



# Victoria Government Gazette

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## Public Health and Wellbeing Act 2008

### SECTION 151

I, Fran Thorn, Secretary to the Department of Health, approve the following statement under, and for the purposes of, section 151 and Column 2 of Table 1 of the Schedule to the **Public Health and Wellbeing Act 2008** as the statement which is to be obtained from the donor.

FRAN THORN  
Secretary  
Department of Health

### BLOOD DONATION STATEMENT

There are some people who **MUST NOT** give blood as it may transmit infections to those who receive it. To determine if your blood or blood products will be safe to be given to people in need, we would like you to answer some questions. These questions are a vital part of our efforts to eliminate diseases from the blood supply.

All donations of blood are tested for the presence of hepatitis B and C, HIV (the AIDS virus), HTLV and syphilis. If your blood test proves positive for any of these conditions, or for any reason the test shows a significantly abnormal result, you will be informed.

All of the questions are important to answer. Answer each question on the form as honestly as you can and to the best of your knowledge.

**There are penalties, including fines and imprisonment, for anyone providing false or misleading information.**

**To the best of your knowledge have you:**

1. In the last 12 months, had an illness with swollen glands and a rash, with or without a fever? YES/NO
2. Ever thought you could be infected with HIV or have AIDS? YES/NO
3. Ever 'used drugs' by injection or been injected, even once, with drugs not prescribed by a doctor or dentist? YES/NO
4. Ever had treatment with clotting factors such as Factor VIII or Factor IX? YES/NO
5. Ever had a test, which showed you had hepatitis B, hepatitis C, HIV or HTLV? YES/NO
6. In the last 12 months engaged in sexual activity with someone you might think would answer 'yes' to any of questions 1-5? YES/NO
7. Since your last donation or in the last 12 months, had sexual activity with a new partner who currently lives or has previously lived overseas? YES/NO

**Within the last 12 months have you:**

8. Had male to male sex? YES/NO
9. Had sexual activity with a male who you think might be bisexual? YES/NO
10. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? YES/NO
11. Engaged in sexual activity with a male or female sex worker? YES/NO

**SPECIAL**

- |     |  |        |
|-----|--|--------|
| 12. | Been injured with a used needle (needlestick)?   | YES/NO |
| 13. | Had a blood/body fluid splash to your eyes, mouth, nose or to broken skin?                       | YES/NO |
| 14. | Had a tattoo (including cosmetic tattooing), body or ear piercing, electrolysis, or acupuncture? | YES/NO |
| 15. | Been imprisoned in a prison or lock-up?  | YES/NO |
| 16. | Had a blood transfusion?   | YES/NO |
| 17. | Had (yellow) jaundice or hepatitis or been in contact with someone who has?                      | YES/NO |

**This declaration is to be signed in the presence of a Blood Service staff member. (Please read the following conditions.)**

Thank you for answering these questions. If you are uncertain about any of your answers, please discuss them with your interviewer.

We would like you to sign this declaration in the presence of your interviewer (a Blood Service staff member) to show that you have understood the information on this form and have answered the questions in the declaration to the best of your knowledge.

Your donation is a gift to the Blood Service to be used to treat patients. In some circumstances, your donation may be used by the Blood Service or other organisations for the purposes of research, teaching, quality assurance, or the making of essential diagnostic reagents. A part of your donation may also be stored for future testing and research. Approval from an appropriate Human Research Ethics Committee must be obtained before any research is undertaken on your donation or any part of it.

You may be asked by the Blood Service to undergo further testing.

**Should you become aware of any reason why your blood should not be used for transfusion, please call us on 13 14 95.** In particular, if you develop a cough, cold, diarrhoea or other infection within a week after donating, please report it immediately.

**Declaration:**

I agree to have blood taken from me under these conditions. I declare that I have understood the information on this form and answered the questions in the declaration honestly and to the best of my knowledge. I have been advised that there are some possible risks associated with donating blood and that I must follow the instructions of the Blood Service staff to minimise these risks.

**Donor** (Please Print)

Surname/Family name

Given name

Date of birth (DD/MM/YY)

Please ONLY sign in the presence of the interviewer

Signature

Date

**Witness** (Please Print)

Donor identity verified

Supplementary questions answered Yes N/A

Surname/Family name

Given name

Signature

Time Date

DD/MM/YY

Donation number:

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**Public Health and Wellbeing Act 2008**

## SECTION 152

I, Fran Thorn, Secretary to the Department of Health, approve the following statement under, and for the purposes of section 152 and Column 2 of Table 2 of the Schedule to the **Public Health and Wellbeing Act 2008** as the statement which is to be obtained from the donor.

FRAN THORN  
Secretary  
Department of Health

**TISSUE DONATION STATEMENT**

There are some people who **MUST NOT** donate tissue as it may transmit infections to those who receive it. To determine if your tissue will be safe to be given to people in need, we would like you to answer some questions. These questions are a vital part of our efforts to eliminate any diseases from the supply of donated tissue or semen.

In the case of donation of tissue, your blood is tested for the presence of hepatitis B and C, HIV 1 and 2 (the AIDS virus), HTLV I and II and syphilis and may be tested for the presence of other infectious diseases. If your blood test proves positive for any of these conditions, or for any reason shows a significantly abnormal result, you will be informed.

All of the questions are important to answer. Answer each question on the form as honestly as you can and to the best of your knowledge. There are penalties, including fines and imprisonment, for anyone providing false or misleading information.

**To the best of your knowledge have you:**

1. Had an illness with swollen glands and a rash, with or without a fever in the last 6 months? YES/NO
2. Ever thought you could be infected with HIV or have AIDS? YES/NO
3. Ever 'used drugs' by injection or been injected, even once, with drugs not prescribed by a doctor or dentist? YES/NO
4. Ever had treatment with clotting factors such as Factor VIII or Factor IX? YES/NO
5. Ever had a test which showed you had hepatitis B, hepatitis C, HIV or HTLV? YES/NO
6. In the last 12 months engaged in sexual activity with someone you might think would answer 'yes' to any of questions 1-5? YES/NO
7. Since your last donation or in the last 12 months have you had sexual activity with a new partner who currently lives or has previously lived overseas? YES/NO

**Within the last 12 months have you:**

8. Had male to male sex? YES/NO
9. Had sexual activity with a male who you think might be bisexual? YES/NO
10. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? YES/NO
11. Engaged in sexual activity with a male or female sex worker? YES/NO
12. Been injured with a used needle (needlestick)? YES/NO
13. Had a blood/body fluid splash to your eyes, mouth, nose or to broken skin? YES/NO

14. Had a tattoo (including cosmetic tattooing), skin piercing, electrolysis, or acupuncture? YES/NO
15. Been imprisoned in a prison or lock-up? YES/NO
16. Had a blood transfusion? YES/NO
17. Had yellow jaundice or hepatitis or been in contact with someone who has? YES/NO

**This declaration is to be signed in the presence of a Tissue Donation Service/Assisted Reproductive Service\* staff member. (Please read the following statements.)**

Thank you for answering these questions. If you are uncertain about any of your answers, please discuss this with your interviewer.

We would like you to sign this declaration in the presence of your interviewer (a person approved by the Tissue Donation Service/Assisted Reproductive Service\*) to show that you have understood the information on the form and answered the questions in the declaration to the best of your knowledge.

Your donation is a gift to the Tissue Donation Service/Assisted Reproductive Service\* to be used to treat patients, or in some circumstances, for teaching, research or quality assurance.

You may be asked by the Tissue Donation Service/Assisted Reproductive Service\* to undergo further blood tests. A part of your donation may be stored for future testing and research. Approval from the appropriate Human Research Ethics Committee must be obtained before any research is undertaken on tissue samples.

Should you become unwell in the 5 days following a donation, please call the Tissue Donation Service/Assisted Reproductive Service\*.

**Declaration:**

I agree to have blood taken from me under the above conditions. I have been advised that there are some possible risks associated with donating tissue and that I must follow the instructions of the Tissue Donation Service/Assisted Reproductive Service\* staff to minimise these risks.

**Donor (Please Print)**

Surname

Given name

Date of birth

Signature

*Please sign in the presence of the interviewer*

**Witness (Please Print)**

Surname

Given name

Signature

Interview date

Supplementary Questions

Donor identity verified Yes/No Donor weight

Donation number:

*\*Delete whichever is inapplicable*

**Public Health and Wellbeing Act 2008**

## SECTIONS 151 AND 152 AND SCHEDULE

I, Fran Thorn, Secretary to the Department of Health, approve the following as the manner of testing under, and for the purposes of, sections 151 and 152 of the **Public Health and Wellbeing Act 2008** (the Act) and column 2 of Table 1 and Table 2 to the schedule of the Act –

- In the case of an action in relation to a person who claims to have been infected with HIV, the approved manner of testing blood or blood products is the use of any test specified in the following table for the presence of HIV and used in accordance with the manufacturer's instructions:

<b>Test for the presence of HIV</b>	
SERODIA HIV DIAGNOSTIC GOODS, IN VITRO, HUMAN IMMUNODEFICIENCY VIRUS	Siemens Medical Solutions Diagnostics Pty Ltd
BIO-RAD LABORATORIES GENELAVIA MIXT HIV-1/HIV-2, DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
DIAGNOSTIC TECHNOLOGY DIAGNOSTIC GOODS IN VITRO HUMAN IMMUNODEFICIENCY VIRUS REAGENTS HIV BLOT 2 .2	Diagnostic Technology Pty Ltd
BIO-RAD LABORATORIES GS HIV-2 EIA, DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
BIO-RAD LABORATORIES MULTISPOT HIV-1/HIV-2 DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
BIO-RAD LABORATORIES NEW LAV BLOT II, DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
BIO-RAD LABORATORIES ELAVIA ANTIGEN 1, DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
BIO-RAD LABORATORIES NEW LAV BLOT I DIAGNOSTIC GOODS IN VITRO	Bio-Rad Laboratories Pty Ltd
ROCHE DIAGNOSTICS AMPLICOR HIV MONITOR TEST, DIAGNOSTIC GOODS IN VITRO	Roche Diagnostics Australia Pty Limited
bioMERIEUX AUSTRALIA VIRONOSTIKA HIV-1 ANTIGEN, MICROELISA AND NEUTRALISATION SYSTEMS, IN VITRO DIAGNOSTICS, NON STERILE	Biomerieux Australia Pty Ltd
BIO-RAD LABORATORIES GENSCREEN HIV 1/2 VERSION 2, IN VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
bioMERIEUX AUSTRALIA NUCLISENS HIV-1 QT AMPLIFICATION AND DETECTION REAGENTS, IVD, NON-STERILE	Biomerieux Australia Pty Ltd
ABBOTT DIAGNOSTICS MUREX HIV-1.2.0 (LN: 9E25) GE94/95, IN VITRO DIAGNOSTICS, NON STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
SIEMENS HEALTHCARE DIAGNOSTICS Versant HIV-1 RNA 3.0 Assay (bDNA), In-Vitro Diagnostics, Non-Sterile	Siemens Healthcare Diagnostics Pty Ltd

ABBOTT DIAGNOSTICS, AxSYM HIV 1/2 gO (LN:3D41-22) AND CONTROLS (LN:3D41-12), IN VITRO DIAGNOSTIC, NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
ROCHE DIAGNOSTICS AMPLICOR HIV-1 MONITOR TEST VERSION 1.5, IN-VITRO DIAGNOSTICS, NON-STERILE	Roche Diagnostics Australia Pty Limited
INVERNESS MEDICAL PROFESSIONAL DIAGNOSTICS AUSTRALIA PTY LTD, DETERMINE HIV-1/2 SERUM PLASMA KIT (LIST NO 7D23-12/13), IN VITRO DIAGNOSTIC, NON-STERILE	Inverness Medical Professional Diagnostics Australia Pty Ltd
VITROS ANTI-HIV 1+2 REAGENT PACK, CALIBRATOR PACK, CONTROL PACK/IN VITRO DIAGNOSTIC/NON-STERILE	Ortho-Clinical Diagnostics
ABBOTT DIAGNOSTICS, PRISM HIV O PLUS, (LIST NUMBER 3D34-48), IN VITRO DIAGNOSTIC NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
ROCHE DIAGNOSTICS AUSTRALIA, COBAS AMPLICOR HIV-1 MONITOR, VERSION 1.5	Roche Diagnostics Australia Pty Limited
BIO-RAD LABORATORIES, GENETIC SYSTEMS HIV-1 ANTIGEN EIA & CONFIRMATORY, IN VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
ROCHE DIAGNOSTICS AUSTRALIA COBAS AMPLISCREEN HIV-1 TEST VERSION 1.5	Roche Diagnostics Australia Pty Limited
BIO-RAD LABORATORIES, GENSCREEN PLUS HIV Ag-Ab, IN VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
BIO-RAD LABORATORIES, ACCESS HIV-1/2 NEW, IN-VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
ABBOTT AUSTRALASIA, MUREX HIV AG/AB COMBINATION ASSAY, IN VITRO DIAGNOSTICS, NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
ABBOTT AUSTRALASIA, AXSYM HIV AG/AB COMBINATION ASSAY, IN-VITRO DIAGNOSTICS, NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
BIOMERIEUX AUSTRALIA, NUCLISENS EASYQ HIV-1 V1.1, IN VITRO DIAGNOSTICS, NON-STERILE	Biomerieux Australia Pty Ltd
ABBOTT AUSTRALASIA PTY LTD (DIAGNOSTIC DIVISION), ARCHITECT HIV AG/AB COMBO ASSAY, IN-VITRO DIAGNOSTICS, NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
ROCHE DIAGNOSTICS AUSTRALIA PTY LIMITED - COBAS TAQMAN HIV-1 ASSAY - HUMAN IMMUNODEFICIENCY VIRUS 1 NUCLEIC ACID KIT	Roche Diagnostics Australia Pty Limited
SIEMENS HEALTHCARE DIAGNOSTICS, ADVIA Centaur HIV 1/O/2 Enhanced assay, In-Vitro Diagnostics, Non Sterile	Siemens Healthcare Diagnostics
Roche Diagnostics Australia Pty Limited, COBAS AmpliPrep/COBAS Taqman HIV-1 Test, In-Vitro Diagnostics, Non-Sterile	Roche Diagnostics Australia Pty Limited

BIO-RAD LABORATORIES PTY LTD - GENSCREEN ULTRA HIV AG-AB, IN-VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
ABBOTT REALTIME HIV-1 (REF 2G31), IN VITRO DIAGNOSTIC NON-STERILE	Abbott Australasia P/L (Molecular Division)
BIOMERIEUX AUSTRALIA Human immunodeficiency virus multiple antibody kit	Biomerieux Australia
Elecsys HIV Combi, In-Vitro Diagnostics, Non-Sterile	Roche Diagnostics Australia Pty Limited
CHIRON BLOOD TESTING, PROCLEIX HIV-1/HCV ASSAY (1000 TEST - PN 301098E AND 5000 TEST PN 301099E), IN VITRO DIAGNOSTICS, NON-STERILE	Chiron Blood Testing Pty Ltd

2. In the case of an action in relation to a person who claims to have been infected with Hepatitis C, the approved manner of testing blood or blood products is the use of any test specified in the following table for the presence of Hepatitis C and used in accordance with the manufacturer's instructions:

<b>Test for the presence of Hepatitis C</b>	
DIAGNOSTIC TECHNOLOGY HCV SPOT, DIAGNOSTIC GOODS IN VITRO	Diagnostic Technology Pty Ltd
ABBOTT DIAGNOSTICS, ABBOTT PRISM HCV LN 6A52-48, IN VITRO DIAGNOSTICS, NON-STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
DIAGNOSTIC TECHNOLOGY HCV BLOT 3.0, DIAGNOSTIC GOODS IN VITRO	Diagnostic Technology Pty Ltd
ORTHO-CLINICAL DIAGNOSTICS BIOSCIENCES CHIRON RIBA HCV 3.0 SIA, DIAGNOSTIC GOODS IN VITRO	Ortho-Clinical Diagnostics
ORTHO-CLINICAL DIAGNOSTICS ORTHO HCV 3.0 ELISA TEST WITH ENHANCED SAVE, DIAGNOSTIC GOODS IN VITRO	Ortho-Clinical Diagnostics
ABBOTT DIAGNOSTICS AxSYM HCV VERSION 3.0 - L/N 3B44, DIAGNOSTIC GOODS, IN-VITRO	Abbott Australasia Pty Ltd (Diagnostic Division)
ABBOTT DIAGNOSTICS, MUREX ANTI-HCV VERSION 4.0 (VK47/VK48) IN VITRO DIAGNOSTICS, NON STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
VITROS ANTI-HCV REAGENT PACK, CALIBRATOR PACK, CONTROL PACK/IN VITRO DIAGNOSTIC/NON-STERILE	Ortho-Clinical Diagnostics
ROCHE DIAGNOSTICS AUSTRALIA, AMPLICOR HCV, VERSION 2.0, IN VITRO DIAGNOSTICS, NON-STERILE	Roche Diagnostics Australia Pty Limited
ROCHE DIAGNOSTICS AUSTRALIA, COBAS AMPLICOR HCV, VERSION 2.0, IN VITRO DIAGNOSTICS, NON-STERILE	Roche Diagnostics Australia Pty Limited

ROCHE DIAGNOSTICS AUSTRALIA, AMPLICOR HCV MONITOR TEST V2.0, IN VITRO DIAGNOSTICS, NON-STERILE	Roche Diagnostics Australia Pty Limited
ROCHE DIAGNOSTICS AUSTRALIA, COBAS AMPLICOR HCV MONITOR V2.0, IN VITRO DIAGNOSTICS, NON-STERILE	Roche Diagnostics Australia Pty Limited
ABBOTT AUSTRALASIA, ARCHITECT ANTI-HCV (LN 6C37), IN VITRO, DIAGNOSTIC GOODS, NON STERILE	Abbott Australasia Pty Ltd (Diagnostic Division)
ROCHE DIAGNOSTICS AUSTRALIA COBAS AMPLISCREEN HCV TEST VERSION 2.0, IN VITRO DIAGNOSTICS NON-STERILE	Roche Diagnostics Australia Pty Limited
BIO-RAD LABORATORIES, MONOLISA ANTI-HCV PLUS VERSION 2.0, IN VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
INNOTEST HCV Ab IV (K1065 AND K1079), IN-VITRO DIAGNOSTICS, NON-STERILE	Asquith Diagnostics Pty Ltd
VERSANT HCV RNA 3.0 bDNA ASSAY IN VITRO DIAGNOSTICS NON STERILE	Siemens Healthcare Diagnostics Pty Ltd
VERSANT HCV RNA QUALITATIVE ASSAY, IN VITRO DIAGNOSTICS, NON-STERILE	Siemens Healthcare Diagnostics Pty Ltd
SIEMENS AUSTRALIA ADVIA CENTAUR HCV ASSAY IN-VITRO DIAGNOSTICS NON-STERILE	Siemens Healthcare Diagnostics Pty Ltd
VERSANT HCV Genotype 2.0 Assay (LiPA), In-Vitro Diagnostics, Non-Sterile	Siemens Healthcare Diagnostics Pty Ltd
VERSANT HCV Amplification 2.0 Kit (LiPA), In-Vitro Diagnostics, Non-Sterile	Siemens Healthcare Diagnostics Pty Ltd
BIO-RAD LABORATORIES PTY LTD - MONOLISA HCV AG/AB ULTRA, IN-VITRO DIAGNOSTICS, NON-STERILE	Bio-Rad Laboratories Pty Ltd
ABBOTT REALTIME HCV (4J86), IN VITRO DIAGNOSTICS, NON-STERILE	Abbott Australasia P/L (Molecular Division)
Elecsys Anti-HCV, In-Vitro Diagnostics, Non-Sterile	Roche Diagnostics Australia Pty Limited
Roche Diagnostics Australia – COBAS Ampliprep/COBAS TaqMan HCV test	Roche Diagnostics Australia Pty Ltd
CHIRON BLOOD TESTING, PROCLEIX HIV-1/HCV ASSAY (1000 TEST - PN 301098E AND 5000 TEST PN 301099E), IN VITRO DIAGNOSTICS, NON-STERILE	Chiron Blood Testing Pty Ltd

FRAN THORN  
Secretary  
Department of Health



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