

AGLAE 2025

PROFICIENCY TESTING SCHEME CATALOGUE

WATERS FOR MEDICAL USE



AGLAE Association

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PTS waters for medical use

82 Endotoxins in waters as described in the pharmacopoeia
83A Microbiology in waters similar to dialysate
83B Microbiology in waters similar to endoscope verification solutions
86 Indicator germs by filtration in bacteriologically controlled waters
86A Non-tuberculous mycobacteria in waters for medical use
86B Indicator germs in waters similar to pharmaceutical process waters

Glossary of the matrices used

Name of the matrix for Biology of waters for medical use	Below the matrices that can be used, alone or mixed, to comply with the representativity of the specified matrix		
	Apyrogen sterile distilled water	Deionised water	Water for injectable preparations
Waters for medical use	x	x	x
Pharmaceutical waters	x		x

Additional services



ADDITIONAL TEST SAMPLES TO TEST ANOTHER METHOD, EVALUATE A TECHNICIAN

- ✓ Test samples available for almost all the tests at half price.
- ✓ Besides your usual distribution, you receive one (or several) additional parcel(s).
- ✓ The results of these samples are not statistically processed by AGLAE but for most tests you get a sheet **in your results file** where to **calculate your z-score**. Note that this sheet can also be used in case of unit error, incorrect results' report, etc.

⇒ Check the **list of samples and their price on your Member Area** (Downloads / Catalogues) and contact us to receive a quote. These additional samples need to be ordered after you registration for the test and up to 2 weeks before the shipment.



QUALITY CONTROL MATERIALS FOR YOUR MONITORING AND IMPROVEMENT OF YOUR ANALYTICAL PERFORMANCE

- ✓ Materials coming from the **solid matrices tests: sediments, sludge, polluted sites and soils**.
- ✓ Purchased at any time during the year and delivered with a certificate presenting the precision values obtained during the test (assigned value and uncertainties).

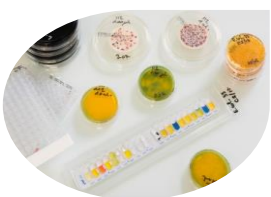
⇒ Check the **list of materials, prices and available quantities on your Member Area** (Downloads / Catalogues) and contact us to receive a quote.



TRAINING SESSIONS IN MICROBIOLOGY: ONE TOPIC POSSIBLY PROVIDED IN ENGLISH

Two-day on-line session to become operational for:

- ✓ Characterising a microbiological method according to ISO 13843 in order to validate it
- ⇒ *Should you be interested in such a session, please get back to us.*



CUSTOMIZED SERVICE: 'PERFORMANCE CHARACTERISTICS OF MICROBIOLOGICAL METHODS'

Do you need to characterise specific methods?

AGLAE can provide you support to establish methods performance characteristics, in conformity with ISO 13843*. Benefit from AGLAE's technical and statistical experience to validate your microbiological method.

* *Water quality — Requirements for establishing performance characteristics of quantitative microbiological methods*

⇒ *Should you have such needs, contact us to study your request together and issue a quote.*



SUMMARY OF YOUR RESULTS FOR WATER MICROBIOLOGY AND WATER FOR MEDICAL USE TESTS

Gather at any time your results and performance: for a selected period, your results are grouped in an Excel file; this is a tool to support you in your Internal Quality Control, your audits...

Programmes' description

One programme includes from 1 to 4 proficiency tests (= rounds).

Prices specified in the catalogue are for the complete programme, which corresponds to several rounds most of the time.

When purchasing a complete programme, the price per test is lower.

Content

For each programme's description, you will find the technical content of the test : volumes, parameters, matrices, dispatch month...

The concentration levels and stabilisation modalities of the samples are available on request.

The samples' dispatch months are given for information only.

Transport costs depend on the destination and tests selected within the programmes; contact us to get a quote.

Our aim is to prepare materials as close as possible to the samples analysed in routine: the contamination levels can therefore be very low or very high.

➔ **Our concentration levels are available on request.**

Caption



This logo shows that the programme is accredited by LABORATORIES section in compliance with ISO/IEC 17043.

PROGRAMME 82: ENDOTOXINS IN WATERS AS DESCRIBED IN THE PHARMACOPOEIA

Test materials are suitable for the check of analyses in waters as described in the pharmacopoeia, waters for irrigation, hemodialysis waters, dialysates, substitution fluids, as well as waters in health care, pharmaceutical and cosmetic establishments.



€ 331 excl. VAT - total amount for 2 tests (excluding transport costs)

60 participants in 2023 - EXPERIENCE > 10 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 85 excl. VAT (excluding transport costs)

2 SHIPMENTS AVAILABLE / YEAR - REFRIGERATED PARCEL

Month	1	2	3	4	5	6	7	8	9	10	11	12
Test			25M82.1					25M82.2				
Matrix			Waters intended for medical use					Waters intended for medical use				

Parameters to analyse for each shipment

Bacterial Endotoxins

PARTICULARITIES

Bacterial endotoxins (LAL enumeration) in accordance with the current pharmacopoeia PE 2.6.14 or USP <85> and <161>.

Please note that only quantitative methods and methods giving results like <X, >Y or [x; y] are taken into account for the statistical processing of data.

Results coming from qualitative methods (presence / absence) cannot be statistically processed.

PROGRAMME 83A: MICROBIOLOGY IN WATERS SIMILAR TO DIALYSATE

Test materials are suitable for the check of analyses in hemodialysis waters, dialysates, generator loop outflow waters, substitution fluids, as well as fresh waters, waters in health care, pharmaceutical and cosmetic establishments.



€ 371 excl. VAT - total amount for 2 tests (excluding transport costs)

76 participants in 2024 - EXPERIENCE > 10 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 95 excl. VAT (excluding transport costs)

2 SHIPMENTS AVAILABLE / YEAR - REFRIGERATED PARCEL

Month	1	2	3	4	5	6	7	8	9	10	11	12
Test		25M83A.1								25M83A.2		
Matrix		Waters intended for medical use								Waters intended for medical use		

Parameters to analyse

25M83A.1

Culturable micro-organisms at 22°C - 7 days with identification

Pseudomonas aeruginosa

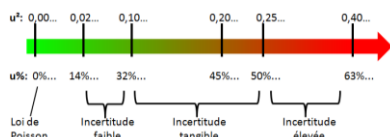
25M83A.2

Culturable micro-organisms at 22°C - 7 days with identification

Yeasts

PARTICULARITIES

Aerobic flora culturable at 22°C during 7 days (by filtration): advised culture media R2A.



For this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty u_r^2 and the reproducibility uncertainty u_R^2 specific to each participant. The uncertainty evaluated for the whole profession is also presented.



Other recommended proficiency tests:

↳ **Programme 31** '*Pseudomonas aeruginosa* and pathogenic staphylococci in clean waters'

↳ **Programme 38** 'Yeasts in clean waters'

PROGRAMME 83B: MICROBIOLOGY IN WATERS SIMILAR TO ENDOSCOPE VERIFICATION SOLUTIONS

Test materials are suitable for the check of analyses in fresh waters, waters in health care, pharmaceutical and cosmetic establishments.



€ 308 excl. VAT – total amount for 2 tests (excluding transport costs)

103 participants in 2024 - EXPERIENCE > 10 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 80 excl. VAT (excluding transport costs)

2 SHIPMENTS AVAILABLE / YEAR - REFRIGERATED PARCEL

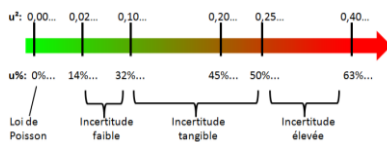
Month	1	2	3	4	5	6	7	8	9	10	11	12
Test			25M83B.1							25M83B.2		
Matrix			Waters intended for medical use							Waters intended for medical use		

Parameters to analyse for each shipment

Culturable micro-organisms at 30°C - 5 days and identification

PARTICULARITIES

Total aerobic mesophile flora culturable at 30°C during 5 days including yeasts: none-selective culture media advised such as PCA or TS.



For this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty u_r^2 and the reproducibility uncertainty u_R^2 specific to each participant. The uncertainty evaluated for the whole profession is also presented.

PROGRAMME 86: INDICATOR GERMS BY FILTRATION IN BACTERIOLOGICALLY CONTROLLED WATERS

Test materials are suitable for the check of analyses in fresh waters, waters in health care, pharmaceutical and cosmetic establishments.



€ 245 excl. VAT - total amount for 2 tests (excluding transport costs)

73 participants in 2024 - EXPERIENCE > 5 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 65 excl. VAT (excluding transport costs)

2 SHIPMENTS AVAILABLE / YEAR - REFRIGERATED PARCEL

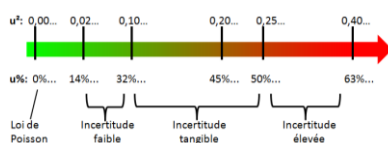
Month	1	2	3	4	5	6	7	8	9	10	11	12
Test			25M86.1							25M86.2		
Matrix			Waters intended for medical use							Waters intended for medical use		

Parameters to analyse for each shipment

Culturable micro-organisms at 22°C
Culturable micro-organisms at 36°C

PARTICULARITIES

Aerobic flora culturable at 22°C and at 36°C on PCA or TS media by filtration of 100 mL.



For this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty u^2 and the reproducibility uncertainty uR^2 specific to each participant. The uncertainty evaluated for the whole profession is also presented.



Other recommended proficiency tests:

- Programme 30 'Microbiology in clean waters' for the analysis of culturable micro-organisms at 22°C and at 36°C by the plate incorporation method
- Programme 31 '*Pseudomonas aeruginosa* and pathogenic staphylococci in clean waters'

PROGRAMME 86A:

NON-TUBERCULOUS MYCOBACTERIA IN WATERS FOR MEDICAL USE

Test materials are suitable for the check of analyses in fresh waters, waters in health care, pharmaceutical and cosmetic establishments

€ 108 excl. VAT - total amount for 1 test (excluding transport costs)

21 participants in 2024 – EXPERIENCE: 3 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): **€ 55 excl. VAT** (excluding transport costs)

1 SHIPMENT / YEAR - REFRIGERATED PARCEL

Month	1	2	3	4	5	6	7	8	9	10	11	12
Test											25M86A.1	
Matrix											Waters intended for medical use	

Parameters to analyse

Non-tuberculous mycobacteria

PARTICULARITIES

In the frame of this test, participating laboratories will detect, and quantify if their method enables it, non-tuberculous mycobacteria in waters for medical use.

This is a **methodological comparison** test, which will enable participants to estimate the reliability of their analytical protocol.

PROGRAMME 86B: INDICATOR GERMS IN WATERS SIMILAR TO PHARMACEUTICAL PROCESS WATERS

Test materials are suitable for the check of analyses in waters as described in the pharmacopoeia, healthcare waters (purified and highly purified waters ...) as well as pharmaceutical and cosmetic establishments.



€ 247 excl. VAT - total amount for 2 tests (excluding transport costs)

23 participants in 2024 - EXPERIENCE > 5 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 65 excl. VAT (excluding transport costs)

2 SHIPMENTS AVAILABLE / YEAR - REFRIGERATED PARCEL

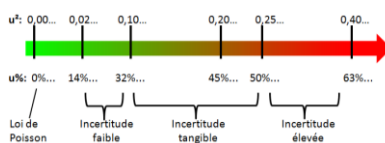
Month	1	2	3	4	5	6	7	8	9	10	11	12
Test			25M86B.1							25M86B.2		
Matrix			pharmaceutical process water							pharmaceutical process water		

Parameters to analyse for each shipment

Culturable micro-organisms at 30-35°C on R2A medium during 5 days

PARTICULARITIES

Aerobic flora culturable at 30-35°C on R2A medium during 5 days **after filtration.**



For this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty u_r^2 and the reproducibility uncertainty u_R^2 specific to each participant. The uncertainty evaluated for the whole profession is also presented.