



TITLE: Vaccine cold box – long-term storage – 10 days	
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Contents:

1. Scope.....	2
2. Normative references.....	2
3. Terms and definitions	3
4. Applicability	4
5. Type-testing procedure.....	5
5.1 Number of samples.....	5
5.2 Test procedure	5
5.2.1 <i>Test 1: Type examination</i>	<i>5</i>
5.2.2 <i>Test 2: Dimensions, weights and vaccine storage capacity.....</i>	<i>7</i>
5.2.3 <i>Test 3-A: Frozen coolant-pack thickness and adhesion test.....</i>	<i>8</i>
5.2.4 <i>Test 3-B: Robustness test for frozen coolant-packs</i>	<i>9</i>
5.2.5 <i>Test 3-C: Robustness test for unfrozen coolant-packs</i>	<i>9</i>
5.2.6 <i>Test 3-D: Lateral pressure leakage test for coolant packs</i>	<i>9</i>
5.2.7 <i>Test 4: Drop test – cold box (Type 2 only).....</i>	<i>10</i>
5.2.8 <i>Test 5: Random vibration – cold box (Type 2 only).....</i>	<i>11</i>
5.2.9 <i>Test 6: Cold life tests (+32°C or +43°C)</i>	<i>12</i>
5.2.10 <i>Test 7: Minimum rated ambient temperature test.....</i>	<i>13</i>
5.2.11 <i>Test 8: Cold climate freeze protection test</i>	<i>14</i>
5.2.12 <i>Test 9: IP rating test to IEC 60529 (Type 2 only).....</i>	<i>14</i>
5.3 Test criteria for qualification:.....	15
6. Quality control checklist.....	15
6.1 Quality control standards	15
6.2 Quality control checklist	15
6.3 Quality control evaluation.....	15
7. Pre-qualification evaluation.....	15
8. Modified products.....	15
Annex 1 – Temperature sensor positions.....	16
Annex 2 – Temperature sensor specification.....	17
Annex 3 - Vial and ampoule specification for test	17
Revision history:.....	19

1. Scope

This document describes the procedure for verifying the performance of thermally insulated vaccine cold boxes and containers which have a particularly long **cold life**. These containers are typically used to maintain the cold chain when vaccines are stored for extended periods at a fixed location such as a health facility which provides immunization services and outreach efforts. Optionally, these devices may also be used for transport. Acceptable **cold life** must be provided for a minimum of 10 days with one charge of **coolant** at cycling day/night temperatures of either **hot zone** temperatures (+43°C/+25°C) and/or at **temperate zone** temperatures (+32°C/+15°C).

Long-term storage cold boxes are passive (non-cyclic) coolers that have no compressor, fan or other temperature control component that would require electrical energy or fossil fuel. They are characterized by **coolant recharging** with frozen water or other phase change materials (PCM) that are re-supplied at regular intervals of approximately one month. They exhibit extreme temperature stability and are not subject to the cycling temperatures, control calibration changes or the same mechanical failures that active (cyclic) refrigeration can experience. Long-term storage cold boxes can replace active refrigerators only when **coolant recharging** is pre-planned and routinely available.

This document covers long-term storage cold box products that may prequalify as either:

Type 1: A stationary cold box; or

Type 2: A combination transportable and stationary cold box.

2. Normative references

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM D999-08: *Standard Test Methods for Vibration Testing of Shipping Containers*

ASTM D4169-09: *Standard Practise for Testing of Shipping Containers and Systems*

ASTM D5276-09: *Standard test method for drop test of loaded containers by free fall*

EMAS: *European Union Eco-Management and Audit Scheme.*

EN 10152: *Electrolytically zinc coated cold rolled steel flat products for cold forming. Technical delivery conditions.*

EN 10169-1: *Continuously organic coated (coil coated) steel flat products - Technical delivery conditions.*

IEC 60529: *Consolidated Edition 2.1 (incl. am1): Degrees of protection provided by enclosures (IP Code).*

ISO 9001: *Quality Management Systems – Requirements.*

ISO 14001: *Environmental management systems - Requirements with guidance for use.*

ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories.*

ISO 20282-1: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*

ISO 27956: *Road vehicles – Securing of cargo in delivery vans –Requirements and test methods.*

ISTA: *Procedure 3H: Performance Test for Products or Packaged-Products in Mechanically Handled Bulk Transport Containers.*

WHO/PQS/E004/CB04: *Performance Specification: Vaccine cold box long-term storage – 10 days.*

WHO/PQS/E005/IP01: *Water-packs for use as ice-packs, cool-packs and warm-packs.*

WHO/PQS/E06/TH02.1: *Fixed gas or vapour pressure dial thermometer.*

WHO/PQS/E06/TH06.1: *Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers*

3. Terms and definitions

Cold climate freeze protection life: The empty container is stabilized at +18°C and loaded with **coolant-packs** which have been stabilized at +8°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the coldest point inside the **vaccine storage compartment** first reaches 0.0°C at a constant ambient temperature of -20°C.

Cold life: The empty container is stabilized at +43°C (or +32°C) and loaded with **coolant** that has been prepared in accordance with the manufacturer's **coolant recharging** instructions. **Cold life** is measured from the moment when the container lid is closed until the temperature of the warmest point in the **vaccine storage compartment** first reaches +10°C, at day/night cycling of +43°C/+25°C (or +32°C/+15°C) and with regular removal of vaccine. The vaccine storage compartment must remain above 0°C at all times when measured with an accuracy of ±0.1°C.

Coolant: Any substance that can be transported and repeatedly used to absorb energy in a long-term storage cold box and that is non-hazardous, non-corrosive and non-flammable.

Coolant-pack:

- A generic PQS prequalified **water-pack** complying with specification **PQS/E005/IP01**.
- A purpose designed **PCM-pack complying with this specification**.
- A purpose designed leak-proof plastic or metal container, filled with water, complying with this specification.

A **coolant-pack** may be used as an **ice-pack**, as a **frozen PCM-pack** or as a **cool-pack**.

Coolant recharging: A standard procedure that supports the sustained operation of the long-term storage cold box. **Coolant** preparation and the equipment needed for this task may be located away from the site where the long-term storage cold box is used.

Cool-pack: A **coolant-pack** pre-cooled to a temperature between + 2°C to +8°C before use. If **PCM-packs** are used for this purpose, they must not be cooled to the point at which they change phase.

Frozen PCM-pack: A **PCM-pack** cooled to the point where there is no remaining liquid **PCM**.

Ice-pack: A water-containing **coolant-pack** frozen to a temperature between -5°C and -25°C before use, to the point where there is no remaining liquid water.

In writing: means communication by letter, fax or email.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Minimum rated ambient temperature: All appliances will be tested to determine the lowest constant ambient temperature at which the vaccine compartment remains above 0°C. The test is carried out at +15°C unless the manufacturer specifies a lower figure.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer

Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

PCM-pack: A leak-proof plastic or metal container filled with water or other PCM material designed to be coupled with the vaccine storage compartment. The PCM fill material must be certified to be non-flammable, non-corrosive and non-toxic, and must change phase completely when exposed to storage temperatures in the range +1°C and +6°C.

Primary container: Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.

Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

Secondary carton: A carton which contains a number of individual primary containers. Most countries store and distribute vaccines in these cartons.

Vaccine storage capacity: The volume of the compartment allocated by the manufacturer for vaccine storage. For square and rectangular compartments, capacity will be measured and published as volume in litres and length, width and height in centimetres. Non-rectangular compartments will be measured and published as volume in litres including maximum width or diameter, minimum width or diameter and height in centimetres. The capacity of products which are supplied with racks or holders designed to retain individual vaccine vials and ampoules will be measured and published as the maximum number of vials and ampoules that can be contained based on the standardized sample of vaccines defined in Annex 3.

Vaccine storage compartment: The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of coolant-packs required to achieve the cold life specified in this document.

Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification PQS/E005/IP01.

4. Applicability

Type-testing will be carried out by an independent ISO/IEC 17025 testing laboratory, accredited by WHO.

5. Type-testing procedure

5.1 *Number of samples*

The [Legal Manufacturer](#) or [Reseller](#) must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. For **Type 1** units, one sample unit is required. For **Type 2** units, two samples are required. For each sample, provide two complete sets of [coolant-packs](#) as recommended by the container manufacturer. The spare set is to be used in the event of leakage or other eventuality. If Tests 3-A to 3-D are conducted, a minimum of 15 additional coolant packs are required.

5.2 *Test procedure*

5.2.1 *Test 1: Type examination*

Sample: Sample 1 for **Type 1** units. Samples 1 and 2 for **Type 2** units.

- **Step 1:** Check all samples for similarities between different models¹, dissimilarities between samples of one model, and any physical or operational defects or damage that could affect form, fit or function.
- **Step 2:** Record any differences between the samples ordered and those received.
- **Step 3:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required [in writing](#) from the [Legal Manufacturer](#) or [Reseller](#) and attach this information to the report:

Identification:

- Code (a unique identifier to be assigned by the testing laboratory).
- Model and serial number (barcode if attached to cold-box).
- [Legal Manufacturer](#) or [Reseller](#).
- Product type (e.g. Type 1 Stationary or Type 2 Combination Transportable and Stationary).
- Country of origin.
- Conformity assessment markings (if any).

Performance characteristics:

- [Vaccine storage capacity](#) conforms/does not conform to specification clause 4.2.1.
- Design principles conform/do not conform to specification clause 4.2.6.
- [Coolant-pack](#) filling requirement conforms/does not conform to specification clause 4.2.7.
- [Coolant-pack](#) colour and markings conform/do not conform to specification clause 4.2.11.
- Door or lid seal conforms/does not conform to specification clause 4.2.12.
- Hinges conform/do not conform to specification clause 4.2.13.
- Lid or door stay conforms/does not conform to specification clause 4.2.14.
- Catches conform/do not conform to specification clause 4.2.15.
- Carrying handles (Type 2 only) conform/do not conform to specification clause 4.2.16.
- Vaccine storage advice conforms/do not conform to specification clause 4.2.17.

¹ The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical device.

- Stacking and handling ability (Type 2 only) conforms/does not conform to specification clause 4.2.18.
- Corrosion resistance conforms/does not conform to specification clause 4.2.19.
- Chemical resistance conforms/does not conform to specification clause 4.2.20.
- IP rating (Type 2 only) conforms/does not conform to specification clause 4.2.21.
- Load restraint equipment and attachment points (Type 2 only) conform/do not conform to specification clause 4.2.23.
- Lock conforms/does not conform to specification clause 4.2.24.
- Thermometer conforms/does not conform to specification clause 4.2.25.
- **Coolant** for immunization sessions conforms/does not conform to specification clause 4.2.26.
- Areas not suitable for vaccine storage conform/do not conform to specification clause 4.2.27.

Environmental requirements:

- Ambient temperature range during transport storage and use conforms/does not conform to specification clause 4.3.1.
- Ambient humidity range during transport storage and use conforms/does not conform to specification clause 4.3.2.

Physical characteristics:

Weight conforms/does not conform to specification clause 4.4.2. (Note: Type 1 containers that are shipped as components must be weighed to assure that no single component exceeds 100 kg).

Interface requirements

- Where applicable, dimensional compatibility with water-packs conforms/does not conform to specification clause 4.5.1.
- Dimensional compatibility with vaccine packaging conforms/does not conform to specification clause 4.5.2.
- Dimensional compatibility with transport modes conforms/does not conform to specification clause 4.5.3.
- Overall dimensions conform/do not conform to specification clause 4.5.4.

Human factors:

- Human factors design conforms/does not conform to specification clause 4.6.

Materials and construction:

- Record materials used for all major components, including exterior casing, insulation, interior casing, hinges, load restraint attachment points, catches and stays.
- Casing materials conform/do not conform to specification clause 4.7.1.
- Thermal insulation foaming agent conforms/does not conform to specification clause 4.7.2.

PCM:

- PCM, if used, conforms/does not conform to the specification in clause 4.7.3. Manufacturer to provide documentation confirming compliance with WHO/PQS/E005/PCMC0.1– PCM specification for Phase-change material containers.

Warranty:

- Warranty conforms/does not conform to specification clause 4.8.

Servicing provision:

Servicing provision conforms/does not conform to specification clause 4.9.

Disposal and recycling:

- Recycling and disposal information conforms/does not conform to specification clause 4.10.

Instructions:

- User and maintenance instructions conform/do not conform to specification clause 4.11.

- **Step 4:** Take a three quarter view digital photograph of each sample with the lid open and the container empty and also with **coolant-packs** in place. Take close-up photographs of the **coolant-packs**, **coolant recharging** system (if supplied), **vaccine storage compartment(s)**, hinges, load restraint attachment points, catches and handles.
- **Acceptance criterion:** Inspection indicates full conformity with all specification requirements.

5.2.2 *Test 2: Dimensions, weights and vaccine storage capacity*

Sample: Sample 1 or 2.

Test conditions: Testing room at +21.0°C (±3.0°C), at a relative humidity of 65% (+/- 10%). Record conditions at the time of the test.

- **Step 1:** Record maximum external dimensions in centimetres (length, width and height, or height and diameter (± 0.5 cm)). Take measurements with handles folded (if applicable).
- **Step 2:** Record minimum internal dimensions in centimetres, without **coolant-packs** (length, width and height, or height and diameter (± 0.5 cm)).
- **Step 3:** Record the empty weight of the container, without **coolant-packs**, in kilograms (± 0.1 kg).
- **Step 4a: Only applicable for water-packs.** Use the number of **water-packs** designated by the container manufacturer. The total volume of water in the set of **water-packs** must equal the following formula:
((**water-pack** manufacturer's rated water volume) x (designated no. of **water-packs**)) (± 2.0%).

Fill each **water-pack** in the set with the equal volumes of tap water, stabilized at a temperature of +20.0°C (±2.0°C). Record the total volume of water used and the total weight of the filled **water-packs**.

- **Step 4b: Not applicable for water packs.** Record the total weight of the filled **coolant-packs** and estimate the total volume of **coolant** based on the pack manufacturer's data.
- **Step 5:** Fully freeze the set of **coolant-packs** in accordance with the manufacturer's specifications. If **water-packs** are supplied, fully freeze at -25.0°C (±0.5°C). Place the frozen **coolant-packs** in the container in accordance with the manufacturer's instructions. Record the minimum overall dimensions of the **vaccine storage compartment**. Where **coolant-packs** immediately abut the load, this is measured between straight edges placed over the bulging internal faces of the **coolant-packs** (length, width and height, or height and diameter, measured up to the manufacturer's designated load line, (± 0.5 cm)). Where there is an inner liner or air space separating the load from the **coolant-packs**, take measurements between the faces of the lining. Multiply the minimum dimensions of the length, width and height together to obtain the nominal

vaccine storage capacity in litres². To determine **vaccine storage capacity** for non-rectangular vaccine containers that will be filled with individual vials and ampoules, use the mix specified in Annex 3 to fill the device and then calculate the total cylindrical volume that can be placed in the vaccine storage compartment(s) in accordance with the formula in specification clause 4.2.1.

- **Step 6:** Weigh the container, in kg (± 0.1 kg), with the **coolant-packs** and inner liner (if any) in place. Multiply the measured **vaccine storage capacity** by 0.8 and record this figure as the *maximum loaded weight* in kg³.
- **Acceptance criteria:** The measured **vaccine storage capacity** must not be less than 5 litres for containers designed to store vaccine in **secondary cartons**, and not less than 2.5 litres of mixed vials and ampoules for containers designed to store vaccines in **primary containers**⁴. The maximum loaded weight must not exceed 50 kg for Type 2 containers. Type 1 containers that are shipped as components must be weighed to check that no single component exceeds 100 kg.
- **Rejection criteria:** Maximum empty weight, maximum loaded weight or component weights outside designated range. **Vaccine storage capacity** below the minimum designated volume.

5.2.3 Test 3-A: Frozen coolant-pack thickness and adhesion test

Note: Test 3-A is not required for **water-packs** which are already WHO PQS prequalified.

Samples: Five filled, labelled, plastic, or metal **coolant-packs**.

Test conditions: As Test 2.

- **Step 1:** Record external dimensions of each filled sample in millimetres (length, width and height, or height and diameter (± 0.5 mm)). Freeze a full set of **coolant-packs** per manufacturer instructions for a minimum of 24 hours at -25.0°C ($\pm 0.5^{\circ}\text{C}$).
- **Step 2:** Remove frozen **coolant-packs** from the freezer. Record whether or not they adhere to one another to the extent that they have to be pulled apart.
- **Step 3:** Measure and record thickness of frozen **coolant-packs** (± 1.0 mm).
- **Step 4:** Thaw the **coolant-packs** at room temperature. Measure and record the thickness of the thawed **coolant-packs** (± 1.0 mm).
- **Step 5:** Return the **coolant-packs** to the freezer for a further 24 hours in preparation for test 3-B.
- **Acceptance criteria:** Increase in sample thickness due to freezing does not exceed the measured dimensions recorded in Step 1 by more than 25% for any of the samples. Thickness of each of the thawed samples equals the measured thickness of the same sample from Step 1 (± 1.0 mm). **Coolant-packs** do not adhere to one another significantly when frozen.
- **Rejection criteria:** One or more frozen samples exceed the permitted increase in thickness and/or one or more thawed samples fail to return to the pre-frozen thickness. **Coolant-packs** adhere strongly to one another when frozen.

² Where the container requires a layer of coolant-packs positioned above the load, the height measurement must exclude the thickness of this layer.

³ 0.8 kg/litre is the 95th percentile density of the mix of vaccines procured by UNICEF in 2011.

⁴ For the purposes of this assessment, vial and ampoule volume is defined as $(PI) \times \text{primary container radius}^2 \times \text{primary container height}$.

5.2.4 Test 3-B: Robustness test for frozen coolant-packs

Note: Test 3-B not required for [water-packs](#) which are already WHO PQS prequalified.

Test conditions: As Test 2.

Samples: Five filled, labelled and frozen [coolant-packs](#) from Test 3-A.

- **Step 1:** Mark each face of the [coolant-pack](#) with a unique test number. For cylinders, mark the top and bottom flat faces, two opposite curved sides and two opposite edges where the flat face is joined to the curved side.
- **Step 2:** Using a free fall drop tester, drop each [coolant-pack](#) from a height of 2.0 metres (measured from the lowest part of the [coolant-pack](#) at the start of each test) onto a smooth dense concrete floor in the following order:

Face	Edges	Corners
1 Flat face top	3 Side edge	5 Top
2 Flat face bottom	4 Side edge +180°	6 Bottom (space diagonal)

Cancel the relevant test number marking after each drop so as to avoid inadvertent duplication.

- **Step 3:** Fully thaw all [coolant-packs](#) in the test chamber in preparation for Test 3-C and Test 3-D. Note any leakage.
- **Acceptance criterion:** All samples pass the leakage examination and the leakage test after completion of the drop tests.
- **Rejection criterion:** Leakage occurs in one or more samples.

5.2.5 Test 3-C: Robustness test for unfrozen coolant-packs

Note: Test 3-C is not required for [water-packs](#) which are already WHO PQS prequalified.

Test conditions: As Test 2.

Samples: Five unused [coolant-packs](#) filled per manufacturer's instructions, labelled and conditioned at +10.0°C for 24 hours.

- **Step 1:** Mark each face of the [coolant-pack](#) with a unique test number. For cylinders, mark the top and bottom flat faces, two opposite curved sides and two opposite edges where the flat face is joined to the curved side.
- **Step 2:** Using a free fall drop tester, drop each [coolant-pack](#) from a height of 2.0 metres (measured from the lowest part of the [coolant-pack](#) at the start of each test) onto a smooth dense concrete floor in the following order:

Face	Edges	Corners
1 Flat face top	3 Side edge	5 Top
2 Flat face bottom	4 Side edge +180°	6 Bottom (space diagonal)

Cancel the relevant test number marking after each drop so as to avoid inadvertent duplication.

- **Step 3:** Carry out the lateral pressure leakage test described in Test 3-D. Check each [coolant-pack](#) for leaks.
- **Acceptance criterion:** All samples pass the leakage examination and the leakage test after completion of the drop tests.
- **Rejection criterion:** Leakage occurs in one or more samples.

5.2.6 Test 3-D: Lateral pressure leakage test for coolant packs

Note: Test 3-D is not required for [water-packs](#) which are already WHO PQS prequalified.

Test conditions: As Test 2.

Samples: Five unused **coolant-packs** filled per manufacturer's instructions, labelled and conditioned at +10.0°C (± 2°C) for 24 hours.

- **Step 1:** Remove **coolant-packs** from the refrigerator. Place an 80kg uniformly distributed load with an area of 10 cm x 30 cm on the flat face of each of the rectangular **coolant-packs** or on the curved face of each of the cylindrical **coolant-packs**⁵ for a period of 30 seconds and check for leakage.
- **Acceptance criterion:** No leakage from any of the samples.
- **Rejection criterion:** Leakage occurs in one or more samples.

5.2.7 Test 4: Drop test – cold box (Type 2 only)

Sample: Sample 1⁶.

- **Test conditions:** As Test 2. Condition the sample in the testing room for 24 hours with the door or lid open. Record conditions at the time of the test.
- **Step 1:** Assemble a dummy vaccine load comprising either:
 - partially filled **water-packs** with a combined density of 0.5 kg per litre of the measured **vaccine storage capacity** or:
 - water-filled individual dummy vaccine vials and ampoules per Annex 3 specification.

Stabilize the load in a cold room or refrigerator at +5.0°C (±0.5°C) at a relative ambient humidity of 65% (+/- 10%) for a minimum of 24 hours.

- **Step 2:** Prepare frozen **coolant-packs** in accordance with the manufacturer's specifications. If **ice-packs** are used, fully freeze at -25.0°C (±0.5°C). If **PCM-packs** are used, fully freeze at the temperature specified by the manufacturer. Place the frozen **coolant-packs** in the container in accordance with the manufacturer's instructions. Place the +5°C stabilized load in the **vaccine storage compartment** per manufacturer's instruction. Close the door or lid of the container. Report the time taken to prepare the **coolant-packs**.
- **Step 3:** Mark the faces of the container and carry out a full free-fall drop test sequence from a height of one metre (measured from the lowest part of the container at the start of each test) onto a smooth dense concrete surface, without rupture hazard, in accordance with ASTM standard D 5276 and in the column sequences shown in the tables below, working down each column and from left to right. Alternative sequences may have to be agreed for products that have different shape characteristics from those described, but 22 drops should be carried out in all cases:

For rectangular containers

Face	Edges	Corners
1 (Top)	1-2 (Front top)	1-2-5 (Front top left)
3 (Bottom)	1-4 (Back top)	1-2-6 (Front top right)
2 (Front)	1-5 (Left side top)	1-4-5 (Back top left)
4 (Back)	1-6 (Right side top)	1-4-6 (Back top right)
5 (Left side)	2-3 (Front bottom)	2-3-5 (Front bottom left)
6 (Right side)	3-4 (Back bottom)	2-3-6 (Front bottom right)
	3-5 (Left side bottom)	3-4-5 (Back bottom left)
	3-6 (Right side bottom)	3-4-6 (Back bottom right)

⁵ Position the load on the coolant-pack so that the major axis of the load is at right angles to, and centred on, the major axis of the coolant-pack. For cylindrical coolant-packs it may be more convenient to use a single 160 kg load uniformly distributed between a pair of cylinders laid side by side.

⁶ Notwithstanding ASTM standard D5276, clause 6.2, only one sample will be drop tested.

For cylindrical or octagonal containers

Face	Edges (chimes)	Edges (chimes)
1-3-5-7 (Top)	1 (Front top)	1-7 (Midpoint)
2-4-6-8 (Bottom)	5 (Back top)	3-5 (Midpoint)
1-2 (Front)	3 (Left side top)	1-3 (Midpoint)
5-6 (Back)	7 (Right side top)	7-5 (Midpoint)
3-4 (Left side)	2 (Front bottom)	2-8 (Midpoint)
7-8 (Right side)	6 (Back bottom)	4-6 (Midpoint)
	4 (Left side bottom)	2-4 (Midpoint)
	8 (Right side bottom)	6-8 (Midpoint)

Stop the test after the final drop or when part of the load falls out, whichever is the sooner. If the load falls out prematurely due to failure of the hinges and/or catches, terminate the test. After each drop note any damage that has occurred. Assess the overall damage at the end of the test according to the following ratings:

Rating	Damage to casing	Rating	Damage to fittings
1	Heavy damage or lid pulled off	1	Hinges and/or catches and/or handles broken
2	Easily repairable damage	2	Hinges and/or catches become undone and/or handles distorted.
3	Superficial damage	3	Hinges, catches and handles function correctly.
4	Slightly marked		
5	Unmarked		

Report all damage to the container and the incidence of broken vials and/or ampoules (if any).

- **Acceptance criteria:** At the end of the test sequence there must be no damage that affects the performance of the container and the container lid or door must still close and latch correctly. Superficial and repairable damage to the container casing and damage to dummy vials or ampoules (if used) is acceptable.
- **Rejection criteria:** Damage to the lid or door which prevents closure, and/or cracks, other damage to the container casing which exposes the thermal insulation to moisture ingress, and/or damage to primary container cassette(s) or other load holding devices where these form part of the container assembly.

5.2.8 Test 5: Random vibration – cold box (Type 2 only)

Sample: Sample 1.

Test conditions: As Test 4.

- **Step 1:** Prepare a dummy vaccine load as described in Test 4, Step 1.
- **Step 2:** Prepare and load the set of **coolant-packs** as described in Test 4, Step 2.
- **Step 3:** Carry out ASTM D4169-09: Schedule F Loose Load Vibration to Assurance Level 1, Acceptance Criterion 3, Distribution Cycle DC3 utilizing test method ASTM D999-08 Test Method B - Repetitive Shock Test (Rotary Motion). Report the incidence of broken vials and/or broken ampoules (if any).

- **Acceptance criteria:** At the end of the test sequence there must be no damage to any vials or ampoules and no damage to the container that affects the performance of the container. The container lid or door must still close and latch correctly. Superficial and repairable damage to the container casing is acceptable.

Rejection criteria: Damage to any vial or ampoule or damage to the lid or door which prevents closure, and/or cracks or other damage to the container casing which exposes the thermal insulation to moisture ingress.

5.2.9 Test 6: Cold life tests (+32°C or +43°C)

Sample: Sample 2.

Test conditions: Stabilize the test chamber at +25.0°C (±0.5°C), at a relative humidity of 65% (+/-10%). Condition the sample in the test chamber for 24 hours with the door or lid open. Record conditions at the time of the test.

- **Step 1:** Prepare and load the set of **coolant-packs** as described in Test 4, Step 2. Close the door or lid of the container and record temperatures every minute until the **vaccine storage compartment** temperature has stabilized and for at least 24 hours. During this period record the total hours to cool the **vaccine storage compartment** to achieve stabilized internal temperatures within the required temperature range (greater than 0.0°C and less than or equal to +8.0°C). No standard is set for the cool-down time but the period will be reported. Halt the test if the temperature does not stabilize within the period specified by the manufacturer, plus six hours, or if the **vaccine storage compartment** fails to stabilize within the required temperature range. If Step 1 is completed successfully proceed immediately to Steps 2A and 2B.
- **Step 2A:** Assemble a dummy vaccine load comprising water-filled individual vials and ampoules per Annex 3 specification. Stabilize the load in a cold room or refrigerator at +5.0°C (±0.5°C) at a relative ambient humidity of 65% (+/-10%) for a minimum of 24 hours. Place sensors per Annex 1 and in consideration of the requirements to regularly remove vials per the vaccine vial removal schedule shown below.
- **Step 2B:** Prepare a second set of **coolant-packs** as described in Test 4, Step 2. Remove the set of **coolant-packs** used in Step 1 and place the newly frozen **coolant-packs** in the container in accordance with the manufacturer's instructions. Place the +5°C load in the **vaccine storage compartment** together with the Annex 2 temperature sensors laid out as shown in the Annex 1 diagram. Ensure that the sensors do not touch the adjacent **coolant-packs**. Close the door or lid of the container and commence the cold life test period.
- **Step 3A:** Over a three-hour period raise the temperature of the test chamber to T: +32.0°C, H: +43.0°C. Then, over a three-hour period, reduce the temperature of the test chamber to T: +15.0°C, H: +25.0°C. Hold this temperature for nine hours. Raise the temperature to T: +32.0°C or H: +43.0°C, over a three-hour period. Hold at T: +32.0°C or H: +43.0°C for a further nine hours. Repeat this 24 hour cycle (three hour + nine hour + three hour + nine hour) as described in Step 4. Record the vaccine load temperature every minute.
- **Step 3B:** To simulate immunization sessions, dummy vaccine vials will be removed from the cold box on a regular basis so that a reserve vaccine stock of 25% remains at the end of the first five days of testing. Removal of vaccine will take place every day for five days at the rate of 15% per removal (15% of total vaccine volume removed per day x five days per week = 75% removed) in

accordance with the **Vaccine vial volume removal schedule** below. The container lid must remain open for five minutes per day at the time of vial removal. The total daily volume of vaccine will be removed at one time and at the beginning of the hottest nine hour period per day. At the time of each vial removal session, one of the vials that has been removed must be replaced with a vaccine vial temperature sensor (including thermal mass component) that has been pre-conditioned at +5.0°C (±0.5°C). The vaccine vial with temperature sensor will be positioned in accordance with the manufacturer’s instructions for conserving open vials while in use. This vaccine vial temperature sensor must remain within the temperature range of 0.0°C to +10.0°C for a 6 hour period immediately following the start of the removal schedule. The vaccine vial sensor is specified in Annex 2.

Vaccine vial volume removal schedule

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
0%	0%	-15%	-15%	-15%	-15%	-15%
Day 8	Day 9	Day 10	(Day 11)	(Day 12)	(Day 13)	(Day 14)
0%	0%	-15%	(-10%) ⁷	(0%)	(0%)	(0%)

- **Step 4:** Repeat the temperature cycle described in Step 3A and the vial removal cycle described in Step 3B until the first **vaccine storage compartment** temperature sensor first reaches +10°C. If the cold life exceeds ten days continue Step 3A and Step 3B until a temperature sensor first reaches +10.0°C and/or no more vaccine remains in the **vaccine storage compartment**⁸. Record the temperature of the coldest point in the load at the time when the test ends. Report the lowest temperatures reached during the test and the time when the **vaccine storage compartment** sensor first reaches +10.0°C. The **cold-life** is defined as the time interval from the moment when the door or lid of the container is closed until the temperature of the warmest point in the **vaccine storage compartment** first reaches +10.0°C.
- **Acceptance criterion:** The cold-life must be a minimum of ten complete days from the start of Step 3A⁹, and no vaccine vial temperature sensor or **vaccine storage compartment** temperature sensor can reach 0.0°C. **Cold life** period will be published for +43°C and/or +32°C.
- **Rejection criteria:** Failure to achieve the minimum **cold life**, temperature recorded by any vaccine vial temperature sensor or **vaccine storage compartment** temperature sensor reaches 0.0°C or temperature of any vaccine vial sensor exceeds +10.0°C during the 6 hour period after vial removal.

5.2.10 *Test 7: Minimum rated ambient temperature test*

Sample: Sample 2

- **Test conditions:** Test chamber at +15.0°C (±0.5°C), or at a lower temperature specified by the manufacturer, and at a relative humidity of 65% (+/- 10%). Condition the sample in the test chamber for 24 hours with the door or lid open. Record conditions at the time of the test.

⁷ Post ten day withdrawals, if made, should be 10% on day 11 with no opening on day 12, or on any subsequent days.

⁸ Alternatively, the manufacturer may elect to end the test at the beginning of the 11th day.

⁹ Because of the initial three hour period in Step 3A, the final high temperature cycle on the last day will be six hours, not nine hours.

- **Step 1:** Pre-cool¹⁰ and load the appliance as described in Test 6 Steps 1, 2A and 2B.
- **Step 2:** Record temperatures every minute for ten days or until any sensor in the [vaccine storage compartment](#) reaches 0.0°C.
- **Step 3:** Report the lowest [vaccine storage compartment](#) temperature reached during the test, the time when the first [vaccine storage compartment](#) sensor reaches 0.0°C and the corresponding test chamber temperature.
- **Acceptance criteria:** Record the lowest test chamber temperature at which all vaccine load temperature sensors remains above 0.0°C throughout the test period. This temperature, rounded up to the nearest multiple of 5°C, is the [minimum rated ambient temperature](#) for the appliance and will be reported as the minimum recommended ambient temperature for the appliance and will be printed in the blue sector of the temperature zone symbol (see specification Annex 1).
- **Rejection criterion:** Failure to pass the test at +15°C.

5.2.11 Test 8: Cold climate freeze protection test

Sample: Sample 2.

Test conditions: Test chambers at -20.0°C (±0.5°C) and +18.0°C (±0.5°C) and at a relative humidity of 65% (+/- 10%). Record conditions at the time of the test.

- **Step 1:** Stabilize the container in the +18°C test chamber for a minimum of 24 hours, with the door or lid open.
- **Step 2:** Condition a dummy vaccine load as described in Test 6, Step 2A.
- **Step 3:** Stabilize the full set of [coolant-packs](#) at +8.0°C (±0.5°C) to create [cool-packs](#). If PCM-packs are used for this purpose, they must not be cooled to the point at which they change phase prior to placing them in the container. Place the [cool-packs](#) in the container in accordance with the manufacturer's instructions. Place the conditioned load in the [vaccine storage compartment](#) together with the Annex 2 temperature sensors laid out as shown in the Annex 1 diagram. Ensure that the sensors do not touch the adjacent [cool-packs](#). Close the door or lid of the container.
- **Step 4:** Place the loaded container in the -20°C test chamber.
- **Step 5:** Monitor temperatures at one minute intervals until the temperature of the coldest point in the vaccine load first reaches 0.0°C. Record the temperature of the coldest point in the load at the time when the test ends. The [cold climate freeze protection life](#) is defined as the time interval from the moment when the door or lid of the container is closed until the temperature of the coldest point in the load first reaches 0.0°C.
- **Acceptance criterion:** No standard set, but results will be published.
- **Rejection criteria:** None.

5.2.12 Test 9: IP rating test to IEC 60529 (Type 2 only)

Sample: Use sample 2 if IP testing is required.

- **Step 1:** Obtain an independent test report from the manufacturer showing full conformity with IEC 60529: IP55. Only if this is not available then proceed with Step 2.
- **Step 2:** Carry out an IP55 test on a single sample. Record results.
- **Acceptance criterion:** IP55 test passed.
- **Rejection criterion:** IP55 test failed.

¹⁰ The pre-cooling step may be shortened if Test 7 immediately follows Test 6.

5.3 Test criteria for qualification:

A final report must be issued after all testing is complete. The report of the tests must contain the following data and analyses:

- **Summary:** Conclusions and recommendations.
- **Test 1:** Provide general comments on the samples received including comments on the overall standard of construction, tabulated results of the type inspection and photographs of samples.
- **Test 2:** Results of dimensions, weights and [vaccine storage capacity](#) test.
- **Test 3A-D:** Results of [coolant-pack](#) physical tests.
- **Test 4:** Results of **Type 2** container drop test.
- **Test 5:** Results of **Type 2** container vibration test.
- **Test 6:** Results of [cold life](#) test(s) including temperature graphs.
- **Test 7:** Results of [minimum rated ambient temperature](#) test, including temperature graphs.
- **Test 8:** Results of [low ambient temperature protection](#) test, including temperature graphs.
- **Test 9:** Results of **Type 2** container IP rating test, or commentary on the independent test report submitted by the container manufacturer.
- **Annexes:** A pre-approved test protocol verifying that the procedures set out in this document have been followed. Description of the test apparatus. Test chamber temperature records. Copy of reference thermometer calibration certificate(s). Thermocouple pre-test and post-test calibration records. Diagrams showing the location and identification codes for temperature sensors, clearly distinguishing between sensors. Additional supporting documentation requested and received from the [legal manufacturer](#) or [reseller](#) during the course of the type-testing.

6. **Quality control checklist**

6.1 Quality control standards

All testing and reporting must be carried out in accordance with the requirements of ISO 17025.

6.2 Quality control checklist

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

6.3 Quality control evaluation

Not required.

7. **Pre-qualification evaluation**

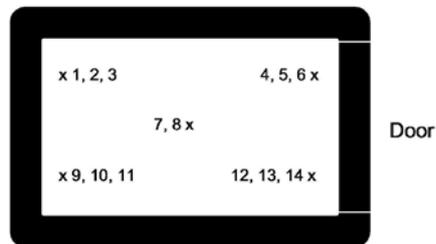
A product will qualify for inclusion on the register of PQS pre-qualified vaccine cold boxes in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E004/CB03.1**.

8. **Modified products**

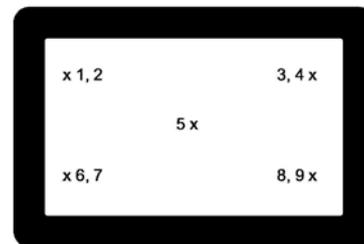
The [legal manufacturer](#) or [reseller](#) must notify WHO **in writing** of any changes in form, fit or function which may affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the test procedures described in this document.

Annex 1 – Temperature sensor positions Rectangular and square cold boxes

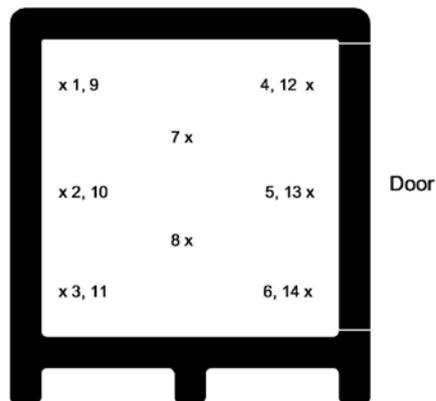
Front opening container: top view



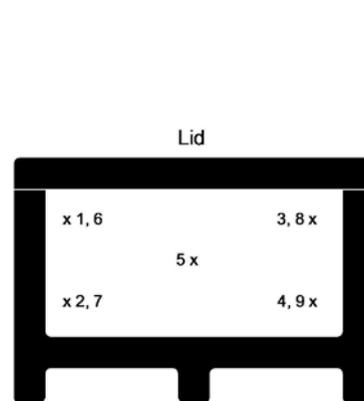
Top opening container: top view



Front opening container: side view

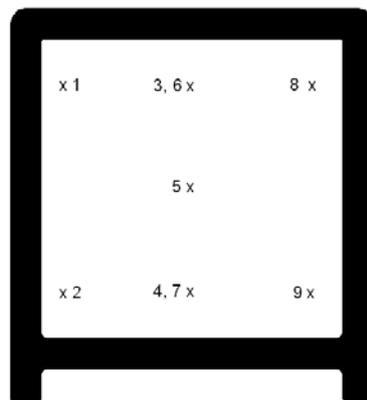


Top opening container: side view

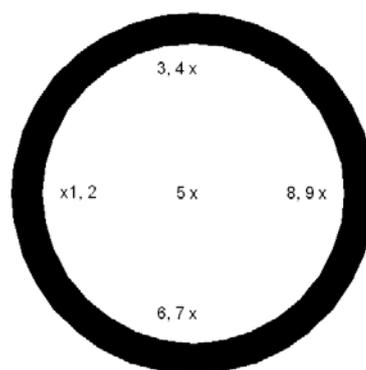


Cylindrical cold boxes

Cylindrical container: side view



Cylindrical container: top view



Notes:

1. Top opening sensor configuration applies to units not exceeding 600mm internal depth. Use the front opening configuration for deeper units.

2. Front opening containers may have intermediate shelves containing [coolant](#). For this configuration, sensor number and location may need to be adjusted in a manner to be agreed between the laboratory and the container manufacturer before tests commence.
3. All measuring points, with the exception of the centre one, must be 25-30 mm from the nearest the [coolant-packs](#). Ensure that this is achieved using suitable fixing devices attached to the dummy load. Ensure that the load cannot rotate, or otherwise become displaced once the sensors are in place.
4. Sensor leads can be introduced into the container using one of two methods: through the door or lid seal, taking care not to affect the quality of the seal or through a hole in the geometric centre of the door or lid, taking care to seal the outer and inner entries adequately.
5. Test 4 requires regular removal of vials and ampoules. Place sensors to allow for regular removal of vials and ampoules.

Annex 2 – Temperature sensor specification

Sensors must comply with IEC 62552, clause 8.7.1. Probe, accurate to $\pm 0.1^{\circ}\text{C}$, inserted into brass or tin-covered copper mass of 25 g ($\pm 5\%$) and of minimum external area (diameter = height = about 15.2 mm)

Annex 3 - Vial and ampoule specification for test

All cold boxes will be tested with a sample of vaccine vials and ampoules. This sample is intended to represent the range of [primary containers](#) that users may insert into the [vaccine storage compartment](#).

If the [vaccine storage compartment](#) is designed to accommodate [secondary cartons](#), then the primary containers must be placed in suitable [secondary cartons](#). These should be sample cartons obtained from the vaccine manufacturer who supplies the sample vials or ampoules. The vials and ampoules must be prefilled with water for all tests. The quantity of water used should be arranged so as to give a consistent mean density for the components of the load, measured when packed in [secondary cartons](#), of 0.5 kg/litre¹¹. Prefilled injections devices are not included in these tests.

Verification protocol tests requiring this sample of vials and ampoules include:

Test 2:	Dimensions, weight and vaccine storage capacity
Test 4:	Cold box drop test (Type 2)
Test 5:	Cold box random vibration test (Type 2)
Test 6	Cold life test
Test 7:	Minimum rated ambient temperature test
Test 8:	Low ambient temperature protection test

¹¹ 0.5 kg/litre is the 50th percentile density of the mix of vaccines procured by UNICEF in 2011, measured in secondary cartons. Where the [storage compartment](#) is designed to hold individual primary containers, the load density must be established by using [secondary carton](#) volume as the denominator.

For every 10 packages use a sample that includes the tallest, the widest and the most common diameter [primary containers](#) as specified below:

Tallest: Quantity two (2) ampoules 1.07 x 9.25 cm (diameter x height $\pm 5\%$)
Widest: Quantity two (2) vials 3.0 x 7.4 cm (diameter x height $\pm 5\%$)
Common: Quantity six (6) vials 1.7 x 5.3 cm (diameter x height $\pm 5\%$)

Revision history:			
Date	Change summary	Reason for change	Approved
25.09.2018	Clause 3 (Terms and definitions) PCM definition edited.	Reflect change to allowance of water-based and PCM-based buffers	I. Gobina
25.09.2018	Bullet on PCM conformity with relevant product specification and compliance with PCM materials specification added to Clause 5.2.1 (Type examination)	Reflects change to allowance of PCM-based buffer materials as per product specification.	I. Gobina