



PQS Independent type-testing protocol

WHO/XXX
Original: English
Distribution: General

TITLE:	SPECIMEN CARRIER
<i>Product verification protocol:</i>	<PQS category>/<unique reference>
<i>Applies to specification ref(s):</i>	<PQS category>/<unique reference>
<i>Date of origin:</i>	<10.12.04>
<i>Date of last revision:</i>	<13 Dec 05> Ver 6
-	Contents: <list the content down to level 1.1.1>
1. Scope:	<briefly describe the purpose of the independent type-testing protocol>
	This document describes the type-testing protocol for SPECIMEN CARRIERS that can be used to transport small quantities of infectious specimens from the site of case investigation to the national laboratory, while maintaining the required temperature limits for a minimum of 72 hours .
2. Normative references:	< list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocol>
	Previous test procedure : E4/PROC/2; No associated ISO or international standard has been found
3. Terms and definitions:	<define any specific terms used in the protocol, particularly terms which may not be widely understood>
	Green highlight: suggested values based on recommendations received from expert advice.
	To add relevant definitions from the separate document under revision
	Cold Life for Specimen Carriers : The interval of time from the time the specimen and IP are loaded until the temperature of the warmest point reaches +4°C , at an ambient temperature of 43°C without opening the lid. The device is initially loaded with IP frozen at -20°C.
4. Applicability:	<state who will carry out the type-testing and state who will carry out on-site inspection of the manufacturer's production facilities (where relevant)>
	Type testing : ISO/IEC 17025 accredited testing laboratory On-site examination : not required.
5. Type-testing procedure	
5.1	<i>Number of samples:</i> <state minimum number of samples to be evaluated> 5 or multiples of 5
5.2	<i>Test procedure:</i> <set out the technical details of the test procedure, including testing ergonomic, health and safety and 'Universal Design' features> Refer to: Annexure 1. Preparation for test procedures & inspection Annexure 2. Drop test procedure and robustness rating Annexure 3. Cold life test procedure
5.3	<i>Test criteria for qualification:</i> <state the minimum requirements for qualification>
	Annexure 1. sec 4. Inspection

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The physical parameters should comply with those noted below :

Type	Length (mm)	Width (mm)	Height (mm)	Max. Weight loaded (kg)	Specimen storage capacity (L)
Medium	300	250	250	4	0.5-1.0
Large	370	250	250	6	1 to 1.5

Annexure 2. Drop test procedure and robustness rating

Minimum acceptable ratings are: casing 2, fittings 2

Annexure 3. Cold life test procedure

- Cold life: should be more than 72 hours at +43°C
- Ice melting rate: no standard set, however performance data will be published in the WHO/UNICEF Product Information Sheets.

6. Quality control checklist

6.1 **Quality control standards:** < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided >

All testing and reporting must be carried out in accordance with the requirements of ISO 17025:1999 or later edition.

6.2 **Quality control checklist:** <list the production quality control features that are to be examined in the course of the on-site inspection (if applicable)>

An on-site inspection of the manufacturing plant is not required.

6.3 **Quality control evaluation:** <state how the quality control checklists are to be evaluated>

7. **Pre-qualification evaluation:** <state the minimum criteria for pre-qualification taking account of results from 5.3 and 6.3 and including any weighting system that may be needed >

A product will qualify for inclusion on the register of PQS pre-qualified devices, in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification <PQS category>/<unique reference>.

8. **Modified products:** <describe the procedure for re-checking products that are already pre-qualified, but which have subsequently been modified by the manufacturer This procedure may not involve full re-verification.>

Annexes: < as required >

Annexure 1. Preparation for test procedures & recording

Annexure 2. Drop test procedure and robustness rating

Annexure 3. Cold life test procedure

Revision history:

Date	Change summary	Reason for change	Approved
ddmmyy	< change item > < etc.>	< reason for change > < etc.>	<name>

Annexure 1. Preparation for test procedures & inspection

General test conditions

1. Introduction

This document describes the preparatory phase for test procedures to assess the relative performance and mechanical characteristics of insulated containers with no integral cooling units other than Ice Packs.

Two main types of test are described:

- The temperature rise test is used to determine the length of time the specimen can be stored in the container at an ambient temperature of +43°C, while maintaining the specimen between -20°C and +4°C.
- The drop test is designed to simulate the effect of rough handling of the container in field conditions. It assesses the resistance of the container.

Temperatures within the container must be capable of being continuously monitored within an accuracy of $\pm 0.5^\circ\text{C}$ without the sensors used influencing the test in any way.

A minimum of 3 simultaneous temperature measurements are required for a specimen carrier. The ambient temperatures at which equipment is tested must remain within a tolerance of $\pm 1^\circ\text{C}$.

2. Loading

The containers are lined with IP as specified by the manufacturer. IP should conform to Specifications E5/IP1 or 2, unless agreed otherwise with the WHO. If no IP are provided by the manufacturer, then IP with the correct specifications are arranged to cover as far as possible the internal surface of the walls of the container and the top of the specimen load.

Icepacks should be frozen at $-20^\circ\text{C} \pm 2^\circ\text{C}$ in contact with the freezing plate for 48 hours before testing to ensure that they are frozen through completely.

Specimen carriers should be loaded with dummy load in both the recommended number of pots provided or meant for use with the carrier.

Loads can be pre-fitted with thermocouples and should be preconditioned at ambient. Loading should be carried out as quickly as possible and the period of loading should be recorded for each container.

3. Temperature recording

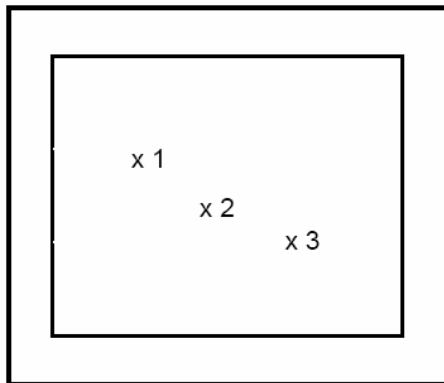
The internal temperature of a cold box, carrier or vaccine package is recorded at specified points within the load during the temperature rise tests. The figure below shows the position of these points, each of which is 2.5/3.0 cm from the nearest icepack surface with the exception of the central points.

Thermocouple leads can be introduced into the container in one of two methods:

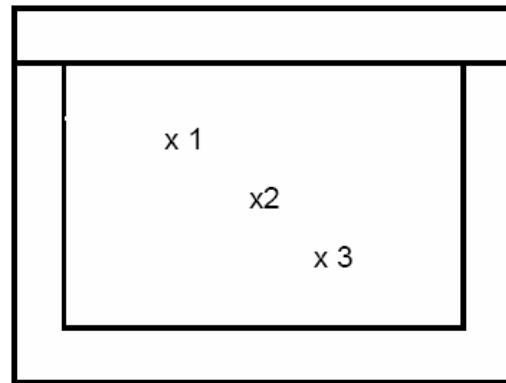
- Through the seal, taking care not to affect the quality of the seal.
- Through a hole in the geometric centre of the lid or of one of the sides of the container, taking care to adequately seal the outer and inner openings.

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Locations of temperature sensors for Specimen carriers



Specimen carrier: top view



Specimen carrier: side view

4. Inspection

On receipt, all containers should be carefully examined to ensure that no serious defects exist. If damage is evident a detailed record of this should be made.

A photograph should be taken showing a corner view of the whole container with the lid open. Borderless colour or black and white prints 10 mm x 70 mm should be taken and attached to the product information sheet.

Each box (and lid if it is detachable) should be marked with an identification number for use during the test. Information on the container should be entered on the product summary table.

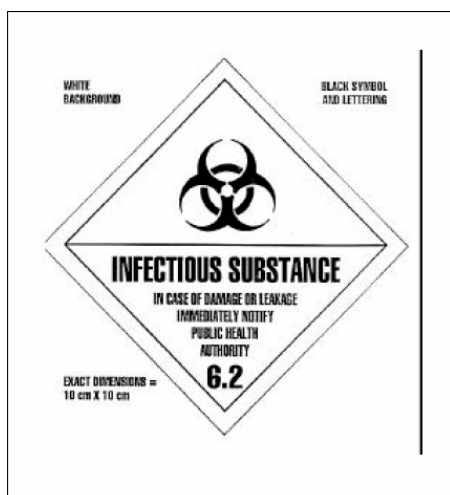
The materials used for the various fittings should also be noted and described in the report, together with a brief discussion of their suitability, if appropriate. The quality of construction should be commented on, particularly with respect to the hinges and fittings.

Additional issues to be inspected are :

- Manufacturer's confirmation that the thermal insulation has been produced using chemicals that are non-ozone depleting, and preferably having minimum global warming potential.
- Schematic / verbal instructions for the loading pattern of IP & specimen pots
- Label warning about the infectious contents.
- Schematic / verbal instructions for on how to disinfect the carrier after use.

An initial inspection report is sent to WHO as soon as possible. It should include :

- Weight and external measurements of appliance.
- Internal volumes
- Projected specimen load
- Icepacks load
- Icepacks distribution
- Projected test cycle



Label for warning infectious contents

Annexure 2. Drop test procedure and robustness rating

Test condition:

Room at ambient temperature and ambient humidity.

Objectives :

To determine damages to the cold box after a series of impacts.

Procedure:

The container is fully loaded with icepacks filling the entire internal volume. The packs should each be filled 1/3 full of water. The container is then dropped from a height of 1 metre (measured from the lowest part of the container) onto a smooth concrete floor.

Twenty-six drops are performed, one on to each face, edge and corner in the following order:

<i>Face</i>	<i>Edges</i>	<i>Corners</i>
<i>Drop No.</i>	<i>Drop No.</i>	<i>Drop No.</i>
1 Top	7 Front top	19 Front top left
2 Bottom	8 Back top	20 Front top right
3 Front	9 Left side top	21 Back top left
4 Back	10 Right side top	22 Back top right
5 Left side	11 Front bottom	23 Front bottom left
6 Right side	12 Back bottom	24 Front bottom right
13 Left side bottom		25 Back bottom left
14 Right side bottom		26 Back bottom right
15 Front left side		
16 Front right side		
17 Back left side		
18 Back right side		

The test is stopped when part of the load falls out. If this stage is reached due to failure of the hinges and/or catches, the lid must be re-secured and the test continued. The damage should be noted after each drop and overall damage assessed at the end of the test on the following scales:

Robustness rating

Rating	Damage to container	Damage to fittings
1	Heavy damage or pulled off	Hinges and /or catches broken
2	Easily repairable damage	Hinges and/or catches become undone
3	Superficial damage	satisfactorily Hinges and catches work
4	Slightly marked	
5	Unmarked	

Annexure 3. Cold life test procedure

Container closed

Test condition: $+43^{\circ}\text{C} \pm 1^{\circ}\text{C}$

Objective :

To determine how long specimen collection kits can be kept at temperatures between -20°C and $+4^{\circ}\text{C}$ in the carrier at an ambient temperature of 43°C .

Procedure:

The cold life of the specimen container is defined as the time from the start of the test until the temperature of the warmest point reaches $+4^{\circ}\text{C}$.

Ice melting rate is calculated as the ratio of the amount cold life over the amount of ice melted.

The temperature difference between the warmest and coldest point is reported at the moment when the warmest point reaches $+8^{\circ}\text{C}$. The position of these points is reported. Possible modifications to the container which would improve poor performance should be proposed.

The test load is composed of sufficient standard specimen collection kits (PIS code E11/02) to entirely fill the specimen carrier when the designated load of IPs is also inserted. The test load is fitted with the temperature sensors and stabilized at $+37^{\circ}\text{C} \pm 2^{\circ}\text{C}$. The cold box is stabilized for at least 24 hours with the lid open at $+8^{\circ}\text{C} \pm 1^{\circ}\text{C}$. The icepacks, which are frozen at $-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ are then fitted, followed by the load, and the cold box lid closed.

Care should be taken to ensure the seal is not broken. Temperatures are recorded at every 15 minutes intervals until the temperature of the coldest point has exceeded $+8^{\circ}\text{C}$.

Test criteria for qualification:

- Cold life: more than **72 hours** at $+43^{\circ}\text{C}$
- Ice melting rate: no standard set, however performance data will be published in the WHO/UNICEF Product Information Sheets.