

## WATERS FOR MEDICAL USE



## 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 RIGOROUS SCHEDULE



- ✓ The number of evaluations per year for each parameter is specified in the catalogue.
- ✓ AGLAE uses "express" shipments for your samples and makes sure of their distribution to your laboratory.
- ✓ A sufficient delay for reporting your analytical 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



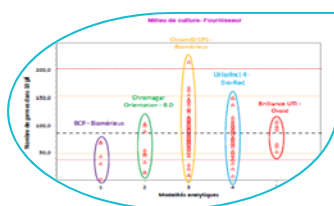
You receive test samples close to those analysed in routine (materials ready for analysis) which enable you to validate the analytical chain from the receipt of the sample to the report of the result.

You have a better visibility of potential anomalies through:

- ✓ An appropriate test design (duplicate samples, repeated measurements),
- ✓ A large number of participants: around 240 laboratories for the blood culture (complete analysis), over 100 for the cytobacteriology of urines.

AGLAE's detailed study:

- ✓ Influence of the analytical methods, manufacturers (equipment and consumables)? Differences between pair groups? ... factors that we study to help you identify the origin of any anomalies.
- ✓ For waters intended for medical use, estimation of your own uncertainties in microbiology.
- ✓ **A personalized report validated by experts of the field** for most tests (list of the members at the end of the report).



### 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 fees)	Discount
3000 ≤ Amount < 6000 € excl. VAT	<b>5%</b>
6000 ≤ Amount < 9000 € excl. VAT	<b>10%</b>
Amount ≥ 9000 € excl. VAT	<b>15%</b>

**And exclusively for AGLAE's members:**  
experimental tests at an attractive price during the year

## 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.*



**328 € excl. VAT** – total amount for 2 tests (excluding transport costs)

**60 participants** in 2022 – 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)

### 23M82.1 - Waters intended for medical use - sent in March 2023 - Refrigerated parcel

Bacterial Endotoxins

### 23M82.2 - Waters intended for medical use - sent in August 2023- 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.



**356 € excl. VAT** – total amount for 2 tests (excluding transport costs)

**72 participants** in 2022 - 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)

### 23M83A.1 - Waters intended for medical use - sent in February 2023 - Refrigerated parcel

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

*Pseudomonas aeruginosa*

### 23M83A.2 - Waters intended for medical use - sent in October 2023 - 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.

☞ Find a specific programme for yeasts: programme 38, as well as a programme for *Pseudomonas aeruginosa*: programme 31.

## 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.*



**296 € excl. VAT** – total amount for 2 tests (excluding transport costs)

**102 participants** in 2022 - 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)

### 23M83B.1 - Waters intended for medical use - sent in March 2023 - Refrigerated parcel

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

### 23M83B.2 - Waters intended for medical use - sent in October 2023 - 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  $u_r^2$  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.*



**236 € excl. VAT** – total amount for 2 tests (excluding transport costs)

**73 participants** in 2022 – 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)

### 23M86.1 - Waters intended for medical use - sent in March 2023 - Refrigerated parcel

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

### 23M86.2 - Waters intended for medical use - sent in October 2023 - 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  $u_r^2$  and the reproducibility uncertainty  $u_R^2$  specific to each participant. The uncertainty evaluated for the whole profession is also presented.

☞ Find the analysis of culturable micro-organisms at 22°C and at 36°C by the plate incorporation method: programme 30.

☞ Find the analysis of *Pseudomonas aeruginosa*: programme 31.

## 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.*



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

**22 participants** in 2022 – 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)

### 23M86B.1 - pharmaceutical process water - sent in April 2023 - Refrigerated parcel

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

### 23M86B.2 - pharmaceutical process water - sent in November 2023 - 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  $ur^2$  and the reproducibility uncertainty  $uR^2$  specific to each participant. The uncertainty evaluated for the whole profession is also presented.