

AGLAE 2024

PROFICIENCY TESTING SCHEME CATALOGUE

WATERS FOR MEDICAL USE



AGLAE Association

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Waters for medical use: new programmes

New programmes in the catalogue

86A Non-tuberculous mycobacteria in waters for medical use

Waters for medical use: list of tests

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

Participate in AGLAE's External Quality Control



A WAY OF WORKING THAT PROVIDES YOU WITH THE HIGHEST STANDARD OF RESULTS WITH CONFIDENTIALITY AND IMPARTIALITY

Each step of the way, AGLAE is there supporting you.

REGISTRATIONS FOR PROFICIENCY TESTING ARE DONE KNOWING THE WHOLE PROCESS, WITH A DETAILED AND RIGOUROUS SCHEDULE

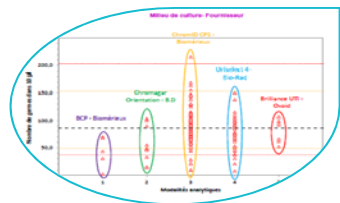


- ✓ The number of evaluations per year for each parameter is specified in the catalogue, concentration levels and stabilisation are available on request.
- ✓ AGLAE uses "express" shipments for your samples and makes sure of their distribution to your laboratory.
- ✓ A sufficient delay to analyse and the report the results.
- ✓ Via your member area, **enter your results and find instructions, assigned codes, reports, summaries of your results, certificate of participation...**

THE OPTIMISATION OF RISK MANAGEMENT FOR YOUR LABORATORY



- You have a better visibility of potential anomalies through:
- ✓ An appropriate test design (duplicate samples, repeated measurements),
 - ✓ A large number of participants: around 200 laboratories in the field of 'base' microbiology and 'base' physico-chemical analyses.



- AGLAE's detailed study:
- ✓ Influence of the analytical methods, manufacturers (equipment and consumables)... factors that we study to help you improve the quality of your analyses,
 - ✓ For waters intended for medical use and water microbiology, estimation of your own uncertainties in microbiology,
 - ✓ Check of your uncertainty estimates in chemistry (zeta-score),
 - ✓ A report validated by experts of the field and personalised for most tests.

ATTRACTIVE DISCOUNTS, PAYMENT CONDITIONS MADE EASIER

- Choose among the various programmes and benefit from discounts up to 15%,
- A possible payment in 2 or 3 folds depending on the amount your participation.
- Payment possible by cheque (in €), bank transfer, credit card on <https://www.helloasso.com/associations/a-g-l-a-e/paiements/aglae>

Amount of your invoice (excluding transport cost)	Discount
3000 ≤ Amount < 6000 € excl. VAT	5%
6000 ≤ Amount < 9000 € excl. VAT	10%
Amount ≥ 9000 € excl. VAT	15%

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 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.

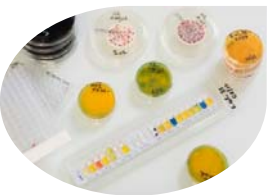


TRAINING SESSIONS IN MICROBIOLOGY: ONE TOPIC POSSIBLY PROVIDED IN ENGLISH

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

Content

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

The concentration levels, volumes 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

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)

Parameters to analyse

24M82.1 - Waters intended for medical use - sent in March 2024 - Refrigerated parcel

Bacterial Endotoxins

24M82.2 - Waters intended for medical use - sent in August 2024- Refrigerated parcel

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.



€ 360 excl. VAT - total amount for 2 tests (excluding transport costs)

71 participants in 2023 - EXPERIENCE > 10 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): **€ 90 excl. VAT** (excluding transport costs)

Parameters to analyse
24M83A.1 - Waters intended for medical use - sent in February 2024 - Refrigerated parcel
Culturable micro-organisms at 22°C - 7 days with identification
<i>Pseudomonas aeruginosa</i>
24M83A.2 - Waters intended for medical use - sent in October 2024 - Refrigerated parcel
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 all the parameters of this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty ur^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 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.



€ 299 excl. VAT – total amount for 2 tests (excluding transport costs)

97 participants in 2023 - EXPERIENCE > 10 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): **€ 75 excl. VAT** (excluding transport costs)

Parameters to analyse

24M83B.1 - Waters intended for medical use - sent in March 2024 - Refrigerated parcel

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

24M83B.2 - Waters intended for medical use - sent in October 2024 - Refrigerated parcel

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 all the parameters of this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty ur^2 and the reproducibility uncertainty uR^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.



€ 238 excl. VAT - total amount for 2 tests (excluding transport costs)

74 participants in 2023 - EXPERIENCE > 5 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): **€ 60 excl. VAT** (excluding transport costs)

Parameters to analyse

24M86.1 - Waters intended for medical use - sent in March 2024 - Refrigerated parcel

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

24M86.2 - Waters intended for medical use - sent in October 2024 - Refrigerated parcel

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 all the parameters of this programme, uncertainties are calculated and provided to the participants. The indicators are the repeatability uncertainty ur^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.

105 € excl. VAT - total amount for 2 tests (excluding transport costs)

New in 2024

12 participants in 2023 - EXPERIENCE:2 YEARS



Need to test another method, evaluate your staff?

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

Parameters to analyse

24M86A.1 - Waters intended for medical use - sent in November 2024 - Refrigerated parcel

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.



€ 240 excl. VAT - total amount for 2 tests (excluding transport costs)

22 participants in 2023 - EXPERIENCE > 5 YEARS



Need to test another method, evaluate your staff?

Order **additional test samples** (parcel in its entirety): € 60 excl. VAT (excluding transport costs)

Parameters to analyse

24M86B.1 - pharmaceutical process water - sent in April 2024 - Refrigerated parcel

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

24M86B.2 - pharmaceutical process water - sent in October 2024 - Refrigerated parcel

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 all the parameters of 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.