

First international external quality assessment of nucleic acid amplification tests for the detection of soil-transmitted helminths – the study protocol

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Background

- Nucleic acid amplification tests (NAATs) are increasingly implemented for the detection of soil-transmitted helminths (STHs)
- Worldwide different in-house protocols of DNA extraction and NAATs have been described
- External quality assessment (EQA) is pivotal for assuring the quality of diagnosis, yet such an EQA is lacking for STHs
- Following the STH Diagnostics Meeting (22 – 23 August 2016, Ghent, Belgium), the development and the evaluation of an EQA of NAATs for the detection of STHs was prioritized
- This poster describes the study protocol of the first international EQA of NAATs for the detection of STHs

Study Protocol

Step 1: Collection of Worm Material

- Helminth species
 - ✓ *Ascaris lumbricoides*, *Trichuris trichiura*, *Necator americanus*, *Ancylostoma duodenale*, *Strongyloides stercoralis*, *Schistosoma* spp.
- Specimens
 - ✓ Stool – clinical trial Ethiopia (www.starworms.org)
 - ✓ DNA – adult worm / larvae

Step 2: Panel Validation

- Dutch Foundation for Quality Assessment in Medical Laboratories (www.SKML.nl)
 - ✓ Internal validation of stool homogenization
 - ✓ Aliquoting and blinding of panel
- Reference laboratories
 - ✓ In-house DNA extraction and qPCR protocol
 - ✓ External validation of stool homogenization (5-replicates)
- Validation criteria per worm species

Test Result	Reference labs	Standard deviation Ct values replicates
Positive	All +	<2
Negative	All -	N/A
Educational	discrepancies	≥2

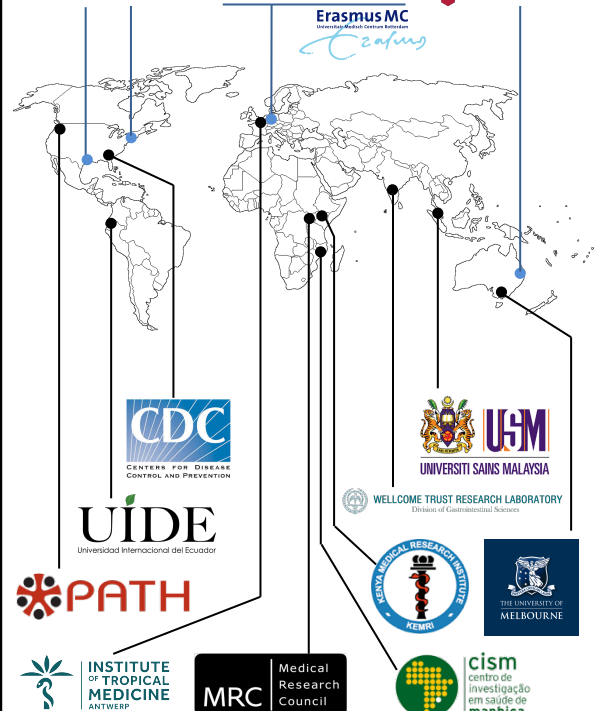
Step 3: Pilot study EQA

- 12 stool samples and 8 DNA samples
- Dutch Foundation for Quality Assessment in Medical Laboratories
 - ✓ Aliquoting and blinding of panel
 - ✓ Central reporting through internet-based Qbase software
- 16 laboratories
 - ✓ 6 reference laboratories
 - ✓ 10 other laboratories across STH endemic and non-endemic areas

Coordination



Reference Laboratories



Other Laboratories

