

Instructions

This template provides a generic format that laboratories that are certified for Performance, Quality and Safety (PQS) testing should use when sending test results to the World Health Organization (WHO). The template's primary purpose is to align how certified laboratories report to WHO so that reports are uniform and facilitate efficient review by the PQS Secretariat. WHO recognizes that the format for reporting will require some flexibility considering the different equipment categories and testing requirements. Laboratories are therefore authorized to make modifications to the provided template, as appropriate. This template can be accessed on the [WHO PQS website](#).

All deviations from the tests in the protocol must be approved by the PQS Secretariat in advance in writing; otherwise, the testing will be invalid.

- *Italic text provides instruction or notes to the author and should be deleted from the file after completion.*
- **Red text should be replaced with your values and changed to black.**
- Black (non-italic) text is a part of the form and can be left alone or updated as appropriate.

Page layout:

- Use A4 (210 x 297 mm) paper in portrait orientation.
- Left, right, top, and bottom margins should be 2.5 cm from the edge.

Word styles: As appropriate, use the following Word styles already configured in this file.

Style name	Typeface	Size	Attributes	Used for
Heading 1	Arial	18 point	Bold 21-point spacing before and 12-point spacing after	First-level headings
Heading 2	Arial	14 point	21-point spacing before and 12-point spacing after	Second-level headings
Heading 3	Georgia	11 point	Bold 18-point spacing before and 6-point spacing after	Third-level headings

Style name	Typeface	Size	Attributes	Used for
Body text	Georgia	11 point	0-point spacing before and 11-point spacing after	Body text

Figures: Figures help to illustrate statistical or temperature data and compare them. If you provide figures, please:

- Label figures in the order in which they appear in the text (e.g., Figure 1, Figure 2, Figure 3).
- Ensure each figure fits on a single A4 (210 x 297 mm) page in portrait orientation.
- Clearly label the axes of graphs and give the relevant units of measurement in parentheses.
- Explain or identify all parts.
- Ensure that all text is legible.
- Label multipanel figures as a, b, c, d, etc.
- Place the caption above the figure. The caption should be informative enough so that the reader can understand the figure without needing to refer to the narrative text.
- Explain any acronyms or abbreviations below the figure in a footnote, even if they previously are defined elsewhere.
- Ensure all lines, legends, colours, and curves are distinguishable from each other.
- Highlight important temperature bands (e.g., if excursions occur outside of 2°C to 8°C, highlight the 2°C to 8°C band).
- Indicate appliance pass/fail for each temperature data figure, as appropriate.
- Where appropriate, use standard International System of Units (SI)ⁱ with correct symbols.

Bulleted lists: Often, the protocol will ask for simple data, in which case we recommend using a bulleted list instead of a table. Avoid more than two levels of bullets or nested lists (i.e., lists within lists), as such document components can decrease readability and serve to confuse. If the list is more than one level, then we recommend using a table.

For example, the text below contains simple data and is appropriate for a bulleted list:

- **Code.** [State the unique identifier assigned by the testing laboratory]
- **Model.** [State the model number; e.g., E0221]
- **Appliance type.** [List the appliance type; e.g., vaccine refrigerator or combined unit]
- **Conformity assessment marking.** [Describe the conformity assessment marking]
- **Temperature zone rating.** [Describe the temperature zone rating]

ⁱ SI is the abbreviation for *Le Système International d'Unités* or the International System of Units.

Table description: *Prior to each table, briefly summarize the main findings.*

For example: The table below details the results of steps 1 and 2 of Test 1, as described in clause 5.3.1 of the PQS protocol WHO/PQS/XXXX-XX. Overall, the product failed Test 1, as testing revealed heavy defects during step 2. Defects included x, y, and z. However, as shown, the product passed all other steps of Test 1.

Tables:

- *Label tables in the order in which they appear in the text (e.g., Table 1, Table 2, Table 3).*
- *Ensure each table fits on A4 (210 x 297 mm) paper in portrait orientation. If a table spans more than a page, ensure that the header rows repeat. If more than three pages, please email PQS the file as an attachment (see Instructions section).*
- *Ensure that all text is legible.*
- *Place the caption above the table. The caption should be informative enough so that the reader can understand the table without needing to refer to the narrative text.*
- *Explain any acronyms or abbreviations below the table in a footnote, even if they previously are defined elsewhere.*
- *Ensure that any special shading or other visual differentiation of data is explained in a footnote.*

Submittal: Laboratories should submit their files by email to gobinai@who.int and copy pqsinfo@who.int. The maximum file size that WHO will accept is 10 MB. If your file(s) are larger than 10 MB, please email gobinai@who.int, and we will reply with submittal instructions. All attachments should have descriptive file names, and the main report should be in PDF format.

Rejected reports: Once completed, the report should be free of spelling mistakes, grammatical errors, punctuation errors, and inconsistencies. Reports will be rejected for review (until corrected) in cases where any one of the following conditions are detected:

- *Current verification protocol has not been applied.*
- *Current verification has been modified in any way.*
- *Documentation is incomplete.*
- *Excessive errors, inconsistencies, or omissions as determined by the PQS Secretariat.*

This section (Instructions) should be deleted in its entirety before submittal.

The results of [name of test and protocol number (e.g., vaccine carrier WHO/PQS/E004/VC01-VP.2)] test on the performance of [product manufacturer, name, type, country of manufacture]

Date submitted to the PQS Secretariat: [dd mmm yyyy]

Date of PQS protocol revision: [dd mmm yyyy]

Date testing was completed: [dd mmm yyyy]

Signature/test carried out by:

[Signature]

[Type your first name and last name]

[Signature]

[Type your first name and last name]

Report approved by:

[Signature]

[Type your first name and last name]

[Position in laboratory]

Contents

To automatically update the table of contents, select the text, press F9, and follow the instructions. Using this table of contents requires the use of Word’s built-in heading styles. More information can be found here (<https://support.office.com/en-us/article/format-or-customize-a-table-of-contents-9d85eb9c-0b55-4795-8abb-a49885b3a58d>).

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Abbreviations

Define any acronyms or abbreviations used in the text in the following abbreviations list, especially those that are not standard in the cold chain equipment field. The list should be in alphabetical order by abbreviation.

PQS	Performance, Quality and Safety (WHO)
WHO	World Health Organization

Summary

Briefly state the key objectives of the investigation, the overall results of the testing, and the name of the product(s) tested. Testing against the latest version of the correct protocol is the responsibility of the manufacturer/reseller, who should check with PQS if there is any doubt as to the correct protocol.

Test laboratory contact

- Lead contact name: [x]
- Organization: [x]
- Email address: [x]
- Full postal address: [x]
- Assistant contact name: [x]
- Assistant email address: [x]

Submitting entity

- Contact name: [x]
- Organization: [x]
- Email address: [x]
- Full postal address: [x]

Manufacturer

- Contact name: [x]
- Organization: [x]
- Email address: [x]
- Full postal address: [x]

Results

Preliminary data

A number of Performance, Quality and Safety (PQS) protocols require preliminary data (e.g., number of samples, evidence of conformity) before the description of the testing procedure. As appropriate, include a preliminary data section that details these data. If not needed, delete this section.

The actual result of a performance test must be recorded in this report. A simple conformance or nonconforming statement is not sufficient.

Results can be displayed graphically; this is in addition to the data being displayed in the text of the report. Such graphs must have clear and appropriate scales where important behaviour (e.g., temperature fluctuations) is maximised.

The table below contains preliminary data regarding [product xxx].

Table 1. Preliminary data.

Clause	Requirement description	Conformance	Result
[x]	<p>[Requirement name in bold. Description]</p> <p><i>For example:</i> Conformity assessment. The product must carry the CE mark, UL mark, and/or equivalent internationally accepted evidence of conformity assessment.</p>	[Yes, No]	<p>Add details and specifics as necessary.</p> <p><i>For example:</i> SuperFreeze ice-lined refrigerator provided a CE mark. See photo 5 in Annex 5 for details.</p>
[x]	<p>[Requirement name in bold. Description]</p> <p><i>For example:</i> Number of samples. The legal manufacturer or reseller supplied at least one sample.</p>	[Yes, No]	<p>Add details and specifics as necessary.</p> <p><i>For example:</i> SuperFreeze ice-lined refrigerator provided one sample as required by the test.</p>

CE: Conformité Européene.

Test 1. Name of test, date first started, date completed [e.g., Identification or performance characteristics, 26 March 2018, 27 March 2018]

Body text: For each section in the report, briefly describe what is contained in the section.

For example: This section details the results of step 4 (identification) of Test 1, as described in clause 5.3.1 of the PQS protocol WHO/PQS/XXXX-XX.

All tables should be numbered in the order in which they appear in the text and should have a brief explanation (caption) above the table so that the reader can easily interpret the data without needing to refer back to the protocol used for testing.

Table 2. Conformance results for PQS tests.

Step/clause number	Requirement description	Conformance	Result
[x]	[Name the test performed as listed in the protocol; for example, Stable running and continuous power consumption test]	[Yes, No]	Add details and specifics as necessary.
[x]	[Name the test performed]	[Yes, No]	Add details and specifics as necessary.
[x]	[Name the test performed]	[Yes, No]	Add details and specifics as necessary.
Overall	Did the product pass the test overall?	[Yes, No]	Add details and specifics as necessary.

PQS: Performance, Quality and Safety.

Table 3. When relevant.

Test parameter	Result
[Name the test performed as listed in the protocol; for example, Stable running and continuous power consumption test]	Add details and specifics as necessary.
[Name the test performed]	Add details and specifics as necessary.
[Name the test performed]	Add details and specifics as necessary.
Did the product pass the test overall?	Add details and specifics as necessary.

Figure 1. When relevant.

Test 2. Name of test, date first started, date completed
[e.g., Identification or performance characteristics, 26 March 2018, 27 March 2018]

Body text: For each section in the report, briefly describe what is contained in the section.

For example: This section details the results of step 4 (identification) of Test 1, as described in clause 5.3.1 of the PQS protocol WHO/PQS/XXXX-XX.

All tables should be numbered in the order in which they appear in the text and should have a brief explanation (caption) above the table so that the reader can easily interpret the data without needing to refer back to the protocol used for testing.

Table 4. Conformance results of PQS tests.

Step/clause number	Requirement description	Conformance	Result
[x]	[Name the test performed as listed in the protocol; for example, Stable running and continuous power consumption test]	[Yes, No]	Add details and specifics as necessary.
[x]	[Name the test performed]	[Yes, No]	Add details and specifics as necessary.
[x]	[Name the test performed]	[Yes, No]	Add details and specifics as necessary.
Overall	Did the product pass the test overall?	[Yes, No]	Add details and specifics as necessary.

PQS: Performance, Quality and Safety.

Table 5. When relevant.

Test parameter	Result
[Name the test performed as listed in the protocol; for example, Stable running and continuous power consumption test]	Add details and specifics as necessary.
[Name the test performed]	Add details and specifics as necessary.
[Name the test performed]	Add details and specifics as necessary.
Did the product pass the test overall?	Add details and specifics as necessary.

Figure 2. When relevant.

Test X. etc.

Conclusion

Report on whether the product passed or failed the tests as demonstrated by the results. Discuss the limitations of the testing, including possible sources of bias or error, and address how these problems affect generalizability. The conclusions should not go beyond the data and should be based on the results and products provided for testing.

Table X summarizes the conformance results of Tests X to X. More details are included in the Results section.

Table X. Conformance results of PQS tests.

Test no.	Name	Clause	Conformance
1	Type examination	X to X	[Yes, No]
2	Cool-down, initial stabilization, and power consumption	X	[Yes, No]
3	Stable running and continuous power consumption test	X	[Yes, No]

No: number; PQS: Performance, Quality and Safety.

Annex 1. Specification protocol

Attach a copy of the specification protocol used for testing.

Annex 2. Verification protocol

Attach a copy of the verification protocol used for testing.

Annex 3. Calibration and certification

For all equipment used to evaluate the test sample, please provide relevant proof of calibration and certification here. You must keep on file longer, more extensive documents (e.g., Excel spreadsheets) and retain them for at least 10 years.

The certificates should also state the uncertainty in the final recorded parameter (e.g., not the uncertainty in the thermocouple but in the temperature actually recorded; not the uncertainty in a linear measurement but in the calculated volume).

Annex 4. Temperature sensor identification number and location

The temperature sensor location should be labelled in accordance with the PQS type testing protocol numbering scheme for temperature sensors. Please include a drawing of the sensor location with a label.

Annex 5. High-resolution images of [xxx] product

Annex 5 contains high-resolution images of the [name] product.

If the product submitted for approval has a required component that is separate from the manufactured product (e.g., solar power system), provide sufficient photos of these.

As requested by the protocol, take photos of the product and include them in this report. In addition, send high-resolution images (no less than 300 dpi) as separate attachments to WHO PQS. When manufacturers submit their products for testing, they should include at least one photo that WHO can use in its materials with a statement that, “This photo is licensed under a [Creative Commons Attribution 4.0 International License](https://creativecommons.org/licenses/by/4.0/)” and an artist attribution.

Please read the file size limits denoted in the Instructions section.

For example:

Figure X. Top external view of the [name] product with the door open.

[insert image here]

Multipart photos should be lettered; for example:

Figure X. External views of the [name] product with the door closed: (a) top, (b) bottom, (c) left, (d) right, (e) front, (f) back.

[insert image here]

a

[insert image here]

b

[insert image here]

c

[insert image here]

d

[insert image here]

e

[insert image here]

f

References¹

Best practices recommend that each reference includes full publication information and be numbered in the order of its initial appearance in the text (using Arabic numerals). Personal communications and unpublished documents are not references and should be referred to in the text directly. References should not include footnotes or other non-citations. In-text citations should appear after the sentence as superscript Arabic numerals.

1. Please see Citing Medicine for the proper formatting of references:
<https://www.ncbi.nlm.nih.gov/books/NBK7256/>.