

Commission Decision of 7 May 2002 on common technical specifications  
for in vitro-diagnostic medical devices (notified under document  
number C(2002) 1344) (Text with EEA relevance) (2002/364/EC)

- Article 1 The technical specifications set out in the Annex to this...
- Article 2 This Decision is addressed to the Member States.

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ANNEX

COMMON TECHNICAL SPECIFICATIONS (CTS)  
FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

1. SCOPE
2. DEFINITIONS AND TERMS
  - (Diagnostic) sensitivity
  - True positive
  - False negative
  - (Diagnostic) specificity
  - False positive
  - True negative
  - Analytical sensitivity
  - Analytical specificity
  - Nucleic acid amplification techniques (NAT)
  - Rapid test
  - Robustness
  - Whole system failure rate
  - Confirmation assay
  - Virus typing assay
  - Sero-conversion HIV samples
  - Early sero-conversion HIV samples
3. COMMON TECHNICAL SPECIFICATIONS (CTS) FOR PRODUCTS REFERRED TO IN ANNEX...
  - 3.1. CTS for performance evaluation of reagents and reagent products for...
    - General principles
    - 3.1.1. Devices which detect virus infections shall meet the requirements for...
    - 3.1.2. Devices intended by the manufacturer for testing body fluids other...
    - 3.1.3. Devices intended by the manufacturer for self-test, i.e. home use,...
    - 3.1.4. All performance evaluations shall be carried out in direct comparison...
    - 3.1.5. If discrepant test results are identified as part of an...
    - 3.1.6. Performance evaluations shall be performed on a population equivalent to...

**Changes to legislation:** There are outstanding changes not yet made to Commission Decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (notified under document number C(2002) 1344) (Text with EEA relevance) (2002/364/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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- 3.1.7. Positive specimens used in the performance evaluation shall be selected...
- 3.1.8. Sensitivity with true positives and sero-conversion samples shall be evaluated...
- 3.1.9. Performance evaluation of screening assays shall include 25 positive (if...
- 3.1.10. Negative specimens used in a performance evaluation shall be defined...
- 3.1.11. For performance evaluations for screening assays (Table 1) blood donor...
- 3.1.12. Devices shall have a specificity of at least 99,5 % on...
- 3.1.13. Devices shall be evaluated to establish the effect of potential...
- 3.1.14. For devices intended by the manufacturer to be used with...
- 3.1.15. For devices intended for use with plasma the performance evaluation...
- 3.1.16. As part of the required risk analysis the whole system...
- 3.1.17. If a new in vitro diagnostic medical device belonging to...
- 3.2. Additional requirements for HIV and HCV antigen and antibody combined...
  - 3.2.1. HIV antigen and antibody combined tests intended for the detection...
  - 3.2.2. Hepatitis C virus (HCV) antigen and antibody combined tests intended...
- 3.3. Additional requirements for nucleic acid amplification techniques (NAT)
  - 3.3.1. For target sequence amplification assays, a functionality control for each...
  - 3.3.2. The analytical sensitivity or detection limit for NAT assays shall...
  - 3.3.2a. Qualitative HIV NAT assays intended to be used to detect...
  - 3.3.2b. Qualitative HIV NAT assays, other than virus typing assays, shall...
  - 3.3.3. Genotype detection shall be demonstrated by appropriate primer or probe...
  - 3.3.4. Results of quantitative NAT assays shall be traceable to international...
  - 3.3.5. NAT assays may be used to detect virus in antibody...
  - 3.3.6. For investigation of potential carry-over, at least five runs with...
  - 3.3.7. The whole system failure rate leading to false-negative results shall...
- 3.4. CTS for the manufacturer's release testing of reagents and reagent...
  - 3.4.1. The manufacturer's release testing criteria shall ensure that every batch...
  - 3.4.2. The manufacturer's batch release testing for screening assays shall include...
- 3.5. CTS for performance evaluation of reagents and reagent products for...
  - 3.5.1. All performance evaluations shall be carried out in direct comparison...
  - 3.5.2. If discrepant test results are identified as part of an...
  - 3.5.3. Performance evaluations shall be performed on a population equivalent to...
  - 3.5.4. Positive specimens used in the performance evaluation shall be selected...
  - 3.5.5. Devices shall be evaluated to establish the effect of potential...
  - 3.5.6. For devices intended for use with plasma the performance evaluation...
- 3.6. CTS for the manufacturer's release testing of reagents and reagent...
  - 3.6.1. The manufacturer's release testing criteria shall ensure that every batch...
  - 3.6.2. Requirements for manufacturers batch release testing are outlined in Table...
- 3.7. CTS for Variant Creutzfeldt-Jakob disease (vCJD) assays for blood screening...

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Acceptance criteria:

Qualifications:

Table 10 Batch release criteria for reagents and reagent products to determine...Specificity testing requirements on each reagent 1. Test reagents Only...

1. Test reagents

Acceptance criteria:

2. Control materials (red cells)

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- (1) [OJ L 331, 7.12.1998, p. 1.](#)
- (2) [OJ L 189, 20.7.1990, p. 17.](#)

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### Changes and effects yet to be applied to :

- Annex Point 2 Text addition by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.4.2 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 2 Text replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 3 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.11 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.1 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 4 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.3 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 1 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.9 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Decision revoked by S.I. 2002/618, reg. 4H(1) (as inserted) by [S.I. 2019/791](#) reg. 3(7)
- Annex point 3.1.4 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(a)(i)
- Annex point 3.1.4 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(a)(ii)
- Annex point 3.1.8 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(b)(i)
- Annex point 3.1.8 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(b)(ii)
- Annex point 3.4.1 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(c)(i)
- Annex point 3.4.1 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(c)(ii)
- Annex words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(d)
- Art. 1 words inserted by [S.I. 2021/873](#) Sch. 2 para. 1
- Art. 2 omitted by [S.I. 2021/873](#) Sch. 2 para. 2