Notification Number: 2009/552/F

Order establishing the conditions for carrying out laboratory diagnosis of the human immunodeficiency virus infection (HIV 1 and 2) and the conditions for performing rapid diagnostic testing in emergency situations.

Date received	:	15/10/2009
End of Standstill	:	18/01/2010
Issue of comments by	:	Commission

Message

Message 002

Communication from the Commission - SG(2009) D/52405
Directive 98/34/EC
Translation of the message 001
Notification: 2009/0552/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200902405.EN)

1. Structured Information Line
MSG 002 IND 2009 0552 F EN 18-01-2010 15-10-2009 F NOTIF 18-01-2010

2. Member State
F

3. Department Responsible
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3. Originating Department

Ministère de la Santé et des Sports
Direction générale de la Santé
Sous direction « Prévention des risques infectieux »
Bureau des infections par le VIH, les IST et hépatites (RI2)

4. Notification Number
2009/0552/F - S10S

5. Title
Order establishing the conditions for carrying out laboratory diagnosis of the human immunodeficiency virus infection (HIV 1 and 2) and the conditions for performing rapid diagnostic testing in emergency situations.

6. Products Concerned
In vitro diagnostic medical devices (reagents or laboratory testing)
Public and private biomedical laboratories
Health establishments and services, medical practices

7. Notification Under Another Act
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8. Main Content
HIV infection screening is currently governed in France by the Order of 28 April 2003 establishing the specific conditions for assessing and using screening reagents and for confirming the presence of anti-HIV 1 and 2 antibodies and anti-HTLV I and II antibodies (see Annex).
According to this text, screening for anti-HIV 1 and 2 antibodies shall be performed:
- by private biomedical testing laboratories under the responsibility of their directors (L. 6211-1 of the French Public Health Code) or by clinical departments in health establishments
- on plasma or serum.
- using two different, mixed reagents (HIV 1 and HIV 2) bearing the CE marking, at least one of which shall be a test using an ELISA technique. In the event of positivity or conflict between the results, a confirmation analysis is carried out using the Western Blot or Immunoblot technique on the same sample. The presence of HIV 1 and HIV 2 antibodies is then confirmed by re-screening on a second sample.

Furthermore, regulation of the placing on the market of HIV reagents using the CE marking procedure defined in Directive 98/79/EC of 27/10/1998 calls for the compliance of anti-HIV 1 and 2 antibody screening assays with minimum performances given in common technical specifications (Commission Decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices).

In October 2008, the French National Health Authority (HAS) published “Recommandations en santé publique sur le dépistage de l’infection par le VIH : Modalités de réalisation des tests de dépistage” (public health recommendations on HIV infection screening: conditions for the performance of screening assays), in which it recommends:

- the use, from now on, of a single reagent instead of the two used currently. This single test must be a fourth generation combined test which detects both anti-HIV 1 and 2 antibodies and p24 antigen with a minimum detection threshold for p24 antigen of 2 international units per millimetre (IU/ml). This threshold corresponds to the one established by the Common Technical Specifications published in 2009 (CTS, 2009/108/EC).

- the use of rapid diagnostic testing in medical facilities in the following 4 emergency situations:
- in the event of accidental exposure to blood, to test the source patient,
- in the event of recent sexual exposure, to test a partner and to potentially propose post-exposure treatment,
- during the labour of a woman with unknown serological status,
- for an emergency diagnosis involving AIDS-like symptoms.
The performance of rapid diagnostic testing must be covered by a formal quality-assurance procedure put in place by these facilities.

The notified Draft Order therefore aims to implement and enforce these new recommendations for public and private biomedical laboratories, health establishments and services and medical practices. In doing so, it repeals the previous Order of 28 April 2003.

The Draft Order also provides for a transition period for application of the new technical screening conditions (Article 1). This period can be broken down into 2 phases (Article 4):
- the first phase authorises laboratories that are not able to implement the conditions immediately to continue HIV screening, for a further 3 months, under current conditions;
- the second phase, from the fourth month following publication of the Order until 30 November 2010, authorises laboratories to use, for screening, either a fourth generation combined test (anti-HIV 1 and 2 antibodies and p24 antigen with analytical sensitivity below 2 IU/ml) or a third generation anti-HIV 1 and 2 antibody test at the same time as a p24 antigen screening assay (with analytical sensitivity below 2 IU/ml). The two options are the same in terms of performance. The date of 30 November 2010 corresponds to the date imposed on manufacturers to adapt to the detection threshold imposed at European level by the Common Technical Specifications (2009/108/EC).

9. Brief Statement of Grounds
This Draft Order revises the technical conditions for HIV infection screening and is enforceable in France in line with the recommendations published in October 2008 by the French National Health Authority (HAS). It also lays down the situations when and the conditions under which rapid diagnostic testing may now be used.

10. Reference Documents - Basic Texts
- Order of 28 April 2003 establishing the specific conditions for assessing and using screening reagents and for confirming the presence of anti-HIV 1 and 2 antibodies and anti-HTLV I and II antibodies.
- “Recommandations en santé publique sur le dépistage de l’infection par le VIH : Modalités de réalisation des tests de dépistage” (public health recommendations on HIV infection screening: conditions for the performance of screening assays), by the French National Health Authority (HAS), October 2008

11. Invocation of the Emergency Procedure
NO

12. Grounds for the Emergency
-

13. Confidentiality
NO

14. Fiscal measures
NO

15. Impact assessment
-

16. TBT and SPS aspects
TBT relevance
a) NO
b) iii) The draft has no significant impact on international trade.

SPS relevance
a) NO
b) i) The draft is not a sanitary or phytosanitary measure within the meaning of Annex A to the SPS Agreement.

Catherine Day
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