



## PQS performance specification

<b>TITLE:</b>	<b>SPECIMEN CARRIER</b>
<i>Specification reference:</i>	<PQS category>/<unique reference>
<i>Product verification protocol:</i>	<PQS category>/<unique reference>
<i>Date of origin:</i>	<06-12-04>
<i>Date of last revision:</i>	< 13 Dec 05> Ver 6
-	<b>Contents:</b> <list the specification content down to level 1.1.1>
1.	<p><b>Scope:</b> &lt;briefly describe the intent of the specification&gt;</p> <p>This document describes the product performance specifications to be complied by a device in the form of a passive portable container called SPECIMEN CARRIER that is to 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 using passive device referred as Ice Packs (IP).</p>
2.	<p><b>Normative references:</b> &lt; list ISO/IEC and other standards that apply to the specification and list any relevant WHO product verification protocols; cross-refer to any other relevant performance specifications&gt;</p> <p>Previous equipment performance specifications : E11/ VC2. No associated ISO or international standard has been found.</p>
3.	<p><b>Terms and definitions:</b> &lt;define any specific terms used in the specification, particularly terms which may not be widely understood&gt;</p> <p><b>To add relevant parts from Terms and Definitions after adaptation when finalised.</b></p> <p><b>Green highlight:</b> suggested values based on recommendations received from expert advice.</p> <p><b>Cold Life for Specimen Carriers :</b> 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.</p>
4.	<b>Requirements</b>
4.1	<p><b>General:</b> &lt;state what is generally required of the product, but not how this is to be achieved; briefly describe the context in which the product is to be used&gt;</p> <p>The device should be in the form of a portable container having an internal storage volume between 0.2 and 1.5 L depending on the type and external dimensions, excluding space required by the recommended number of IPs of standard approved type, with good thermal insulation to transport infectious specimen from the site of investigation to the national laboratory.</p>

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The device must safely maintain the temperature of infectious specimen within the recommended temperature range (-20°C and +4°C) using the recommended number of frozen IPs, in an external ambient temperature of +43°C.

- 4.2 **Performance:** <set out the specific performance characteristics required, including limits on energy consumption, where relevant>

The internal thermal insulation should have sufficiently low thermal conductivity to allow a cold life of at least 72 hours at an external ambient temperature of +43°C.

- 4.3 **Environmental requirements:** <quantitatively define the operating environment in respect of temperature range, humidity, shock, vibration, etc.>

The device should withstand storage and usage at an external ambient temperature between -10 °C & + 45°C.

The device should be robust enough to withstand shocks caused by accidental drops or knocks and should not be damaged due to vibrations of the type caused by road transport. The device should have an external lid that can be safely closed and remain closed on suffering accidental drops and knocks.

- 4.4 **Physical characteristics:** <set out critical physical characteristics such as limits on weight, size, etc., but only to the extent that these data are essential to satisfy human factors and/or interface requirements>

The following physical parameters must be met:

Type	Length (mm)	Width (mm)	Height (mm)	Max. Weight loaded (kg)	Specimen storage capacity (L)	No. of specimen kits (pots)
Medium	300	250	250	4	0.5-1.0	>4
Large	370	250	250	6	1 to 1.5	>8

The device should have a yellow external body and a non detachable, preferably embossed international sign designating “infectious material” as shown below, to inform the user about its infectious contents.



- 4.5 **Interface requirements:** <describe form and fit requirements to the extent that these impact on other related products; for example, size of icepacks to suit a specific range of cold boxes>

The internal dimensions of the device should be sufficient to accommodate the largest tolerance of the WHO approved standard IP ( PQS #XYZ) and accommodate the number of IP as recommended by the manufacturer.

The device lid should be safely closed. It should remain closed on suffering accidental drops and knocks.

- 4.6 **Human factors:** <describe ergonomic requirements, including percentile of users; ‘Universal Design’ principles; health and safety issues, etc.>

For convenience of transport the device should have a handle for holding and/or strap to hang across the shoulder.

The device should permit easy stacking of the device in a stable condition.

The device should have the international warning of infectious contents embossed on it

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to inform the user about its infectious contents. If embossing is not possible the international warning label of hazardous contaminated materials should be fixed in a non-detachable manner. .

The following instructions in English, French, Spanish, Arabic and Russian (available from WHO) should be printed on the internal side of the lid:

**"Disinfect thoroughly before re-use"**

Two self adhesive international warning label should be printed in each language (English, French, Spanish, Arabic and Russian; artwork available from WHO) and should be included within each carrier shipped.

- 4.7 *Materials:* <specify materials that are to be used or excluded only to the extent that this is absolutely necessary; for example to ensure adequate corrosion or wear resistance, to minimize toxicity, or to comply with international agreements (e.g. the Montreal Protocol)>

The thermal insulation should be produced using chemicals that do not belong to the family of CFC (chemicals specified in annexures A & B of the Montreal Protocol) which are ozone depleting, and should preferably have minimum global warming potential.

- 4.8 *Reliability:* <define reliability requirements in quantitative terms and define the conditions under which these requirements must be met>

**Robustness:**

The device shall withstand a one meter drop on every face, edge, and corner. As a result the maximum acceptable damage to the casing should be easily repairable (rating 2) and the hinges and catches get undone in the worst case (rating 2).

The casing and internal surfaces should withstand chemicals used for disinfecting (e.g. sodium hypochlorate. 5.25% in water)

**Cold Life** as defined for Specimen carrier (-20°C to +4°C) : Min cold life of 72 hours without opening.

- 4.9 *Maintainability:* <define maintainability issues in as quantitative manner as possible; for example, mean time between maintenance, level of maintenance skill needed, etc.>

To check regularly that the device is properly disinfected, the lid closes properly on the carrier and the carrying strap is not damaged. The IP provided or reserved for use with the device are not interchanged for any other use.

- 4.10 *Disposal and recycling:* <state specific requirements relating to end-of-life disposal, including any requirements for recycling of materials or components>

The Manufacturer should state life span over which the measured / claimed cold life performance is assured, and how to dispose off device at end of life without polluting the environment.

- 4.11 *Instructions:* <if user and/or maintenance instructions are required, state in which languages they are to be supplied >

**Instructions/information :**

The device should have the following information embossed on its casing:

1. Indication of Infectious content
2. date of manufacture

In addition the device should have the following information in 6 UN languages (Arabic, Chinese, English, French, Russian and Spanish) attached to itself using a laminated sheet ::

1. Specimen pots and IP loading pattern
2. Duration of the cold life

3. How to disinfect the device after use

4.12 **Training:** <if user training is required, state who is to be trained and for what purpose>

4.13 **Verification:** <state how product performance is to be verified, by citing the relevant type-testing, type-examination or full quality-assurance protocol>

**Type Examination Protocol :** #

5. **Packaging:** <state any specific requirements for packaging>

6. **On-site installation<sup>1</sup>:** <where a product requires on-site installation (e.g., a standby generator) clearly define who is to be responsible for each stage in the process, such as:

Not Required

7. **Product dossier:** <state what supporting information and/or samples the manufacturer (legal manufacturer or re-seller) or approved installer is to provide when submitting a product for pre-qualification, including details of quality systems (QA) in place>

1. Sample of the device with the required standard IP
2. Manufacturer's data on the following :
  - a. External and internal measurements
  - b. Specimen pots storage capacity and IP load
  - c. Weight Empty
  - d. Weight when fully loaded
3. Manufacturer's test results if available for the following :
  - a. Cold life
  - b. Ice melting rate
  - c. Results of drop test
4. Manufacturer's own QA standard and procedures

8. **On-site maintenance:** <if on-site maintenance is required state the desired performance criteria with regard to response rate and the like>

9. **Change notification:** <state how the manufacturer or approved installer is to report future changes in product specification, manufacturing location and manufacturing methods to WHO/UNICEF and define the conditions under which re-testing may be required>

Manufacturers should keep WHO informed of any change in the design of the box that affect the compliance with the specification and and/or is likely to alter performance.

10. **Defect reporting:** <state how the manufacturer or approved installer is to notify purchasers, end-users and WHO/UNICEF in the event of safety-related product recalls, component defects and other similar events>

WHO PQS secretariat should be informed of such event as soon as they are identified - in writing by mail or email.

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<sup>1</sup> This section may have to take the form of a guideline to the 'client' who draws up a site-specific specification. See for example WHO/V&B 02.33. *Equipment performance specifications and test procedures. E1: Cold rooms and freezer rooms.*