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WWARN

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WWARN

Quality Assurance/Quality Control

Proficiency testing and reference standard programmes

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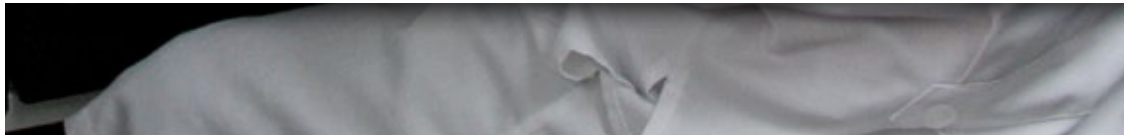


For laboratories conducting antimalarial drug assays, WWARN initiated a Quality Assurance/Quality Control (QA/QC) programme with two major components: a proficiency testing programme and a reference material programme.

The WWARN QA/QC programme is based in the Pharmacology Department of the Mahidol-Oxford Research Unit, Faculty of Tropical Medicine, Mahidol University in Bangkok, Thailand but operates as an independent entity.

Proficiency testing programme

The WWARN pharmacology proficiency testing programme is designed to help participating laboratories assess their ability to carry out drug analysis, resolve any potential problem areas and to improve their results — and in doing so improve the quality of antimalarial pharmacokinetic data published and shared, including with networks like WWARN.

How does it work?

Blinded Quality Control (QC) samples are distributed to participating laboratories once per year in a single batch. Samples are divided into three cycles and laboratories must complete analysis of each cycle by the given time.

Analysis

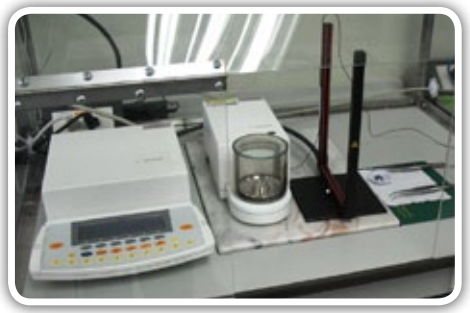
Participating laboratories may request QC samples from the WWARN QA/QC Unit at any time within a cycle. Participating laboratories should carry out analyses using their choice of analytical method. Methods must be those used for routine work and should not be specially adapted for the proficiency test. Results must be reported to the QA/QC Unit within two weeks of the cycle end date.

Results

After each cycle closes, the assigned value (i.e. concentration used for all calculations) for each antimalarial drug substance in every sample will be disclosed to participating laboratories, along with all anonymised results. Each laboratory will be given a unique code and will only be able to identify their own laboratory results.

The results will be subjected to statistical analysis and converted into scores by the WWARN QA/QC Unit. Each laboratory will receive confidential reports on their performance, assessed on the basis of the deviation of measurement results from assigned values. This data will be provided with the objective of confirming and enhancing analytical services at participating laboratories.

The WWARN QA/QC Unit will keep all participants fully informed of their progress in the programme and will provide advice to participating laboratories, as needed.



Reference materials programme

To ensure the quality of pharmacokinetic data, it is important that laboratories use proper reference standards. By utilising the same source of standards for all laboratories, it will be possible to minimise bias arising from poor quality reference standards. Also, by providing antimalarial drug standards from a central point, it will be possible to lower the cost of these standards.

How does it work?

Central storage — Reference standards will be stored at the central QA/QC Unit under optimal conditions — humidity, temperature, and stability data will be monitored continually to maximise usage of the material.

Distribution — Reference standards will be aliquoted in small quantities (0.4000-2.000 mg) using an ultra-micro balance. Each participating pharmacology and *in vitro* laboratory will have the opportunity to receive shipments of a total amount of standard equal to approximately 20 mg per drug or metabolite per year. Participating pharmacology laboratories will also be supplied with small quantities of appropriate internal standards.

WWARN reference materials will be provided to laboratories that:

- participate in the QA/QC programme; and
- agree to sign relevant Material Transfer Agreements for the reference materials requested.

Initially, laboratories may participate in the QA/QC programme and receive standards without charge. WWARN plans to introduce a cost-recovery system to ensure the programme is sustainable whilst maintaining wide access to the services. Participants will be notified of any intended changes.

Antimalarial reference standards currently available:

Chloroquine Diphosphate	Artemisinin	Desethyl chloroquine
Lumefantrine	Dihydroartemisinin	Pyronaridine
Mefloquine Hydrochloride	Piperaquine	Carboxymefloquine
Quinine	Artesunate	Artemisone
Amodiaquine	Artemether	Desbutyl lumefantrine
Pyrimethamine	Primaquine	Tafenoquine
Sulfadoxine	Desethylamodiaquine	Doxycycline
Azithromycin Dihydrate	Halofantrine	Otovaquone

Internal standards:	Amodiaquine-D10	Chloroquine analog
N-Desethylamodiaquine-D5	Artesunate-D4	Azithromycin-13CD3
Dihydroartemisinin-13CD4	Artemether-13CD3	Artemisone-D4
Piperaquine-D6	Piperaquine analog	
Primaquine-13CD3	Amodiaquine analog	

Available soon:	Lumefantrine analog	Naphtoquine-13C6
Carboxyprimaquine	Carboxyprimaquine-13CD3	3-Hydroxy quinine
Primaquine analog	Pyronaridine-13C2D4	
Carboxyprimaquine analog	Naphtoquine	

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