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,	See general principle in § 3.1.8

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

			a justification shall be made)	
	Sero-conversion panels[a]	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

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

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/1244, ANNEX.