PQS Combined performance specification and independent type-testing protocol

WHO/PQS/E004/CB06.1
Original: English
Distribution: General

TITLE: Vaccine cold box – Ultra-low temperature storage (provisional)

Specification reference:	E004/CB06.1
Product verification protocol:	N/A – this is combined for provisional use
Issue date:	20 January 2021
Date of previous revision:	New specification and protocol

Contents

1. Scope

Some Ebola and early production and trial vaccines against COVID-19 are likely to require ultra-low temperature (ULT) storage, unless the vaccine temperature stability is further defined or improved. Storage and transportation equipment, especially passive (unpowered) equipment, is needed but limited equipment has been developed and tested extensively. Under the assumption that new equipment specifically designed for ULT use will not be developed quickly enough, this verification protocol for modified use establishes a process to verify provisionally that currently manufactured equipment is fit for this new purpose. The legal manufacturer shall specify the nominal ULT the equipment is designed to achieve between -25°C and -80°C PQS may, at a later date, revisit this document and establish a new, non-provisional category for this ULT equipment.

Since this verification protocol is limited to confirming performance fit to modified ULT use, all equipment verified by this protocol shall be WHO-PQS prequalified in one of the following categories: **WHO-PQS E004**, **CB01**, **CB02**, **CB03**, or **CB04**. This excludes **WHO-PQS E004**, **CB05** because freeze-prevention is not relevant for vaccines that require storage below freezing, at ULT. If there is equipment that could be used for this purpose but is not already PQS prequalified, it will need be prequalified using the most applicable cold box specification and verification protocol in addition to the requirements in this document. If this is the case, testing to both protocols and submission to PQS for review, prequalification and approval for provisional ULT use can be done at the same time.

2. Terms and definitions

Cooling medium: The material used to cool a passive device to the target temperature. In the case of materials like water or PCM that may be used repeatedly, this includes the container.
Nominal ULT: A single temperature below which the equipment is able to maintain the vaccine storage compartment, designated as a multiple of 5, between -25°C and -80°C (inclusive).
ULT cold life: The empty equipment is stabilized at +43°C and loaded with the specified amount and type of cooling medium. ULT cold life is measured from the moment when the equipment lid is closed until the temperature of the warmest point in the vaccine storage compartment warms to the designated nominal ULT after initially cooling to below the nominal ULT, at a constant ambient temperature of +43°C.
In writing: 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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.
Montreal Protocol: Montreal Protocol and Kigali Amendments 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.
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.
ULT vaccine storage capacity: The total volume available for storing vaccine in the equipment when prepared for use at the nominal ULT.
Vaccine storage compartment: The zone within an insulated piece of equipment which is designated by the legal manufacturer as suitable for storing vaccine when the equipment is loaded with the necessary amount of cooling medium to achieve the ULT cold life specified in this document.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying with specification **PQS/E005/IP01**.

3. Normative references

Use the most recent version.

EMAS: European Union Eco-Management and Audit Scheme.
IEC 62552: 2013: Household refrigerating appliances – Characteristics and test methods.
ISO 9001: Quality Management Systems – Requirements.
ISO 14001: 2004: Environmental management systems - Requirements with guidance for use.
ISO/IEC 17025: 2005: General requirements for the competence of testing and calibration laboratories.
WHO/PQS/E004/CB01.3: Performance Specification: Vaccine cold box.
WHO/PQS/E004/CB02.1: Performance Specification: Large capacity vaccine cold box.
WHO/PQS/E004/CB03.1: Performance Specification: Vaccine cold box – long-term storage - 35 days.
WHO/PQS/E004/CB04.1: Performance Specification: Vaccine cold box – long-term storage - 10 days.
WHO/PQS/E004/CB05.3: Performance Specification: Vaccine cold box with freeze-prevention technology.
WHO/PQS/E004/CB01-VP.3: PQS Independent type-testing protocol: Vaccine cold box.
WHO/PQS/E005/IP01.3: Performance Specification: Water-packs for use as icepacks, cool-packs and warm-packs.
WHO/PQS/E005/PCMC02.1: Performance Specification. [Currently being drafted at the time of this publication]
WHO/PQS/E005/PCMC02-VP.1: PQS Independent type-testing protocol. [Currently being drafted at the time of this publication]

4. Applicability

Testing should be carried out by an independent **ISO/IEC 17025** and PQS-accredited testing laboratory. However, at the time of publication, fully documented testing carried out by the legal manufacturer or another entity selected by the legal manufacturer may receive provisional approval by WHO.

An additional Product Dossier shall be submitted to WHO for modified ULT use of the equipment.

Minor “retrofitting” of the equipment as previously prequalified is allowable in order to constrain or position the ULT cooling medium. If any retrofitting or additional components are required for ULT use, these shall be made separately procurable for any entities that might want to purchase them in order to use previously procured equipment at ULT.

The equipment can be targeted to achieve a specified internal temperature dependent on the intended vaccine storage requirements. Manufacturers may offer variations using different cooling media that achieve different internal temperatures. The nominal ULT shall be specified between -25°C and -80°C as a multiple of 5 in the dossier submitted to WHO PQS. The equipment will be tested and approved for provisional use based on this temperature designation. As of the publication of this document, it is recommended that manufacturers target -70°C as a lowest- or worst-case temperature under the assumption that more heat stable vaccines could also be stored and transported in the same equipment.

The following are additional or modified requirements specific to modified use of the equipment at ULT.

4.1 Additional user instructions

The legal manufacturer shall supply detailed, separate, modified user instructions that are clearly and explicitly for use of the equipment at ULT. These instructions shall be available and submitted in French and English (as a minimum) at the time of Product Dossier submission to WHO. Furthermore, at the time of procurement, instructions shall be provided in the UN language (Arabic, English, French, Mandarin Chinese, Russian, or Spanish, or other language by special order) most appropriate to the country of use.

In addition to the original, general equipment instructions for use at non-freezing temperatures, these modified user instructions for use at ULT shall include, but are not limited to the following supplemental information:

1. Detailed and clear description of the cooling medium required for use at ULT:
    a. If the cooling medium is reusable, (e.g. permanently sealed Phase Change Material (PCM) containers), specification of the chemical components and inclusion of Safety Data Sheets (SDS), and separate, detailed description of proper spill, clean-up and disposal procedures for the cooling medium. Additionally, clear instructions on procurement of the reusable cooling medium whether directly from the legal manufacturer or another entity.
    b. If consumable (e.g. dry ice), a clear description of the cooling medium specifying the type, form and any other details necessary for sourcing and procurement.

2. Handling and safety precautions specific to the cooling medium:
    a. The legal manufacturer shall include recommended handling and safety instructions, including PPE requirements, specific to the equipment and cooling medium.
3. Clear description of the loading procedure for both the cooling medium and vaccine. These shall include:
    a. A clear and descriptive graphical version of the loading procedure in addition to text,
    b. Direction on limiting the frequency and duration of opening the equipment,
    c. Instructions for how to load vaccines if the equipment is only partially or minimally filled.
4. Explicit description of the freezing, storage and additional equipment necessary to freeze the cooling medium and otherwise facilitate use of the equipment at ULT.
    a. Specifically, if reusable cooling medium containers are used, the instructions shall indicate the required performance capabilities of ULT freezers needed to freeze the cooling medium. This shall also include clear instructions on how to freeze or otherwise prepare the cooling medium for use.
5. Explanation of any additional precautions or handling instructions to protect the equipment from damage or failure during use at ULT.
6. Explicit instruction if there is any retrofitting or additional components necessary in order to use the ULT cooling medium and equipment at ULT.
    a. If the necessary cooling medium is consumable (i.e. turns to gas during use as in the case of dry ice), there shall be a means for the gas to vent to avoid any chance of extremely elevated pressures inside the equipment.

4.2 Allowable and required deviations for ULT use

If reusable and removable containers are used for the cooling medium (e.g. PCM), the containers shall comply with **PQS/E005/PCMC02.1** and the related verification protocol **PQS/E005/PCMC02-VP.1**.[1]

Any and all requirements placed on water-packs in the applicable cold box specifications for the equipment are not applicable for this provisional modified use. Specifically, water-packs compliant with **PQS/E005/IP01** are normally required. If reusable cooling medium is required for ULT use, two complete sets shall be provided with the equipment and they shall be obviously, visibly differentiated from PQS-prequalified water-packs, shall be permanently-sealed and otherwise comply with **PQS/E005/PCMC02.1** and the related verification protocol **PQS/E005/PCMC02-VP.1**.[1]

The labels normally required on the inside of the door or lid of the equipment illustrating vaccine storage advice and load restraint instructions shall be

[1] These two documents are currently being drafted at the time of this publication, but are pre-referenced due to the need for expedition

modified to be relevant for the use at ULT and use of the applicable ULT cooling medium. On the inside of the door or lid, the modified instructions shall include ULT cooling medium and vaccine loading instructions. If reusable cooling medium is required, these instructions should refer to the size and labelling of the cooling medium containers, clearly indicating that the specific cooling medium must be used. These instructions should be predominately graphic/visual. This label shall be in the UN language most appropriate to the country of use (Arabic, English, French, Mandarin Chinese, Russian, or Spanish, or other language, by special order). In the case that procuring entities are intending to use previously-procured equipment, these instruction labels shall be made separately procurable for any entities that might want to purchase them in order to use the equipment at ULT.

Since the equipment needs to be visually distinguishable to avoid risks of confusion with standard equipment and possible injury, the legal manufacturer should provide a distinguishing label that can be applied to the outside of the equipment to distinguish it for ULT use. This label should be supplied with new equipment and also separately procurable with the instructions label noted above. It is recommended that this include a generic cold hazard sign (as shown below) and may contain other information such as the nominal ULT.

Any additional deviations or modifications required by the legal manufacturer shall be cleared with WHO prior to submission.

4.3 Material compatibility with ULT

The legal manufacturer shall submit, in their Product Dossier, an itemized list of all materials and components comprising the equipment. For each separate material or component, the legal manufacturer shall confirm either that the minimum operating temperature is below the nominal ULT, or provide detailed justification and preferably documented testing outcomes showing that continuous service or use at the nominal ULT in its specific location and application in the equipment presents limited risk of failure. Note that high impact polystyrene (HIPS), Acrylonitrile butadiene styrene (ABS), polyvinyl chloride (PVC) and polypropylene all have relatively high minimum operating temperatures compared to ULTs. Detailed justification of their acceptability for use in equipment at ULTs shall be provided (e.g. these components are strictly external and will not be subject to ULTs, etc.).

4.4 Procurement of cooling medium & additional components

The legal manufacturer shall provide in their Product Dossier, a detailed assessment and explanation of how they intend or expect the cooling medium to

be procured for use in the equipment. If a reusable cooling medium is necessary (e.g. PCM filled containers) or any retrofitting components, the legal manufacturer shall provide details on procurement. If consumable cooling medium use is necessary (e.g. liquid nitrogen, dry ice), the legal manufacturer should consider the likelihood that it can be procured continually in countries in which the legal manufacturer has typically sold products. If available, the legal manufacturer is encouraged to provide, in their Product Dossier and to procurement agencies, any evidence in the form of a narrative justification including a description of any confirmatory research carried out to confirm that procurement of the cooling medium is realistic.

4.5 Product Dossier

The Product Dossier submitted to WHO PQS by the legal manufacturer or reseller for provisional approval of use at ULT shall contain the following:

1. Dossier examination fee in US dollars.
2. General information about the legal manufacturer, including name and address.
3. Unique identification reference for the product type.
4. Brand name of the product.
5. Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
6. A set of digital photographs showing the unit with the lid closed, with the lid fully opened, and a top view of the interior with the applicable cooling medium in place.
7. Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
8. Certified photocopies of the legal manufacturer's **ISO 9001** quality system certification.
9. Where available, certified photocopies of the legal manufacturer's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to legal manufacturers who are able to demonstrate compliance with good environmental practice.
10. Laboratory test report(s) proving conformity with PQS specifications as specified in Section 5.3 below.
11. Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2010).
12. Designation of the nominal ULT for the equipment.
13. User instructions as specified in Section 4.1 above.
14. Cooling medium explanation as specified in Section 4.1 above.
15. Material compatibility justification and information as detailed in Section 4.3 above.
16. Procurement information as detailed in Section 4.4 above.

5. Type-testing procedure

5.1 Number of samples

Two samples of the product shall be tested, together with re-usable cooling medium as applicable.

5.2 Test procedure

5.2.1 Test 1: Revised, ULT vaccine storage capacity

Test conditions: Testing room at +21°C (±3°C). Record conditions at the time of the test.

- **Step 1:** Record maximum external dimensions in centimetres (length, width and height, with handles folded, (± 0.5 cm)).
- **Step 2:** Place the cooling medium in the equipment in accordance with the legal manufacturer's instructions. Record the minimum overall dimensions of the vaccine storage compartment. Where cooling medium faces define the vaccine storage area, this is measured between straight edges placed over any bulging faces of the cooling medium containers (length, width and height, measured up to the legal manufacturer's designated load line, (± 0.5 cm)). Where there is an inner liner separating the load from the cooling medium, take measurements between the faces of the lining. Multiply length, width and height if rectangular (or horizontal cross-sectional area and height) together to obtain the nominal ULT vaccine storage capacity in litres.[2, 3]

Acceptance criteria: The measured ULT vaccine storage capacity shall not be less than five litres.

5.2.2 Test 2: ULT Cold Life Test

Sample: Samples 1 and 2.

Test conditions: Test chamber at +43.0°C (±1°C).

- **Step 1:** Pre-assemble a dummy vaccine load comprising containers partially filled with water so that the vaccine storage compartment contains a total of 0.4 kg of water per litre of the measured ULT vaccine storage capacity. Ignore the mass of the load containers in this calculation. To allow flexibility for the size and shape of the vaccine storage areas of different equipment, specific load containers are not required, however it is recommended that water-packs compliant with **PQS/E005/IP01** be used or other, similar polymer

[2] Where the equipment requires a layer of cooling medium containers positioned above the load, the height measurement shall exclude the thickness of this layer.

[3] If the inside faces of the equipment are not at 90° to the equipment floor, the vaccine storage capacity is established by multiplying the minimum length and width by the vertical height.

containers able to withstand the nominal ULT. Fill the water-filled load containers to approximately 75% of their volume capacity to allow for expansion. If possible, the load should be arranged so that it substantially fills the vaccine storage compartment, leaving voids for the sensor positions shown in **Annex 1**. However, if the load does not fill the vaccine storage compartment completely, refer to the equipment instructions to confirm how the cooling medium should be configured and placed for the testing.

- **Step 2:** Stabilize the sample to be tested in the +43°C test chamber for a minimum of 24 hours, with the lid open.
- **Step 3:** Condition the load at the nominal ULT for minimum of 24 hours.
- **Step 4:** Fully freeze or otherwise assemble or prepare the cooling medium as described in the provided equipment instructions.
- **Step 5:** Place the prepared cooling medium and conditioned load in the vaccine storage compartment in accordance with the equipment instructions along with the temperature sensors as specified in **Annex 1.**
- **Step 6:** Monitor temperatures at one-minute intervals at least until the temperature measured at any sensor warms to 0ºC or warmer after initially cooling to below the nominal ULT.
- **Step 7:** Repeat the test, Steps 1 through 6, then repeat the test twice for the second sample, for a total of four tests.
- **Analysis and calculations:** Using the recorded data for both samples and all four tests, calculate the ULT cold life in addition to the time to cool to 0°C, -20°C, and the nominal ULT. Also record the total test time to return or re-warm to -20°C and 0°C after initially cooling below those temperatures. Specifically calculate for each test:
    - The reported cool-down time as the elapsed time from the moment when the equipment lid is closed until the temperatures measured by all temperature sensors in the vaccine storage compartment first reach the nominal ULT or colder.
    - ULT cold life as the elapsed time from the moment when the equipment lid is closed until the temperature measured by any temperature sensor in the vaccine storage compartment warms back to the nominal ULT or warmer after initially cooling to the nominal ULT or colder.
    - The elapsed time from the moment when the equipment lid is closed until the temperatures measured by all temperature sensors in the vaccine storage compartment first reach 0°C or colder and -20°C or colder.
    - The elapsed time from the moment when the equipment lid is closed until the temperature measured by any temperature sensor in the vaccine storage compartment warms back to -20°C or warmer and 0°C or warmer after initially cooling below -20°C.

  Record and report all of these calculated durations and include for each one, reference to the location and number or identifier of the sensor at the location they occurred.

Acceptance criterion: The ULT cold life shall be a minimum of 48 hours for both samples and the shortest of the four calculated durations will be reported as the official ULT cold life. No requirement set on the other reported durations.

Rejection criteria: Either of the following:

- Failure to achieve the minimum ULT cold life.
- Any temperature is measured during this test lower than 20°C below the nominal ULT.

5.2.3 Test 3: Drop test - robustness & material compatibility with ULT use

NOTE: Drop testing is normally required of cold boxes using a free fall drop tester and dropping 26 times from a height of one meter **(**see **PQS/E004/CB01-VP.3 Test 3** for reference**)**. However, to expedite testing and availability of equipment for provisional use, this testing has been relaxed in the procedure below. If or when this document is revised, it is expected that the previous format of drop testing will again be required for this ULT equipment. As noted in Section 4.3, testing and detailed reporting verifying the robustness of the materials and equipment at ULT is also required.

Test conditions: Testing room at +21°C (±3°C). Record conditions at the time of the test.[4]

- **Step 1:** Assemble a dummy vaccine load as in Test 2, Step 1.
- **Step 2:** Stabilize the sample to be tested in the testing room for a minimum of 24 hours, with the lid open.
- **Step 3:** Condition the load at the nominal ULT for minimum of 24 hours.
- **Step 4:** Fully freeze or otherwise assemble or prepare the cooling medium as described in the provided equipment instructions.
- **Step 5:** Place the prepared cooling medium and conditioned load in the vaccine storage compartment in accordance with the equipment instructions.
- **Step 6:** Mark the faces of the sample and carry out a full freefall drop sequence consisting of seven drops from a height of one metre (measured from the lowest part of the equipment at the start of each test) onto a smooth dense concrete surface, without rupture hazard. The drops shall be onto the bottom, top, one side, two vertices and two edges for rectangular equipment (or seven similar drops for other geometries).
- **Step 7:** Drop test in accordance with **ASTM D5276**. However, for this expedited testing, if a freefall drop testing apparatus is not available, simplified testing without the apparatus may be acceptable by PQS with a detailed description of the testing procedure

[4] Notwithstanding ASTM standard D5276, Clause 6.2, only one sample will be drop tested.

documented in the test report. It is recommended to discuss the acceptability with PQS before carrying out this testing.

- **Step 8**: 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 obvious damage that has occurred.
- **Step 9:** Record all damage to the equipment. Additionally, document visible damage to the equipment with photographs.

Acceptance criteria: At the end of the test sequence there shall be no damage that significantly affects the performance of the equipment. The lid or door shall still close and latch correctly. Superficial and repairable damage to the equipment is acceptable, but should be reported.

Rejection criteria: If any of the following are true:

- There is damage to the lid or door that prevents closure.
- The door or lid opens during testing.
- There is damage that significantly affects the performance of the equipment.
- If PCM is used as the cooling medium, there are any obvious leaks, cracks, or fractures in the PCM containers.

5.2.4 PCM removable container ULT testing

If reusable containers are required for ULT use of the equipment they shall comply with **PQS/E005/PCMC02.1** and the related verification protocol **PQS/E005/PCMC02-VP.1**.[5] No additional, separate testing in the equipment besides that in this document is required at this time.

5.3 Test criteria for qualification

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

- **Summary:** Including but not limited to conclusions and recommendations and a brief description of the facilities and laboratory used for the testing.
- **Description of the testing entity:** If the testing entity is not the legal manufacturer, the test report shall include general information about the entity that carried out the testing, including name and address. Also include any relevant certifications such as ISO/IEC.
- **Test 1:** Results of the vaccine storage capacity test.
- **Test 2:** Results of cold life tests, including temperature graphs of each test showing temperature vs time for all temperature sensors. Include all calculated durations.
- **Test 3:** Results of equipment drop testing for robustness including detailed notes and images of any damage to the equipment or cooling medium containers.

[5] these two documents are currently being drafted at the time of this publication, but are pre-referenced due to the need for expedition

- **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. A record of any test deviations including documentation of any deviations approved by WHO PQS and/or the legal manufacturer.

6. Quality control checklist

6.1 Quality control standards

All testing and reporting should be carried out in accordance with the requirements of **ISO 17025:2017** or later edition.

6.2 Quality control checklist

An on-site inspection of the manufacturing plant may be required at the discretion of WHO PQS.

6.3 Quality control evaluation

Not required.

7. Evaluation of provisional approval for modified ULT use

A product will qualify for inclusion on a list of PQS prequalified vaccine cold boxes that are additionally approved for provisional use at ULT provided the required testing and submitted report and information indicate that the equipment meets the acceptance criteria and the additional requirements noted in Section 4 of this document.

8. Modified products

The legal manufacturer or reseller shall notify WHO in writing of any changes in form, fit or function which may affect the performance of the product prior to the distribution and sale of the modified 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 and otherwise.

9. Defect Reporting

The legal manufacturer or reseller shall advise WHO and the UN purchasing agencies in writing in the event of safety-related equipment recalls, component defects, and other similar events. This reporting should occur immediately upon the legal manufacturer receiving notification of the complaint or event and shall occur within 30 days. If requested to do so by WHO/UNICEF, the manufacturer shall submit a report to WHO/UNICEF stating the number of affected pieces of

equipment and the number of component repairs/replacements provided, together with copies of any associated reports.

Annex 1 – General test conditions

For tests carried out in a test chamber, temperatures should be controlled to ±1ºC and humidity kept within the range of 45% to 75% unless otherwise stated. The equipment should be positioned in the test chamber at least 50 mm clear of all chamber walls.

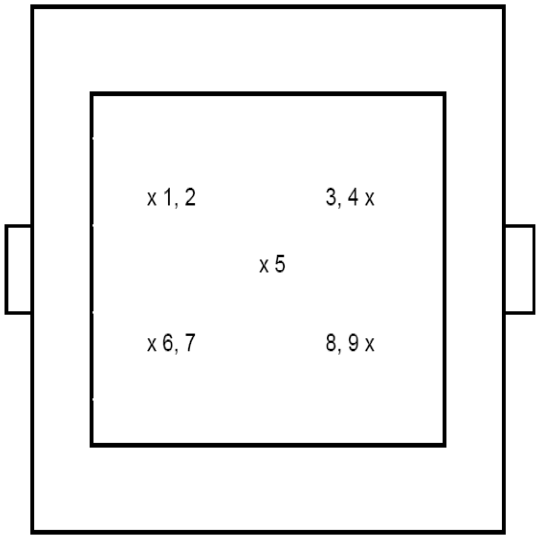
Temperatures within the equipment shall be continuously monitored with the presence of the sensors influencing the test as minimally as possible. Thermocouples that are sealed within the appliance are most commonly used. The suggested temperature sensor locations are shown in **Annex 2**.

Annex 2 – Temperature sensors and monitoring locations

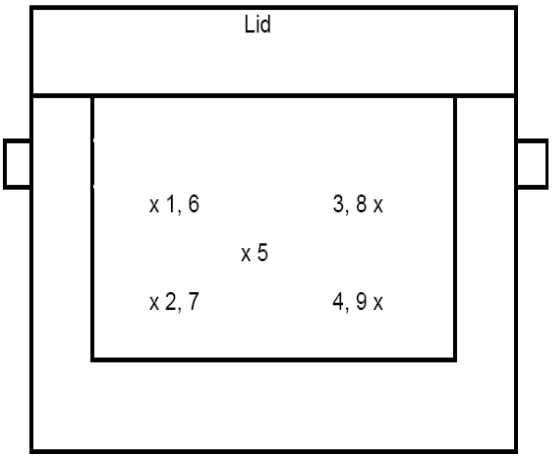
1. Temperature sensors shall comply with **IEC 62552**, Clause 8.7.1, namely inserted into brass or tin-covered copper mass of 25 g ± 5% and of minimum external surface area (diameter = height = about 15.2 mm). Sensor total uncertainty[6] shall be ±0.5°C or better.
    a. Verification of temperature accuracy shall be done both pre- and post-testing using a NIST traceable, calibrated dry-well or RTD, recorded, and reported as required in the annexes of the final report.
2. Sensor positions are indicated by the figures below for equipment with rectangular vaccine storage compartments. Testing of alternative vaccine storage area configurations shall include a total of nine sensors at indicative locations for all surfaces, edges and corners in the vaccine storage area as well as at other positions that are likely to experience extremes of temperature. Such positions might be near lid seals or areas where air circulation is restricted by the equipment design.
3. Except for centrally placed sensors, sensors should be within 25 mm of walls and corners of the vaccine storage area and should not be in direct contact with the dummy vaccine load.
4. Sensors may be fixed in position using thin rigid wire, tape or similar materials that will minimally affect the thermal performance and temperature measurements. Sensor leads can be introduced into the equipment using one of two methods: through the lid or door or through the door seal, taking care to affect the quality of the seal as little as possible or through a hole in the geometric centre of the lid or door, taking care to seal the outer and inner entries adequately.

[6]Total uncertainty being from the tip of the sensor to the readout or data-recording.

Cold box: top view



Cold box: side view



Revision history			
Date	**Change summary**	**Reason for change**	**Approved**