DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/350

of 28 February 2020

amending Decision 2002/364/EC as regards definitions of first–line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays

(notified under document C(2020) 1086)

(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 the first subparagraph of 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 update the common technical specifications laid down in Decision 2002/364/EC.

(3) The definitions of first-line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays should be amended in order to take into account the evolved state of the art, the changes in clinical needs, new scientific knowledge available and the new types of devices present on the market.

(4) The manufacturers should be allowed time to adapt to the changes in common technical specifications. The date of application of this Decision should therefore be deferred. However, in the interest of public health and patient safety, manufacturers should be allowed to comply with the common technical specifications as amended by this Decision before its 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

1. This Decision shall apply from 2 March 2021.

2. Notwithstanding paragraph 1, from 2 March 2020 until 1 July 2020 Member States shall apply the presumption of compliance laid down in Article 5(3) of Directive 98/79/EC for all in vitro diagnostic medical devices that comply with any of the following:

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

(b) the common technical specifications laid down in Decision 2002/364/EC as amended by Commission Implementing Decision (EU) 2019/1244 ([5]);

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

3. Notwithstanding paragraph 1, from 2 July 2020 until 1 March 2021 Member States shall apply the presumption of compliance laid down in Article 5(3) of Directive 98/79/EC for all in vitro diagnostic medical devices that comply with either of the following:

(a) the common technical specifications laid down in Decision 2002/364/EC as amended by Implementing Decision (EU) 2019/1244;

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

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 28 February 2020.

For the Commission
Stella KYRIAKIDES
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).

([5]) 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 (OJ L 193, 19.07.2019, p.1).

ANNEX

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

1. Section 2 is amended as follows:

   (a) the following definition of 'First line assay' is inserted between the definition of 'Whole system failure rate' and the definition of 'Confirmation assay':

   '**First-line assay**

   First-line assay means an assay used to detect a marker or analyte, and which may be followed by a confirmatory assay. Devices intended solely to be used to monitor a previously determined marker or analyte are not considered first-line assays.';

   (b) the definition of 'Confirmation assay' is replaced by the following:

   '**Confirmatory assay**

   Confirmatory assay means an assay used for the confirmation of a reactive result from a first-line assay.';

2. Section 3 is amended as follows:

   (a) 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, Table 3, Table 4 and Table 5, which apply to them taking account of the intended purpose of the devices concerned, virus type and entities to be detected (antigen and/or antibody). See also principle 3.1.11 for first-line assays.';

   (b) Sub-section 3.1.3 is replaced by the following:

   '3.1.3. Devices for self-testing shall meet the same CTS requirements for sensitivity and specificity as respective devices for professional use. Relevant parts of the performance evaluation shall be carried out (or repeated) by appropriate lay users to validate the operation of the device and the instructions for use. The lay users selected for the performance evaluation shall be representative of the intended users groups.

   Performance evaluation of a device for self-testing shall include, for each body fluid claimed for use with the device, e.g. whole blood, urine, saliva, etc., at least 200 lay users that are known positive for the infection and at least 400 lay users that do not know their status, of which at least 200 are at high risk of acquiring the infection. The sensitivity and specificity of the device for self-testing in the hands of lay users shall be defined against the confirmed patient infectious status.';

   (c) Sub-section 3.1.9 is replaced by the following:

   '3.1.9. Performance evaluation of first line assays shall include 25 positive (if available in the case of rare infections) 'same day' fresh serum samples (≤ 1 day after sampling).';

   (d) Sub-section 3.1.11 is replaced by the following:

   '3.1.11. For performance evaluations for first line assays (Table 1 and Table 3) blood donor populations shall be investigated from at least two blood donation centers and consist of consecutive blood donations, which have not been selected to exclude first time donors.';

   (e) Sub-section 3.4.2 is replaced by the following:

   '3.4.2. The manufacturer's batch release testing for first line assays shall include at least 100 specimens negative for the relevant analyte.'.

3. Table 1 is replaced by the following:

'Table 1

First-line assays, excluding rapid tests: 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'

4. Table 3 is replaced by the following:

'Table 3

Rapid tests: anti-HIV 1/2, HIV 1/2 Ag/Ab, anti-HCV, HCV Ag/Ab, HBsAg, anti-HBc, anti-HTLV I and II

		anti-HIV 1/2, HIV 1/2 Ag/Ab	anti-HCV, HCV Ag/Ab	HBsAg	anti-HBc	anti-HTLV I and II	Acceptance criteria
Diagnostic sensitivity	Positive specimens	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1
	Sero-conversion panels	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1	Same criteria as in Table 1
Diagnostic specificity	Negative specimens	[2]1 000 blood donations	1 000 blood donations	1 000 blood donations	1 000 blood donations	1 000 blood donations	≥ 99 % (anti-HBc: ≥ 96 %)'
		200 clinical specimens	200 clinical specimens	200 clinical specimens	200 clinical specimens	200 clinical specimens	
		200 samples from pregnant women	200 samples from pregnant women	200 samples from pregnant women		200 samples from pregnant women	
		100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	100 potentially interfering samples	

5. Table 4 is replaced by the following:

'Table 4

Confirmatory and supplementary assays for anti-HIV 1/ 2, HIV 1/2 Ag/Ab, anti-HTLV I and II, anti-HCV, HCV Ag/Ab, HBsAg

		anti-HIV 1/2, HIV 1/2 Ag/Ab confirmatory assays	anti-HTLV I and II confirmatory assays	anti-HCV, HCV Ag/Ab supplementary assays	HBsAg confirmatory assays	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 HIV-1 and 100 HIV-2 Including samples from different stages of infection and reflecting different antibody patterns	200 HTLV-I and 100 HTLV-II	300 HCV (positive samples) Including samples from different stages of infection and reflecting different antibody patterns. Genotypes 1 – 4: > 20 samples (including non-a subtypes of genotype 4; Genotype 5: > 5 samples; Genotype 6: if available	300 HBsAg Including samples from different stages of infection 20 'high pos' samples (>26 IU/ml); 20 samples in the cut-off range	Correct identification as positive (or indeterminate), not negative
	Sero-conversion panels	15 sero-conversion panels/low titre panels		15 sero-conversion panels/low titre panels	15 sero-conversion panels/low titre panels	

		anti-HIV 1/2, HIV 1/2 Ag/Ab confirmatory assays	anti-HTLV I and II confirmatory assays	anti-HCV, HCV Ag/Ab supplementary assays	HBsAg confirmatory assays	Acceptance criteria
Analytical sensitivity	Standards				Third International Standard for HBsAg, subtypes ayw1/adw2, HBV genotype B4, NIBSC code: 12/226	
Diagnostic specificity	Negative specimens	200 blood donations 200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other confirmatory assays	200 blood donations 200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other confirmatory assays	200 blood donations 200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other supplementary assays	10 false positives as available from the performance evaluation of the first line assay ([1]). 50 potentially interfering samples	No false-positive results/ ([1]) no neutralisation

([1]) Acceptance criteria: no neutralisation for HBsAg confirmatory assay.'