EUROPEAN
COMMISSION

Brussels, XXX
[…](2016) XXX draft

ANNEX 1

**ANNEX**

**to the**

**Commission Decision**

**amending Decision 2002/364/EC as regards requirements for HCV antigen/antibody combined tests and Nucleic Acid Amplification techniques in qualitative HIV assays**

**ANNEX**

Section 3 of the Annex is amended as follows:

(1) the title of Section 3.2. is replaced by the following:

**‘Additional requirements for antibody/antigen combined tests.’**

(2) the following Sub-section 3.2.3. is added:

‘3.2.3. HCV antibody/antigen combined tests intended for anti-HCV and antigen detection shall comply with the requirements set out in Table 1.’

(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, a World Health Organisation (WHO) International Standard or reference material calibrated against the WHO International Standard.’

(4) the following Sub-sections 3.3.2a and 3.3.2b are inserted:

(a) ‘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**.**

(b) 3.3.2b. Qualitative HIV NAT assays, other than virus typing assays, shall be designed to compensate the potential failure of a HIV-1 NAT target region, including by using two independent target regions.’