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**General requirements for single-use,
sterile, plasticized polyvinyl chloride
(PVC) blood packs for whole blood
and blood components**

Part 1: Single blood packs



STANDARDS AUSTRALIA



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Australian Medical Devices and Diagnostics Association
Australian Red Cross Society
Australian Society of Anaesthetists
Department of Administrative Services N.S.W.
Department of Community Services and Health
Department of Health, N.S.W.
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Australian Standard®

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(PVC) blood packs for whole blood
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Part 1: Single blood packs

First published as AS 3787.1—1990.

PREFACE

This Standard was prepared by the Standards Australia Committee on Transfusion Equipment for Medical Use, under the direction of the Health Technology Standards Board.

This Part of AS 3787 deals with single blood packs whereas Part 2 of the Standard deals with multiple blood pack systems.

The Standard was originally developed by the Commonwealth Therapeutic Goods Standards Committee's Subcommittee on Blood Bags and submitted to Standards Australia as the basis for the development of an Australia Standard suitable for adoption as an Order under the Therapeutic Goods Act 1966.

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CONTENTS

	<i>Page</i>
1 SCOPE	4
2 REFERENCED DOCUMENTS	4
3 DEFINITIONS	4
4 DESIGN	4
5 BLOOD PACK COMPONENTS	4
6 PERFORMANCE OF BLOOD COLLECTION PACK	6
7 ANTI-COAGULANT SOLUTION	8
8 PACKAGING	8
9 MARKING	8
APPENDICES	
A METHOD OF TESTING STRENGTH OF JOINT	14
B METHOD OF TESTING NEEDLE PROTECTOR FOR LEAKAGE	14
C METHOD FOR DETERMINING STRENGTH OF CONNECTION AND LEAKAGE BETWEEN COLLECTION TUBE AND SOFT-WALLED CONTAINER (CAG)	16
D METHOD FOR DETERMINING STRENGTH OF CONNECTION BETWEEN CLOSURE PIERCING DEVICE AND OUTLET PORT	18
E METHOD OF TEST FOR STRENGTH OF SUSPENSION DEVICE (S)	20
F METHOD FOR DETERMINING TRANSPARENCY.....	21
G METHOD OF TEST FOR LOSS OF CONTENTS	23
H METHOD FOR DETERMINING RESISTANCE TO STRENGTH	24
I METHOD FOR DETERMINING LEAKAGE OF THE BLOOD COLLECTION PACK UNDER PRESSURE	25
J METHOD FOR DETERMINING THE TIME FOR FILLING THE BLOOD COLLECTION PACK TO ITS NOMINAL CAPACITY (COLLECTION RATE)	26
K METHOD FOR DETERMINING DELIVERY VOLUME	28
L METHOD FOR DETERMINING AIR CONTENT OF BLOOD COLLECTION PACK	29
M METHOD OF TEST FOR PARTICULATE CONTAMINATION (LIMIT TEST)	30
N METHOD FOR DETERMINING RESISTANCE TO CENTRIFUGATION	31
O METHOD OF TEST FOR PYROGENS (BACTERIAL ENDOTOXINS)	32
P METHOD OF TEST FOR HEMOLYTIC EFFECTS	34
Q METHOD OF TEST FOR CYTOTOXICITY	35
R METHODS FOR PREPARATION AND IDENTIFICATION OF EXTRACTS FOR CHEMICAL TESTING	39
S METHOD OF TEST FOR EPOXIDIZED OILS	41
T METHOD OF TEST FOR DI(2-ETHYLHEXYL) PHTHALATE (DEHP)	42
U METHOD OF TEST FOR TRI(2-ETHYLHEXYL) TRIMELLITATE (TETM)	43
V METHOD OF TEST FOR N,N'-DIACYLETHYLENEDIAMINES	44
W METHOD OF TEST FOR VINYL CHLORIDE MONOMER (VCM)	45
X METHOD OF TEST FOR POLYVINYL CHLORIDE	47
Y METHOD OF TEST FOR TRACE METALS	48
Z METHOD OF TEST FOR CALCIUM	50
AA METHOD OF TEST FOR ZINC	51
AB METHOD OF TEST FOR REDUCING SUBSTANCES	53
AC METHOD OF TEST FOR RESIDUE ON EVAPORATION	54
AD METHOD OF TEST FOR ALKYLENE (ETHYLENE OR PROPYLENE) OXIDE GAS RESIDUES	55
AE METHOD FOR DETERMINING VOLUME OF ANTI-COAGULANT SOLUTION	57

STANDARDS AUSTRALIA

Australian Standard

General requirements for single-use, sterile, plasticized polyvinyl chloride (PVC) blood packs for whole blood and blood components**Part 1—Single blood packs**

1 SCOPE. This Standard specifies requirements for sterilized, non-vented, collapsible, plasticized polyvinyl chloride (PVC) single blood packs for the collection, storage, transportation and administration of whole blood.

The Standard does not apply to blood bag systems used for the freezing of red cells.

2 REFERENCED DOCUMENTS. The following documents are referred to in this Standard:

AS

1386 Cleanrooms and clean workstations

2103 Dial gauges and dial test indicators (metric series)

2134 Recommended practice for chemical analysis of materials by atomic absorption spectrometry

2134.1 Part 1: Flame atomic absorption spectrometry

2134.2 Part 2: Graphite furnace spectrometry

2145 Hypodermic equipment—Hypodermic needle tubing

2385 Single-use (sterile) infusion sets for general medical use

CK19 Code of recommended practice for the chemical analysis of materials by ultraviolet visible spectrophotometry

BS

5736 Evaluation of medical devices for biological hazards

Part 4: Method of test for intracutaneous reactivity of extracts from medical devices

British Pharmacopoeia (BP), 1988, Vol. 2, Appendix XIVK, p.A183

British Pharmacopoeia (BP), 1988, Appendix XJII

Therapeutic Goods Order No. 11, Standard for sterile therapeutic goods

Therapeutic Goods Order No. 32, General requirements for labels of therapeutic goods

United States Pharmacopoeia (USP), XXII Monograph 85

3 DEFINITIONS. For the purposes of this Standard the definitions below apply.

3.1 Blood collection pack—a single pack, not connected to any other pack, and having an integral collection tube, needle, needle protector, outlet port and a soft-walled container (bag) containing a solution with anti-coagulant (see Figure 1).

3.2 Outer container—a container to hold one or more blood collection packs.

3.3 Collection tube/cross-matching tube—the tube through which blood is collected from the donor and a means by which blood from the blood collection pack can be sampled.

3.4 Outlet port—blood collection pack outlet with integral tamper-evident closure.

3.5 Suspension device—means by which the blood collection pack can be suspended.

3.6 Water for injections—water of purity satisfying the requirements of the British Pharmacopoeia.

DESIGN.

4.1 General. The design of the blood collection pack shall provide for the safe and convenient collection, storage, processing, transportation and administration of whole blood and red cell concentrates.

4.2 Cross-matching. The design of the blood collection pack shall permit the collection of clearly identified samples for laboratory testing without compromising the sterility of the blood collection pack.

5 BLOOD PACK COMPONENTS.

5.1 Tubing. The collection tube shall—

(a) comply with the requirements of Clauses 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, and 6.3;

(b) be not less than 2.7 mm in internal diameter;