II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/1244

of 1 July 2019

amending Decision 2002/364/EC as regards requirements for HIV and HCV antigen and antibody combined tests and as regards requirements for nucleic acid amplification techniques with respect to reference materials and qualitative HIV assays

(notified under document C(2019) 4632)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ([1]), and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

(1) Pursuant to Article 5(3) of Directive 98/79/EC, Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of devices designed and manufactured in conformity with common technical specifications. The common technical specifications for in vitro diagnostic medical devices are laid down in Commission Decision 2002/364/EC ([2]).

(2) In the interest of public health and patient safety and in order to reflect scientific and technological progress, including the evolution in the intended use, performance and analytical sensitivity of certain devices, it is appropriate to further revise the common technical specifications laid down in Decision 2002/364/EC.

(3) Taking into account the evolving state of the art, changing clinical needs, growing scientific knowledge, and the new types of devices present on the market, the common technical specifications should be amended with respect to the requirements for HIV and hepatitis C virus (HCV) antigen and antibody combined tests, as well as the requirements for nucleic acid amplification techniques as regards reference materials and qualitative HIV assays.

(4) The manufacturers should be allowed time to adapt to the new common technical specifications. The date of application of the requirements laid down in this Decision should therefore be deferred. However, in the interest of public health and patient safety, manufacturers should be allowed to follow the new common technical specifications before the date of application on a voluntary basis.

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 6(2) of Council Directive 90/385/EEC ([3]),

([1]) OJ L 331, 7.12.1998, p. 1.
([2]) Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).
([3]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/364/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 2 July 2020.

Until that date, Member States shall apply the presumption of compliance referred to in Article 5(3) of Directive 98/79/EC for all *in vitro* diagnostic medical devices that comply with either of the following specifications:

(a) the common technical specifications laid down in the Annex to Decision 2002/364/EC as amended by Commission Decision 2011/869/EU ([4]);

(b) the common technical specifications laid down in the Annex to Decision 2002/364/EC as amended by this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 1 July 2019.

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

([4]) Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63).

ANNEX

The Annex to Decision 2002/364/EC is amended as follows:

(1) Sub-section 3.1.1 is replaced by the following:

'3.1.1 Devices which detect virus infections shall meet the requirements for sensitivity and specificity set out in Table 1 and Table 5 according to virus type and entities detected (antigen and/or antibody). See also principle 3.1.11 for screening assays.'

(2) Section 3.2 is replaced by the following:

'3.2. **Additional requirements for HIV and HCV antigen and antibody combined tests.**

3.2.1. HIV antigen and antibody combined tests intended for the detection of HIV-1 p24 antigen and HIV-1/2 antibody shall meet the requirements for sensitivity and specificity set out in Table 1 and Table 5.

3.2.2. Hepatitis C virus (HCV) antigen and antibody combined tests intended for the detection of HCV antigen and HCV antibody shall meet the requirements for sensitivity and specificity set out in Table 1 and Table 5. HCV seroconversion panels for the evaluation of HCV antigen and antibody combined tests shall start with one or more negative bleeds and comprise panel members from early HCV infection (HCV core antigen and/or HCV RNA positive but anti-HCV negative). HCV antigen and antibody combined tests shall demonstrate enhanced sensitivity in early HCV infection when compared to HCV antibody only tests.'

(3) Sub-section 3.3.2 is replaced by the following:

'3.3.2. The analytical sensitivity or detection limit for NAT assays shall be expressed by the 95 % positive cut-off value. This is the analyte concentration where 95 % of test runs give positive results following serial dilutions of an international reference material, where available, such as a World Health Organisation (WHO) International Standard or reference material calibrated against a WHO International Standard.'

(4) The following sub-sections 3.3.2a and 3.3.2b are inserted:

'3.3.2a. Qualitative HIV NAT assays intended to be used to detect the presence of HIV in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration shall be designed to detect both HIV-1 and HIV-2.

3.3.2b. Qualitative HIV NAT assays, other than virus typing assays, shall be designed to compensate for the potential failure of a HIV-1 NAT target region, e.g. by using two independent target regions.'

(5) Table 1 is replaced by the following:

'Table 1

Screening assays: anti-HIV 1/2, HIV 1/2 Ag/Ab, anti-HTLV I/II, anti-HCV, HCV Ag/Ab, HBsAg, anti-HBc

		anti-HIV 1/2, HIV 1/2 Ag/Ab	Anti-HTLV-I/II	anti-HCV, HCV Ag/Ab	HBsAg	Anti-HBc
Diagnostic sensitivity	Positive specimens	400 HIV-1 100 HIV-2 including 40 non-B-subtypes, all available HIV/1 subtypes shall be represented by at least 3 samples per subtype	300 HTLV-I 100 HTLV-II	400 (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotype 1-4: > 20 samples per genotype (including non-a subtypes of genotype 4); 5: > 5 samples; 6: if available	400 including subtype-consideration	400 including evaluation of other HBV-markers
	Sero-conversion panels	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available	20 panels 10 further panels (at Notified Body or manufacturer)	20 panels 10 further panels (at Notified Body or manufacturer)	To be defined when available
Analytical sensitivity	Standards				0,130 IU/ml (WHO International Standard: Third International Standard for HBsAg, subtypes ayw1/adw2, HBV genotype B4, NIBSC code: 12/226)	
Specificity	Unselected donors (including first-time donors)	5 000	5 000	5 000	5 000	5 000
	Hospitalized patients	200	200	200	200	200
	Potentially cross-reacting blood-specimens (RF+, related viruses, pregnant women, etc.)	100	100	100	100	100'

(6) Table 5 is replaced by the following:

'Table 5

HIV 1 antigen, HIV Ag/Ab, HCV antigen, HCV Ag/Ab

		HIV-1 antigen and HIV Ag/Ab assays	HCV antigen and HCV Ag/Ab assays	Acceptance criteria
Diagnostic sensitivity	Positive specimens	50 HIV-1 antigen positive 50 cell culture supernatants including different HIV-1 subtypes and HIV-2	25 HCV core antigen and/or HCV RNA positive but anti-HCV negative samples, comprising HCV genotypes 1-6 (if a genotype is not available, a justification shall be made)	See general principle in § 3.1.8
	Sero-conversion panels ([1])	20 sero-conversion panels/low titre panels	20 sero-conversion panels/low titre panels	
Analytical sensitivity	Standards	HIV-1 p24 Antigen, First International Reference Reagent, NIBSC code: 90/636	HCV core antigen detection limit shall be investigated using dilutions of the WHO International HCV core antigen Standard: (HCV core Ag product code: PEI 129096/12)	For HIV-1 p24 antigen: ≤ 2 IU/ml
Diagnostic specificity		200 blood donations 200 clinical samples 50 potentially interfering samples	200 blood donations, 200 clinical samples, 50 potentially interfering samples	≥ 99,5 % after neutralisation or, if no neutralisation test available, after resolution of the sample status according to general principles in § 3.1.5

([1]) The total number of seroconversion panels for combined Ag/Ab assays (from tables 1 and 5) need not be greater than 30.'