

# Investigating whether a new test can be used to differentiate between viruses, malaria and bacteria as causes of fever among children in Ghana

<b>Submission date</b> 06/03/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/03/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study will evaluate a new test for the cause of fever in African children. There is an unmet need for diagnostic tests that can be used in African countries where resources are scarce. Most of the time, when children have a fever, the only test available is a malaria test. If this test is negative, they often receive antibiotic treatment because tests to distinguish between other causes of infection (e.g., bacteria or viruses) are unavailable. The aim of this study is to use how the human immune system responds to infection to tell which type of infection someone has. The researchers will detect genes that are turned on and off in the blood which are specific to either bacterial, viral, or malaria infection.

### Who can participate?

Children between the ages of 1 month and 15 years presenting to the recruiting facilities with fever

### What does the study involve?

The study will record participant data, some of which include the clinician's notes on the signs /symptoms, medications, and preexisting conditions, and demographic information such as age, sex, location, and ethnicity. In addition to this, the researchers will request the results of laboratory tests run for routine healthcare. They will also take about a spoonful of blood for laboratory testing for the study.

### What are the possible benefits and risks of participating?

There are no direct benefits to taking part in this study. However, it is hoped that the information gained from this study may someday make it easier and faster for doctors to diagnose individuals infected with germs that cause illness and fever. This study will benefit the scientific community by providing information for future use in the evaluation of this new test. There is minimal risk associated with the collection of a blood specimen. The participant may experience some mild pain, discomfort, and/or bruising. These risks are no greater for this study

than for routine testing from blood samples. Well-trained laboratory personnel will perform this according to standard guidelines to minimize the possible risks.

Where is the study run from?

The West Africa Centre for Cell Biology of Infectious Pathogens at the University of Ghana (Ghana)

When is the study starting and how long is it expected to run for?

August 2022 to August 2026

Who is funding the study?

The study is funded by the NIHR (NIHR-Global Health Research Group's Digital Diagnostics for African Health Systems, project reference NIHR134694) using UK International Development funding from the UK Government to support global health research. The views expressed are those of the authors and not necessarily those of the NIHR or the UK government.

Who is the main contact?

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

NIHR134694

**Study information****Scientific Title**

Evaluating the potential of a Lacewing host-response assay to distinguish between malaria, bacterial and viral infection as causes of acute childhood febrile illness in The Gambia and Ghana

**Acronym**

LacewingAFI

**Study objectives**

The measurement of the expression of a small number of genes in blood using a point-of-care molecular diagnostic test can be used to distinguish between viruses, bacteria and malaria infections

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

1. Approved 09/10/2023, Ghana Health Service Ethics Review Committee (Research and Development Division, Ghana Health Service, Accra, MB190, Ghana; +233 (0)302681109; [ethics.research@ghs.gov.gh](mailto:ethics.research@ghs.gov.gh)), ref: GHS-ERC: 017/06/23

2. Approved 29/06/2023, Ethics Committee for Basic and Applied Sciences (Ethics Committee for Basic and Applied Sciences, University of Ghana, Accra, LG1195, Ghana; +233 (0)302213820; ethicscbas@ug.edu.gh), ref: ECBAS 038/ 22-23

### **Study design**

Multicenter cross-sectional study

### **Primary study design**

Observational

### **Secondary study design**

Cross sectional study

### **Study setting(s)**

Hospital

### **Study type(s)**

Diagnostic

### **Participant information sheet**

Not available in web format. please use contact details to request a participant information

### **Health condition(s) or problem(s) studied**

Diagnosis of malarial, viral and bacterial infections among children with fever

### **Interventions**

Clinical samples will be obtained from participants recruited from the hospitals and stored samples from previous ethically approved studies. These will be tested for host signature transcripts using a benchtop reverse transcription loop-mediated isothermal amplification (RT-LAMP) assay and the Lacewing device. The diagnostic performance, sensitivity and specificity of the device will be assessed by comparing results with gold standards such as microscopy, bacterial cultures, and molecular diagnostics (for example TaqMan array card).

### **Intervention Type**

Device

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Lacewing

### **Primary outcome measure**

Diagnostic accuracy will be measured using the area under the receiver operator curve (AUC) for the results of the Lacewing device compared against reference standard (blood film microscopy, sterile site culture, and molecular pathogen detection), assessed at the time of clinical presentation.

## **Secondary outcome measures**

1. The prevalence of different types of infection classified by gene expression test will be assessed for samples collected at time of clinical presentation
2. The usability of the test will be evaluated through stakeholder engagements on the day that the primary outcome is measured

## **Overall study start date**

01/08/2022

## **Completion date**

31/08/2026

# **Eligibility**

## **Key inclusion criteria**

1. The participant is between the ages of 1 month and 15 years
2. Participant has a reported fever or recorded fever of  $\geq 37.5^{\circ}\text{C}$  in the past 24 hours and is suspected by a clinician to have an infection
3. Parental permission and child assent have been obtained

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

1 Months

## **Upper age limit**

15 Years

## **Sex**

Both

## **Target number of participants**

230

## **Total final enrolment**

353

## **Key exclusion criteria**

1. Children aged 16 years or older
2. Children without recorded/reported fever.
3. Inability to provide informed consent.
4. Children with fever from a suspected hospital-acquired infection
5. Children suspected by clinicians to have a high-consequence infectious disease such as viral haemorrhagic fever
6. Children with known HIV or other immunodeficiency

**Date of first enrolment**

15/03/2024

**Date of final enrolment**

10/03/2025

## **Locations**

**Countries of recruitment**

Ghana

**Study participating centre****Ledzokuku-Krowor Municipal Hospital**

Ghana Health Service

Teshie-Tsuibleoo

Accra

Ghana

GZ-103-2962

**Study participating centre****Oda Government Hospital**

Ghana Health Service

Akyem-Oda

Oda

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**Study participating centre****Kintampo Municipal Hospital**

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**Study participating centre****War Memorial Hospital**

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# Sponsor information

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University/education

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## ROR

<https://ror.org/01r22mr83>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Global Health Research Group on Digital Diagnostics for Africa

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

20/06/2026

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Aubrey Cunnington (a.cunnington@imperial.ac.uk) or Dr. Samuel Duodu (Sa.duodu@ug.edu.gh)



## **IPD sharing plan summary**

Available on request