCV, and requirements and recommendations on testing strategies for HCV.

This survey report describes the testing requirements for HCV in the different EU/EEA countries during the period when the ECDC guidelines were being developed, providing baseline information to the EU/EEA countries on the testing landscape before the publication of the guidelines on 1 June 2026 [4].

In 2015, a prior mapping exercise was performed by the Directorate-General for Health and Food Safety, aiming to provide information on more stringent testing requirements adopted by Member States for blood [5] and tissues and cell [6] donors, than the requirements established 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, covering information on the national testing recommendations and laboratory test methods for HCV, was shared with ECDC SoHO-Network national focal points (NFP) for the 30 EU/EEA countries for blood, tissues and cells, and medically assisted reproduction (MAR).

Data collection

The survey mainly included closed-ended questions. It was shared with the SoHO-Net NFPs in July 2024 and was due by September 2024. Additional data were collected during the data validation periods, between May and June 2025 and 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 HCV 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. Where relevant, the results were summarised in tables or represented in maps, and the comments provided by the participating countries were extracted and summarised.

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 was added to the draft report.

Non-responding countries

No results were included for those countries which did not respond.

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 HCV 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 HCV testing strategies at national and/or regional level.

In addition to the mandatory serological testing for antibodies against HCV (anti-HCV), the use of the HCV ribonucleic acid (RNA) nucleic acid (amplification) testing (NAT) is mandatory or recommended in 24 (96%) of the participating countries.

In 13 of these countries (54%), HCV RNA NAT is performed on individual donations, while ten (42%) countries did not specify whether they test in individual donations (ID) or in minipools (MP). Less than half of the countries reported a required limit of detection (LOD) for HCV RNA NAT [range: 1.0 – 5 000.0 international units (IU) per ml]. None of the countries reported using HCV Ag in their blood donor testing strategy for HCV. Additional information can be found in Table 1.

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

Country	Anti-HCV	HCV Ag	HCV RNA NAT – ID	HCV RNA NAT - MP	HCV RNA NAT (not specified)	Minimum 95% LOD NAT (IU/ml)
Austria[a]						700.0
Belgium						
Bulgaria						
Croatia						3.0
Cyprus						3.0
Czechia						150.0
Denmark						
Estonia						5000.0
Finland						
France[b]						None required
Germany						5000.0
Greece						
Hungary						
Iceland						
Ireland						
Italy						
Latvia						3.0
Liechtenstein						
Lithuania						
Luxembourg[c]						5000.0
Malta						4.3
Netherlands[d]						
Norway						
Poland[e]						5000.0
Portugal						None required
Romania						
Slovakia[f]						

Country	Anti-HCV	HCV Ag	HCV RNA NAT – ID	HCV RNA NAT - MP	HCV RNA NAT (not specified)	Minimum 95% LOD NAT (IU/ml)
Slovenia						
Spain[g]						1.0
Sweden[h]						

Ag: antigen. HCV: hepatitis C virus. ID: individual donation. IU: international unit. LOD: limit of detection. MP: minipools. NAT: nucleic acid test. RNA: ribonucleic acid.

Comments from the countries:

[a] **Austria** – *(…) A NAT test for HCV RNA may be legally required in addition to anti-HCV testing; however, only if a donation facility intends to apply the reduced exclusion periods after risks of exposure to HCV.*

[b] **France** – *Pools of 96 donations for plasma for fractionation are recommended at the national level, in accordance with the specifications of the fractionation laboratory.*

[c] **Luxembourg** – *HCV RNA NAT is performed in pools of 96 donations.*

[d] **Netherlands** – *HCV RNA NAT is performed in minipools of six donations.*

[e] **Poland** – *In the case of HCV RNA NAT performed in minipools, it is performed in minipools of four [transcription-mediated amplification (TMA)] or six donations [polymerase chain reaction (PCR)].*

[f] **Slovakia** – *The national transfusion service, which accounts for 75% of all donations, also performs HCV NAT ID, although this is not yet in the national regulations.*

[g] **Spain** – *The same testing strategy [anti-HCV and HCV RNA NAT (not specified)] is recommended at the regional level. HCV RNA NAT is performed in minipools of four or six donations.*

[h] **Sweden** – *NAT is legally required if available in the regions. One region is currently performing HCV RNA NAT. Sweden will have legally binding testing with anti-HCV and HCV RNA ID NAT in place at all establishments by 2027. The aim is to introduce MP-NAT at a later stage.*

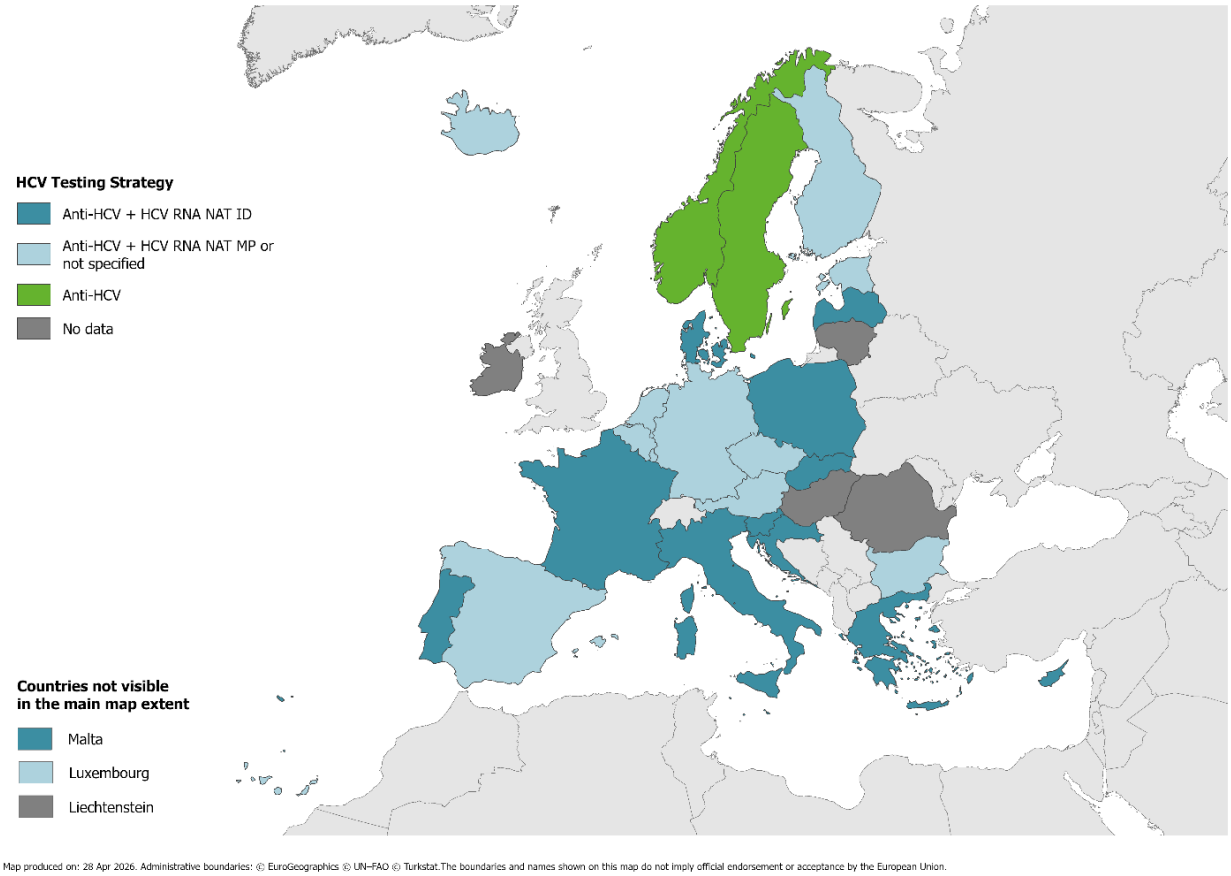
	Additional recommendation/guidance available		
	None	National recommendation	Regional recommendation
Legally binding testing strategy			
No legally binding testing strategy			
No data			

Practice in place

Testing algorithms

All responding countries provided information regarding the testing algorithm currently used. There is limited variability in the HCV testing strategies, mostly depending on whether HCV RNA NAT is performed for individual donations, as represented in Figure 1.

Figure 1. HCV main testing strategies (legally binding and/or recommended at national level) in blood donors, EU/EEA, 2025



HCV: hepatitis C virus. ID: individual donation. MP: minipools. NAT: nucleic acid test. RNA: ribonucleic acid.

Twenty-one countries (84%) reported performing the tests included in the main testing strategy simultaneously, with one country (4%) reporting the possibility of either a stepwise or a simultaneous approach to HCV testing. None of the countries reported the inclusion of HCV Ag or combined HCV antigen-antibody tests in the donor testing strategy. Repeatedly reactive samples for anti-HCV often lead to additional testing for anti-HCV using a different technique, or to confirmation through Western blot or Immunoblot. Additional information is available in Table 2.

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

Country	Main testing strategy	Test performance	Details of the algorithm
Austria	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*Serology testing is legally binding for every blood component. For blood products that are collected for direct transfusion without virus inactivation procedures, a determination of HIV and HCV genomes using NAT has to be performed (at the same time).*
Belgium	Anti-HCV + HCV RNA NAT MP, or not specified.	NR	*No testing algorithm is specified.*
Bulgaria	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	No additional information provided.
Croatia	Anti-HCV + HCV RNA NAT ID.	Simultaneous	*If the result of anti-HCV and/or HCV RNA NAT ID is positive, alternative anti-HCV and confirmatory immunoblot tests are performed.*

Country	Main testing strategy	Test performance	Details of the algorithm
Cyprus	Anti-HCV + HCV RNA NAT ID.	Simultaneous	*All donations in the Cyprus Blood Establishment are tested individually using two different methods: - CLIA for HIV Ag/Ab, HBsAg, syphilis IgG/IgM, and anti-HCV; - NAT (multiplex) detecting HIV RNA/HCV RNA/HBV DNA. (…) Repeatedly reactive samples for anti-HCV or HCV RNA or for both are also tested at the Reference Laboratory for anti-HCV (with both ELISA and CLIA techniques) and HCV Western blot to confirm if the donor has a positive, indeterminate or false positive result, or maybe is in a window period. Depending on the results from the Reference Laboratory, we take additional actions based on the testing algorithm.*
Czechia	Anti-HCV + HCV RNA NAT MP.	Simultaneous	No additional information provided.
Denmark	Anti-HCV + HCV RNA NAT ID.	Simultaneous	No additional information provided.
Estonia	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*All blood establishments can perform NAT in MP according to law, but blood establishments often opt to perform NAT ID (multiplex test against HIV, HBV and HCV). If the multiplex NAT test is positive, the next test will be discriminatory ID NAT.*
Finland	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*If either test is reactive, re-testing in duplicates will follow. Repeatedly reactive anti-HCV in the primary screening test will lead to testing with a second anti-HCV screening (different technology), and if the second screening is reactive, a confirmatory test (Immunoblot) is performed.*
France	Anti-HCV + HCV RNA NAT ID.	Simultaneous	*HCV serology is based on a test detecting anti-HCV alone and not a combined Ag/Ab test, as is the case for HIV. HCV Ag test is not performed on blood donations (…).*
Germany	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*Tests are performed for each donation. If quarantine storage of fresh frozen plasma is waived, screening with an ID or MP HCV RNA NAT with a sensitivity of at least 1900 IU/ml is required.*
Greece	Anti-HCV + HCV RNA NAT ID.	Simultaneous	No additional information provided.
Hungary			
Iceland	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*Anti-HCV is a basic requirement for whole blood units and blood components obtained by apheresis. HCV RNA NAT implemented from and including 1 July 2025, according to Regulation Nr. 1091 12 September 2024, on the (7th) amendment to Regulation No. 441/2006 on the collection, processing, preservation, and distribution of blood.*
Ireland			
Italy	Anti-HCV + HCV RNA NAT ID.	Simultaneous	No additional information provided.
Latvia	Anti-HCV + HCV RNA NAT ID.	Simultaneous	No additional information provided.
Liechtenstein			
Lithuania			
Luxembourg	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*Both tests are performed simultaneously for all blood donations.*
Malta	Anti-HCV + HCV RNA NAT ID.	Simultaneous	*If anti-HCV is repeatedly reactive from initial donation and fresh sample, a confirmatory test is performed. If multiplex NAT is reactive, a discriminatory test for HCV is performed.*
Netherlands	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	*HCV RNA NAT is performed in a multiplex assay (in minipools of six donations).*
Norway	Anti-HCV	NA	*If non-negative anti-HCV, supplementary tests are performed, such as HCV RNA NAT, as well as alternative or supplementary anti-HCV tests. Donors are always excluded if the primary test is not negative.*
Poland	Anti-HCV + HCV RNA NAT ID.	Stepwise or simultaneous	*Algorithm I is performed in sequential order: anti-HCV negative donations are screened for HCV RNA. Algorithm II is also allowed, in which anti-HCV and HCV RNA NAT are performed simultaneously. In the event of a donation in which anti-HCV and/or HCV RNA NAT are repeatedly reactive, the sample will be referred for supplementary HCV RNA NAT and/or Western blot.*

Country	Main testing strategy	Test performance	Details of the algorithm
Portugal	Anti-HCV + HCV RNA NAT ID.	NR	No additional information provided.
Romania			
Slovakia	Anti-HCV HCV RNA NAT ID.	Simultaneous	*In the National Transfusion Service (responsible for 75% of all donations in Slovakia): anti-HCV + HCV RNA ID simultaneously. In the event of a positive result, we send it to the National Reference Centre for confirmatory testing.*
Slovenia	Anti-HCV + HCV RNA NAT ID.	Simultaneous	*Each of the two assays is performed from its own sample: anti-HCV and NAT ID (combined assay for HCV RNA, HBV DNA, HIV RNA).* *In the event of an anti-HCV reactive result or grey-zone result, tests are repeated in duplicate; in the event of a repeatedly reactive or repeatedly grey-zone anti-HCV result: confirmatory anti-HCV test (Immunoblot assay).* *In the event of a reactive multiplex NAT result, repeat in duplicate and perform discriminatory NAT tests (HCV RNA, HBV DNA, HIV RNA).*
Spain	Anti-HCV + HCV RNA NAT MP, or not specified.	Simultaneous	No additional information provided.
Sweden	Anti-HCV.	Simultaneous	*In the regions where HCV RNA NAT is available, it is performed simultaneously (in individual donations).*

Ag: antigen. 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. RNA: ribonucleic acid. RR: repeatedly reactive.

Note: the text in italics denotes verbatim replies provided by the countries.

	No data

Additional measures

Of the 25 responding countries, two (8%) reported having more stringent measures than the mandatory or recommended measures – namely performing HCV RNA NAT on individual donations.

Table 3. Additional measures applied beyond mandatory/recommended HCV testing strategy and proportion of donations tested with additional methods, EU/EEA, 2025

Country	More stringent measures? (Yes/No)	If yes, which ones:				
		HCV Ag	HCV RNA NAT - ID	HCV RNA NAT - MP	HCV RNA NAT (not specified)	Other
Austria						
Belgium	No					
Bulgaria	No					
Croatia	No					
Cyprus	Yes					
Czechia	No					
Denmark	No					
Estonia	No					
Finland	No					
France	No					
Germany	No					
Greece	No					
Hungary						
Iceland	No					
Ireland						
Italy	No					
Latvia	No					
Liechtenstein						
Lithuania						
Luxembourg	No					
Malta	No					
Netherlands	No					
Norway	No					
Poland						
Portugal	No					
Romania						
Slovakia	Yes					
Slovenia	No					
Spain	No					
Sweden	No					

Ag: antigen. HCV: hepatitis C virus. ID: individual donation. MP: minipools. NAT: nucleic acid test. RNA: ribonucleic acid.

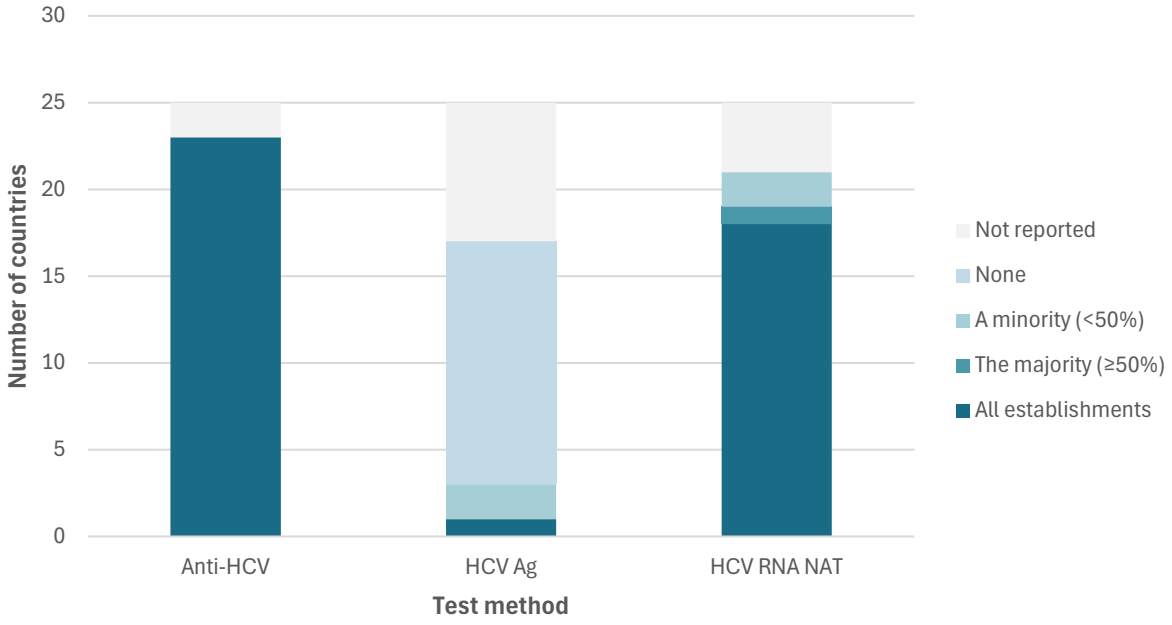
	Reported as an additional test
	Not reported as an additional test
	No data

Implementation of test methods in SoHO establishments

Twenty-three countries provided information regarding the proportion of establishments performing different test methods for HCV screening. In 19 countries (82%), the majority, or all blood establishments are currently performing HCV RNA NAT (Figure 2). With regard to HCV Ag, only one country reported that all establishments perform the test, and in two countries, less than 50% of the establishments perform HCV Ag. However, as reported above, HCV Ag is not included in the main blood donor testing strategy for HCV (Table 2).

In addition, two countries (Finland and Latvia) reported that all blood donations are tested in one establishment, while in Slovenia, HCV RNA NAT is centralised at one establishment, while serological tests are performed at three establishments.

Figure 2. Proportion of SoHO establishments performing different HCV screening test methods, EU/EEA, 2025



Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid

Tissues and non-reproductive cells

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

National HCV 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 HCV testing strategies for tissues and non-reproductive cell donors (living and deceased) at the national and/or regional level.

Living donors

In addition to the mandatory serological testing for anti-HCV, the use of HCV RNA NAT is mandatory or recommended in 11 (58%) of the participating countries. One country (6%) reported using HCV Ag in their donor testing strategy for HCV. Additional information can be found in Table 4.

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

Country	Anti-HCV	HCV Ag	HCV RNA NAT
Austria[a]			
Belgium[b]			
Bulgaria			
Croatia			
Cyprus			
Czechia			
Denmark			
Estonia			
Finland			
France			
Germany[c]			
Greece			
Hungary			
Iceland			
Ireland			
Italy			
Latvia			
Liechtenstein			
Lithuania			
Luxembourg			
Malta			
Netherlands			
Norway			
Poland			
Portugal			
Romania			
Slovakia			
Slovenia			
Spain			
Sweden			

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

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 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 these viruses.*

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

[c] **Germany –** *For the screening of allogenic hematopoietic progenitor cell (HPC) donors, HCV RNA NAT is performed in addition to the serological tests.*

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

Deceased donors

In addition to the mandatory serological testing for anti-HCV, thirteen of the 19 participating countries (68%) reported mandatory or recommended use of HCV RNA NAT. One country (6%) reported using HCV Ag in their donor testing strategy for HCV. More details can be found in Table 5.

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

Country	Anti-HCV	HCV Ag	HCV RNA 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			

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

	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 HCV molecular testing (i.e. NAT) in pools for tissues and non-reproductive cell donors. The number of pooled samples applied was not specified.

Minimum LOD requirements for HCV RNA NAT

For this question, the countries were told to consider that 2.73 copies of HCV RNA equal 1 IU/mL. Estimates for the minimum LOD for HCV RNA NAT relating to tissues and non-reproductive cells were provided by the following countries:

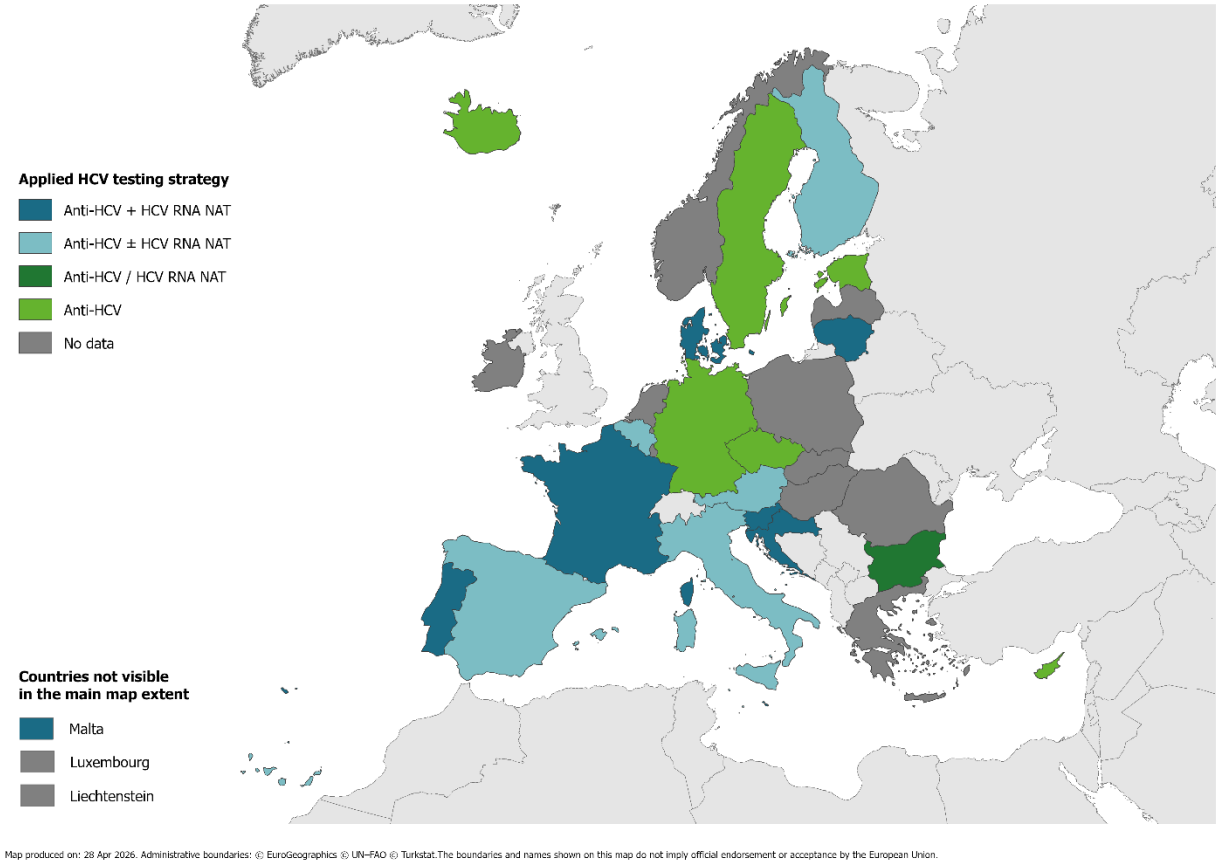
- Croatia – 3.0 IU/mL
- Denmark – 25.0 IU/mL
- Germany - ≤5 000.0 IU/mL, including in case of haematopoietic progenitor cells (HPC)
- Slovenia – 3 IU/mL
- Spain – 50 IU/mL.

Practice in place

Testing algorithms

Sixteen countries (84%) provided detailed information regarding the testing algorithm currently used. There is some variability in the HCV testing strategies applied by the countries for testing in tissues and non-reproductive cell donors (see Figure 3). This variability is mainly linked to the use of HCV RNA NAT in specific donor groups or to allow for waiving quarantine.

Figure 3. HCV applied testing strategies (legally binding and/or recommended at the national level) in tissue and non-reproductive cell donors, EU/EEA, 2025



HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

Most countries where anti-HCV and HCV RNA NAT are performed reported carrying out the tests simultaneously, with one country reporting a stepwise approach to HCV testing. Three countries (15%) report the possibility of skipping HCV RNA 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 HCV screening tests in tissues and non-reproductive cell donors, EU/EEA, 2025

Country	Main testing strategy	Details of the algorithm
Austria	Anti-HCV ± HCV RNA NAT	*Serology and HCV RNA NAT are performed simultaneously if no quarantine is applied. When the donation is quarantined, only a serological test is performed at the time of donation and repeated after six months.*
Belgium	Anti-HCV ± HCV RNA NAT	*All donors must undergo at least the following biological tests:* *A. In living donors:* *- anti-HCV* *B. In all deceased donors, the tests referred to in A are also carried out, with, unless the treatment includes an inactivation step that is validated for the viruses concerned, the following additional tests:* *- HCV RNA NAT.* *Where human body material from living donors for allogeneic use can be stored for long periods, the sampling and testing should be repeated after a period of 180 days. In the event of repeat tests, the sample taken at the time of donation may be collected within thirty days before donation and within seven days after donation.* *When human body material from living donors for allogeneic use cannot be stored for long periods and therefore re-sampling is not possible, NAT testing is performed, unless the treatment includes an inactivation step that is validated for the virus in question.* *If, in the case of a living donor, the 'sample taken at the time of donation' is also tested using the nucleic acid amplification technique for HCV, it is not necessary to re-test a second blood sample. The same applies when the treatment includes an inactivation step that is validated for the viruses in question.*
Bulgaria	Anti-HCV *or* HCV RNA NAT	*Anti-HCV is performed, or only HCV RNA NAT is performed.*
Croatia	Anti-HCV + HCV RNA NAT	*The tests are performed simultaneously.*
Cyprus	Anti-HCV	No additional information provided.
Czechia	Anti-HCV	No additional information provided.
Denmark	Anti-HCV + HCV RNA NAT	*The tests are performed simultaneously.*
Estonia	Anti-HCV	*Anti-HCV is performed. If the tissue establishment has chosen to also test for HCV RNA NAT, they are tested simultaneously.*
Finland	Anti-HCV ± HCV RNA NAT	*HCV RNA NAT mandatory only for deceased donors. All tests are performed simultaneously.*
France	Anti-HCV + HCV RNA NAT	*All tests are necessary and must be performed simultaneously.*
Germany	Anti-HCV	*HCV DNA NAT is performed for certain tissues such as cardiovascular tissues, musculoskeletal tissues, ocular tissues and amniotic membranes (except for tissues for which a validated inactivation procedure is used).*
Greece		
Hungary		
Iceland	Anti-HCV	*Autologous hematopoietic stem cells only.*
Ireland		
Italy	Anti-HCV ± HCV RNA NAT	Living donor (HPC): *Anti-HCV and HCV RNA NAT are performed simultaneously.* Living donor (tissues): *Anti-HCV, followed by quarantine of 180 days. If not quarantined, it is necessary to perform HCV RNA NAT.* Deceased donors: *Anti-HCV. If anti-HCV is positive, HCV RNA NAT is performed sequentially.*
Latvia		
Liechtenstein		
Lithuania	Anti-HCV + HCV RNA NAT	*All tests are performed simultaneously*

Country	Main testing strategy	Details of the algorithm
Luxembourg		
Malta	Anti-HCV + HCV RNA NAT	*The tests are performed simultaneously.*
Netherlands		
Norway		
Poland		
Portugal	Anti-HCV + HCV RNA NAT	No additional information provided.
Romania		
Slovakia		
Slovenia	Anti-HCV + HCV RNA NAT	*Tests are performed sequentially: first anti-HCV, followed by anti-HCV in double samples, and HCV RNA NAT.*
Spain	Anti-HCV ± HCV RNA NAT	*Anti-HCV tests are legally binding. HCV RNA NAT is required for non-reproductive cells. HCV Ag can be used sometimes.*
Sweden	Anti-HCV	*All tests are performed simultaneously.* *No legally binding recommendation for HCV RNA NAT exists across all tissue and cell types.*

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid. '±' was applied if HCV RNA NAT can be performed to waive quarantine.

Note: the text in italics denotes verbatim replies provided by the countries.

	No data

Additional measures

Sixteen countries responded to this question. Six countries (38%) apply more stringent measures beyond mandatory or recommended ones, with additional testing corresponding to HCV RNA NAT (Table 7).

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

Country	More stringent measures? (Yes/No)	If yes, which ones:	
		HCV Ag	HCV RNA NAT
Austria			
Belgium	No		
Bulgaria	Yes		
Croatia			
Cyprus	Yes		
Czechia	Yes		
Denmark	No		
Estonia	Yes		
Finland			
France	No		
Germany	Yes		
Greece			
Hungary			
Iceland	No		
Ireland			
Italy	No		
Latvia			
Liechtenstein			
Lithuania	No		
Luxembourg			
Malta	No		
Netherlands			
Norway			
Poland			
Portugal	No		
Romania			
Slovakia			
Slovenia	No		
Spain	No		
Sweden	Yes		

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

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

Validation of tests for deceased donors

Among the 17 responding countries, 14 (82%) confirmed that the tests used for HCV screening are validated for application in deceased donors. Additional information is available in Table 8.

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

Country	Screening tests validated (Yes/No)	Anti-HCV	HCV Ag	HCV RNA NAT	Other
Austria	Yes				
Belgium	Yes				
Bulgaria					
Croatia	Yes				
Cyprus	No				
Czechia	Yes				
Denmark	Yes				
Estonia	Yes				
Finland					
France	Yes				
Germany	Yes				
Greece					
Hungary					
Iceland	No				
Ireland					
Italy	Yes				
Latvia					
Liechtenstein					
Lithuania	Yes				
Luxembourg					
Malta	Yes				
Netherlands					
Norway					
Poland					
Portugal	No				
Romania					
Slovakia					
Slovenia	Yes				
Spain[a]	Yes				
Sweden[b]	Yes				

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

Comments from the countries:

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

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

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

Additional information related to tissues and non-reproductive cells donation

Eligibility of donors with documented treatment and cure

Donors with a history of hepatitis C (anti-HCV-positive and HCV RNA-negative), with documented treatment and cure of the infection (i.e. sustainable virological response) are eligible as tissue donors in five countries (Austria, Belgium, France, Slovenia and Spain). The following notes were added by the NFPs:

- Belgium: 'in the event of allogenic donation, the decision on the eligibility of anti-HCV-positive and HCV RNA-negative donors with documented treatment and cure is made by the treating physician and clinical team, based on a documented risk assessment. There is no national or legal ad hoc guidance in our country on this subject'.
- France: 'there is a specific regulation detailing these situations: https://www.legifrance.gouv.fr/loda/id/JORFTEXT000031690049/2022-05-29/'.
- Spain: 'donation from anti-HCV-positive and HCV RNA-negative donors with documented treatment and cure has only been accept in specific tissue establishments, for a few selected donors'.

Reproductive cells

Eighteen EU/EEA countries responded to the survey (participation rate 60%). As of January 2026, no data had been provided for Greece, Hungary, Ireland, Latvia, Liechtenstein, Luxembourg, Malta, Norway, Poland, Portugal, Romania, or Slovakia.

National HCV testing strategies for donors

All 18 reporting countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Iceland, Italy, Lithuania, Netherlands, Slovenia, Spain and Sweden) provided information on the HCV testing strategy for reproductive cells (third-party donation and within relationship use) at national and/or regional level.

Third-party donation

In addition to the mandatory serological testing for anti-HCV, the use of HCV RNA NAT is mandatory or recommended in nine (50%) of the participating countries. One country (6%) reported using HCV Ag in their donor testing strategy for HCV. Additional information can be found in Table 9.

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

Country	Anti-HCV	HCV Ag	HCV RNA 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. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

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

In addition to the mandatory serological testing for anti-HCV, the use of HCV RNA NAT is mandatory or recommended in four (22%) of the participating countries. One country (6%) reported using HCV Ag in their HCV testing strategy for partners who contribute with their SoHO. Additional information can be found in Table.

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

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

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test. RNA: ribonucleic acid.

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.*

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

Molecular testing in pools

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

Minimum LOD requirements for HCV RNA NAT

For this question, the countries were asked to consider that 2.73 copies of HCV RNA equal 1 IU/mL. Seven countries provided information on minimum LOD requirements for HCV RNA NAT. Estimates for the minimum LOD for HCV RNA NAT in relation to reproductive cells were provided by Slovenia (3 IU/mL); these minimum LOD values apply to both third-party donation and within relationship use. Six countries reported that no minimum LOD for HCV RNA NAT is defined in legislation and/or recommendations.

Practice in place

Testing algorithms

Fifteen of 18 countries (95%) provided information on the testing algorithm. Four countries specified different algorithms applied for third-party donation and within-relationship use. Eight countries reported that, if HCV RNA 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 HCV screening tests in reproductive cell donation, EU/EEA, 2025

Country	Main testing strategy	Details of the algorithm
Austria	Anti-HCV ± HCV RNA NAT	Third-party donation: *Serology and NAT are performed simultaneously. If HCV RNA NAT is performed, no quarantine is applied.*
Belgium	Anti-HCV ± HCV RNA NAT	*The tests are performed simultaneously.* *HCV RNA NAT, if performed at donation, can allow waiving of quarantine.*
Bulgaria	Anti-HCV *or* HCV Ag *or* HCV RNA NAT	*From the serological tests, either anti-HCV or HCV Ag tests can be chosen, or only HCV RNA NAT can be performed. In the event of a positive serological test, HCV RNA NAT must be performed.*
Croatia	Anti-HCV	No additional information provided.
Cyprus	Anti-HCV	No additional information provided.
Czechia	Anti-HCV	No additional information provided.
Denmark	Anti-HCV + HCV RNA NAT	*The tests are performed simultaneously.*
Estonia	Anti-HCV	*Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by NAT for HIV, HBV and HCV (i.e. in addition to anti-HIV-1 and -2, HBsAg, anti-HBc and anti-HCV serology), testing of a repeat blood sample is not required.*
Finland	Anti-HCV	Third party donations: *Sperm donor quarantine for 180 days and subsequent testing of the donor prior to release. No quarantine needed if HCV RNA NAT is performed.* Within relationship use: *Initial testing for anti-HCV, additional testing only if treatment exceeds 24 months. Sperm collected for within-relationship use may be used even if HCV-serology is positive, at the discretion of the physician and in agreement with the parties involved, but the sperm must be stored separately.*
France	Anti-HCV + HCV RNA NAT	Third-party donation: *Initial assessment for donation: anti-HCV and HCV RNA NAT; if any of these tests are positive, the donor will not be selected.* *At the time of donation or at last collection (if donations were made on more than one date): repeat serological tests and HCV RNA NAT. If NAT is not performed, serological markers are repeated six months after the donation or the last collection (…).* Within relationship use: *Tests are performed within the six months preceding the first collection or removal of gametes or germ tissue, the first insemination, the first embryo transfer from a donor, the first use of gametes/germ tissue stored as part of fertility preservation.* *Between two attempts, if a risk is identified: repeat screening.*

Country	Main testing strategy	Details of the algorithm
Germany	Anti-HCV	Third party donations: *Anti-HCV for every donation, quarantine for 180 days and subsequent testing of the donor prior to release. No quarantine needed if HCV RNA NAT is performed (no defined LOD), or if the processing of the donation includes a virus inactivation step which has proven to be effective.* Within relationship use: *Initial testing for anti-HCV, additional testing only if treatment exceeds 24 months. Sperm collected for within-relationship use may be used even if HCV serology is positive, at the discretion of the physician and in agreement with the parties involved, but the sperm must be stored separately.*
Greece		
Hungary		
Iceland	Anti-HCV	*According to one of the MAR clinics in Iceland (private sector):* *Oocyte donation:* *Preliminary tests (as part of donor screening) – anti-HCV* *Continuously test (after egg donor approval, prior to egg collection and/or egg release) – anti-HCV.* *Sperm donation:* *Initial test (part of the sperm donor screening): should always be by both NAT and serology for HCV (anti-HCV).* *Tests for release of donations or where there are risk habits: both NAT and serology for HCV (anti-HCV).*
Ireland		
Italy	Anti-HCV ± HCV RNA NAT	Third-party donation: *Anti-HCV (quarantine of 180 days). If no quarantine, it is necessary to perform HCV RNA NAT.*
Latvia		
Liechtenstein		
Lithuania	Anti-HCV + HCV RNA NAT	*All tests are performed simultaneously.*
Luxembourg		
Malta		
Netherlands	Anti-HCV	*Anti-HCV initially; if positive, then HCV RNA NAT is performed.*
Norway		
Poland		
Portugal		
Romania		
Slovakia		
Slovenia	Anti-HCV + HCV RNA NAT	*Tests are performed sequentially: first anti-HCV, then anti-HCV in double samples, and HCV RNA NAT.*
Spain	Anti-HCV	*In the event of positive anti-HCV, HCV RNA NAT is performed; if NAT is negative, the donation is accepted.*
Sweden	Anti-HCV	*Tests are performed on donation, with a retest at Day 180 after storage, unless HCV RNA NAT is used.*

Ag: antigen. HBV: hepatitis B virus. HCV: hepatitis C virus. HIV: human immunodeficiency virus. MAR: medically assisted reproduction. NAT: nucleic acid test. RNA: ribonucleic acid.

Note: the text in italics denotes the verbatim replies provided by the countries.

	No data

Additional measures

Fourteen of 18 countries responded to this question. Six (43%) countries apply measures that are more stringent than the mandatory or recommended measures, and the majority of these relate to additional testing with HCV RNA NAT (Table 12).

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

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

Ag: antigen. HCV: hepatitis C virus. NAT: nucleic acid test.

Comments from the countries:
[a] **Belgium** – *Some establishments require anti-HCV for every donation within couple use.*
[b] **Bulgaria** – *When the non-partner sperm sample taken at the time of donation is tested with HCV RNÃ NAT after the quarantine period, these tests do not need to be repeated, and no quarantine is performed after a negative HCV RNA NAT.*
[c] **Iceland** – *Applicable for sperm donors* (see 'Details of the algorithm' above).
[d] **Italy** – *HCV RNA NAT is performed in the event of an anti-HCV reactive result within relationship use.*

	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 cell donors must be tested for hepatitis C infection, with serological testing for the detection of anti-HCV.

Over the last two decades, countries across the EU/EEA have been updating their testing strategies to include other tests in addition to a serological test. Some countries have already reported introducing molecular techniques (i.e. HCV RNA NAT) into 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 HCV RNA 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 HCV RNA NAT is legally required, or recommended (24/25), followed by the tissues and non-reproductive cells field (13/19). Performing HCV RNA NAT in individual donations or in minipools varies, depending on the type of SoHO and the characteristics of the screened donor, with testing in minipools being more frequent in the blood field.

In the reproductive cells field, for third-party donation, HCV RNA NAT is used as an additional measure to allow quarantine of donations to be waived, along with the need for repeat serological testing of donors to release donations from quarantine. When the use of HCV RNA NAT to waive quarantine is taken into consideration, the number of countries where HCV RNA NAT is applied increases from nine to 12 (out of 18).

One overall observation for the different SoHO fields is the reduced use of HCV Ag testing, and the absence of combined anti-HCV/HCV Ag tests.

In contrast to hepatitis B virus (HBV), there is not so much variability in the HCV testing strategies adopted by the countries. In the blood field, it is mainly linked to whether HCV RNA NAT is performed in individual donations or in pools, while in tissues and non-reproductive cells, it is related to the use of HCV RNA NAT in specific donor groups, or to allow for quarantine to be waived.

The overall aim of the SoHO Regulation is to harmonise practices in the SoHO field among EU/EEA countries. The ECDC guidelines contribute to this goal, focusing on the prevention of communicable disease transmission. 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 HCV through SoHO in the EU/EEA and the entry into force of the SoHO Regulation.

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

Blood and blood components

1. National HCV testing strategies for donors

1.1. Which HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ID ☐ HCV RNA NAT MP (please specify below the number of mini pools) ☐ HCV RNA NAT ID or MP not specified ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ID ☐ HCV RNA NAT MP (please specify below the number of mini pools) ☐ HCV RNA NAT ID or MP not specified ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ID ☐ HCV RNA NAT MP (please specify below the number of mini pools) ☐ HCV RNA NAT ID or MP not specified ☐ Other (please specify)
If you selected "HCV RNA 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 HCV RNA NAT is required, please specify:
(please consider 1 IU = 2.73 HCV RNA 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 HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ID ☐ HCV RNA NAT MP (please specify below the number of mini pools) ☐ HCV RNA NAT ID or MP not specified ☐ Other (please specify)
If you selected "HCV RNA 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: anti-HCV	Answer:
Serology: HCVAg	Answer:
HCV RNA 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 HCV testing strategies for donors

1.1. Which HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA 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 HCV RNA NAT is required, please specify:
(please consider 1 IU = 2.73 HCV RNA 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 HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA 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 HCV screening validated for deceased donors?

○ Yes
○ No

2.4. Are anti-HCV-positive and HCV RNA-negative donors with documented treatment and cure (i.e. sustainable virological response) considered elegible for tissue donation in your country?

○ Yes
○ No

2.5. Please add any additional comments if needed:

Reproductive cells

1. National HCV testing strategies for donors

1.1. Which HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)
National recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)
Regional recommendation	Answer: ○ Yes ○ No	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)	Answer: ☐ Serology: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA 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 HCV RNA 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 HCV 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: anti-HCV ☐ Serology: HCVAg ☐ HCV RNA NAT ☐ Other (please specify)
If you selected "Other", please specify here:		Answer:

2.3. Please add any additional comments if needed:

European Centre forDisease Prevention and Control (ECDC)

Gustav III:s Boulevard 40
169 73 Solna, Sweden

Tel. +46 858 60 10 00
ECDC.info@ecdc.europa.eu

www.ecdc.europa.eu

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