COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1966

THERAPEUTIC GOODS ORDER NO. 34

STANDARD FOR DIAGNOSTIC GOODS OF HUMAN ORIGIN

I, PETER STAPLES, Minister of State for Aged, Family and Health Services, pursuant to Section 17 of the Therapeutic Goods Act 1966, by this Order REVOKE Therapeutic Goods Order No. 19 made on the 23 September 1984, and pursuant to sections 13, 15 and 23F of that Act by this Order -

(a) DETERMINE that with respect to quality and method of preparation, the standard for goods which contain materials of human origin and which are intended as laboratory reagents for diagnostic tests, shall be the standard specified in this Order;

(b) DIRECT that for the purposes of Sections 19, 20 and 22 of the said Act, such goods shall be labelled in the manner specified in this Order; and

(c) DETERMINE that the procedures to be carried out in the production of such goods shall include the procedures specified in this Order.

Application

1.

(1) Subject to sub-clauses (2) and (3), the goods to which this Order applies are goods which contain materials of human origin and which are intended as laboratory reagents in diagnostic tests.

(2) Clauses 7 to 9 inclusive do not apply to goods manufactured by a process such that human immunodeficiency virus (HIV) would be inactivated.

(3) This Order does not apply to -

(a) goods which, due to either the nature or scarcity of the final product, cannot be prepared from material that is non-reactive when tested for hepatitis B virus surface antigen (HBsAg) or antibody to HIV; or

(b) goods which have been treated at 60°C for 10 hours.

Interpretation

2. In this Order -

"donor" means a person from whom body fluids or tissues are obtained for the purpose of preparing diagnostic goods;

"donor serum" means serum or plasma obtained from a donor and which is intended for the preparation of diagnostic goods of human origin;

"final bulk" means the finished homogeneous material present in the container from which the final containers are filled;

"final lot" means a collection of sealed final containers that have been filled during one working session from a single final bulk and further processed under conditions which ensure its physical, chemical and microbial homogeneity;

"goods" means goods for therapeutic use as defined in the Therapeutic Goods Act 1966;

"HBsAg" means hepatitis B virus surface antigen;

"HIV" means any human immunodeficiency virus known to cause acquired immune deficiency syndrome;

"manufacture" includes the process of collection and testing of starting material as well as subsequent processing of that material into diagnostic goods;

"pooled sera" means a pool of all donor serum or plasma which is processed into a final bulk or final lot; and

"reference panel of sera" means the panel of human sera which is designated by the Commonwealth Department of Community Services and Health as the Australian reference panel of human sera for tests for hepatitis B virus surface antigen.

Source material

3. Goods shall consist of or be derived from source material obtained from donors who are free from -

(a) signs of infectious diseases transmissible by blood products; and

(b) signs of injection with narcotics,

unless, by its nature, such source material must be obtained from donors suffering from specific illness.

Test for hepatitis B virus surface antigen in donor serum

4.

(1) A serological test for HBsAg complying with the specifications of clause 6 shall be carried out on individual donor sera during manufacture.

(2) Donor serum giving a positive reaction for HBsAg shall not be used to prepare goods to which this Order applies.

Test for hepatitis B virus surface antigen in final bulk or final lot

5.

(1) A serological test for HBsAg complying with the specifications of clause 6 shall be carried out by the manufacturer on the final bulk or the final lot.

(2) A final bulk which gives a positive reaction for HBsAg that can be neutralised with antibody to HBsAg shall not be used to prepare goods to which this Order applies.

(3) The final lot, when tested for the presence of HBsAg in accordance with clause 6, shall give a negative reaction.

Sensitivity of hepatitis B virus surface antigen test

6.

(1) The sensitivity of the serological test for HBsAg shall be sufficient to give a positive reaction in all twenty sera labelled FH001 -FHO17 and FHO23 - FHO25 in the reference panel of sera.

(2) A positive control serum known to be weakly reactive shall be included in each test and a positive reaction shall be obtained with this positive control serum for the test to be valid.

Test for antibody to human immunodeficiency virus in donor serum

7.

(1) A serological test for antibody to HIV that is a test in accordance with clause 9 shall be carried out on individual donor sera during manufacture.

(2) Donor serum which gives a positive reaction to a test referred to in clause 9 shall not be used to prepare goods to which this Order applies.

Test for antibody to human immunodeficiency virus in final bulk or final lot

8.

(1) Unless the sera to be used in the manufacture of diagnostic goods of human origin has been collected in premises licensed for such a purpose, being subject to inspection, and using tests approved by the competent Health Authority of a particular country, whose standards are recognised by the Secretary of the Commonwealth Department of Community Services and Health, and supplied with specific certification from the primary manufacturer that the units of blood used in the manufacture of identified production lots were tested for antibody to HIV and found non-reactive, then a serological test for antibody to HIV complying with the specifications of

clause 9 shall be carried out by the manufacturer on the pooled sera prior to further consolidation, or on the final bulk, or the final lot.

(2) A pooled sera or final bulk which gives a positive reaction to a test referred to in clause 9, shall not be used to prepare goods to which this Order applies.

(3) The final lot, when tested for the presence of antibody to HIV in accordance with a test referred to in clause 9, shall give a negative reaction.

Sensitivity and specificity of human immunodeficiency virus antibody test

9.

(1) The test for the presence of antibody to HIV shall, if performed in Australia, be either:-

(a) a test performed using a test kit specified in the Schedule to this Order; or

(b) a test performed using a method of greater sensitivity and specificity than that used in a test kit which has been so specified.

(2) The results of a test referred to in paragraph 9 (1) (b) will take precedence over the results of a test referred to in paragraph 9 (1) (a).

(3) The test for the presence of antibody to HIV shall, if performed outside Australia, be either:-

(a) a test performed using a test kit of equal sensitivity and specificity to one specified in paragraph 9 (1) (a); or

(b) a test performed using a method of greater sensitivity and specificity than that used in a test kit which has been so specified.

(4) The results of a test referred to in paragraph 9 (3) (b) will take precedence over the results of a test referred to in sub-clause 9 (3) (a).

Labelling requirements

10. Unless the goods are goods manufactured by a process such that human immunodeficiency virus would be inactivated -

(a) the goods shall include an information leaflet containing -

(i) certification that tests for HBsAg and antibody to HIV have been performed on the goods and have been found to be negative; and

(ii) a warning that the product may be infectious; and

(b) the label attached or affixed to goods shall contain an expiry date or recommended shelf life.

Dated this third day of August 1990

PETER STAPLES
Minister of State for
Aged, Family and Health
Services

THE SCHEDULE

Test kit	**Marketing companies**
Genetic Systems LAV EIA	Biomediq Australia
Abbott Recombinant HIV-1	Abbott Diagnostic
ENI Virgo HIV PLA	Integrated Sciences Pharmacia Australia
Anti-HTLV III Wellcozyme VK 50/5l	Wellcome Australia
Wellcozyme HIV Recombinant VK 56/57	Wellcome Australia
Bio-Enzabead HTLV-III Elisa	Organon Teknika
Vironostika Anti-HTLV III Microelisa	Organon Teknika
OUVA 21 Enzygnost HIV	Behring Diagnostics
Dupont HIV-1 Elisa	Dupont Australia CSL
Biochrom HIV-1 Elisa	Clin-Path Services