BIOSYNEX AMPLIQUICK® MALARIA
PARASITOLOGY

Fast molecular test for a precise diagnosis of Malaria

Combined detection

- Pf: specific gene of *Plasmodium falciparum*
- PAN: gene common to 5 pathogenic species for humans

Highly sensitive

- Detection limit of 0,3 parasite /µL on venous blood sample
- Detection limit of 0,05 parasite /µL on extracted DNA
- Better sensitivity than the microscopic observation (≈100 parasites /µL)

Convenient

- Prefilled microtubes with ready to use Master Mix aliquots: reduced risk of contamination
- Simplified blood sample protocol: less than 10 minutes of preparation and result in 1 hour
- Extracted DNA protocol : qualitative or quantitative and highly sensitive method in less than 2 hours

BIOSYNEX

THE SOLUTION

According to the latest figures from the World Health Organization (WHO), there were an estimated 229 million cases of malaria in 2019 in the world, resulting in 409,000 deaths, a large part of which were found in sub-Saharan Africa. Children under 5 years are the most vulnerable and account for 67% of deaths globally. Malaria infection is transmitted by female Anopheles mosquitoes. WHO recommends diagnosis and early treatment to reduce the intensity of the disease and the number of deaths. Several techniques are feasible for the diagnosis of *Plasmodium* infection: thin-smear, thick-smear, rapid test and molecular test (eg PCR).
Biosynex offers a molecular test to detect the presence of the species of parasite responsible for malaria in humans (*P. falciparum, P. ovale, P. vivax, P. malaria, P. knowlesi*), from an EDTA / heparin blood sample and in one hour. The test also makes it possible to highlight the specific presence of *P. falciparum* in order to optimize the management of patients.

PROCEDURE (for EDTA/heparin whole blood)*

1

Mix 50 µL of whole blood with **50 µL of lysis buffer**. Incubate for **4 minutes** at **95°C,** then centrifuge for **2 minutes** at **20,000 g**.

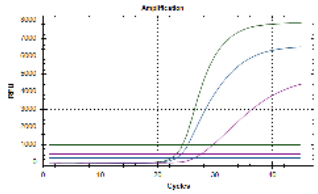
2

Transfer 8 µL of supernatant directly into the pre-filled **microtubes** of Master Mix.

3

Place the tubes in the **thermal cycler** and start the PCR **amplification** program.

4



Interpret the results obtained.

**Simplified procedure. See the instructions for use for the extracted DNA procedure.*
Open kit, validated on the main thermal cyclers on the market.

RESULTS

FAM	HEX	Cy5	Interpretation
			Patient with *Plasmodium falciparum*-specific DNA and who may also have a co-infection status.
			
			Patient with *Plasmodium spp.* DNA other than *Plasmodium falciparum.*
			
			Patient with no detectable *Plasmodium spp.* DNA.
			PCR inhibition or problem of detecting flurorescence on the thermocycler. Run a new test.

PERFORMANCE **

Detection limit :

- Venous blood: 0.3 parasites /µL
- Extracted DNA: 0.05 parasites /µL

Sensitivity	Specificity
100 %	100 %

*** Source: see instructions for use.*

KIT CONTENTS

BIOSYNEX AMPLIQUICK® Malaria

Ref. 3120019

- Microplate with 96 single microtubes containing the Master Mix
- 1 positive control tube
- 1 negative control tube
- 1 bar of standard range ready to use
- 4 tubes of lysis buffer
- 1 bag of caps
- 1 instructions for use

CE Manufacturer: BIOSYNEX S.A. (France)

In vitro diagnostic medical devices.
Read the instructions for use carefully.

FLY_3120019_EN_V02202103R02
Rev : 05/21

BIOSYNEX S.A.
22 Boulevard Sébastien Brant
67400 ILLKIRCH-GRAFFENSTADEN - France
Phone: +33 3 88 77 57 52 - Fax: +33 3 88 78 76 78
E-mail: export@biosynex.com
www.biosynex.com