



Validation and field
operationalization of one- and two-stage
LAMP assay for diagnosis of
COVID-19 in low-resourced health facilities in Ghana
(VoLCOV)

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**UNIVERSITY
OF GHANA**

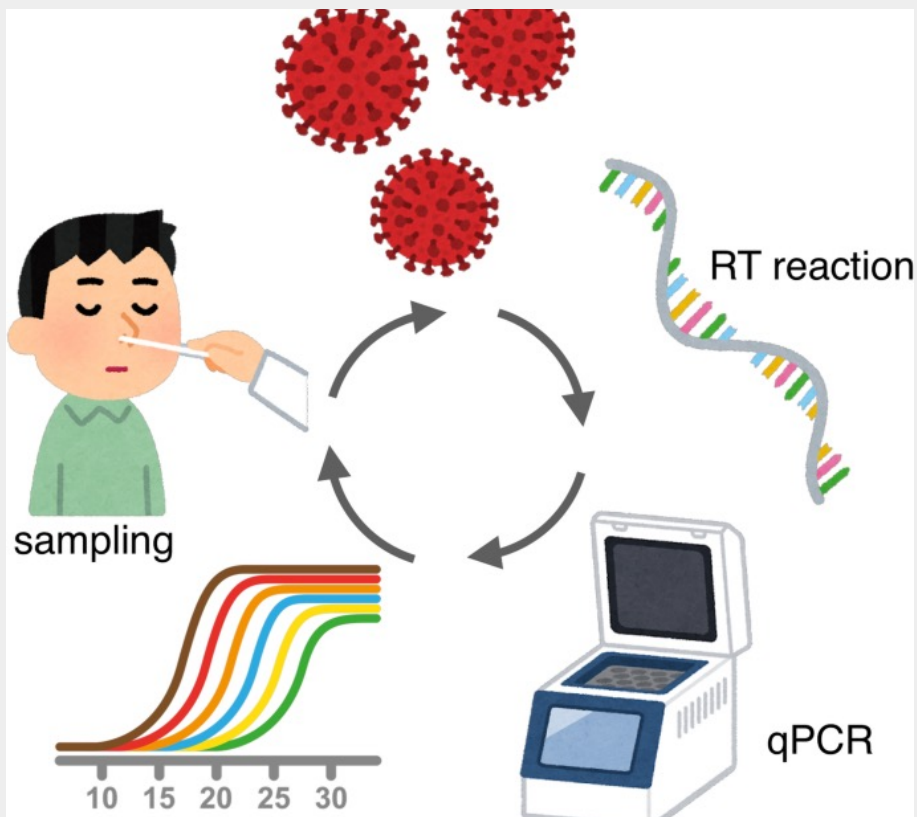


NMIMR

NOGUCHI

Memorial Institute for Medical Research
University of Ghana

Project Aim



Validate the use of a **cheap PCR-based diagnostic** method for detection of COVID-19 and **build capacity** in its use at low-resourced health facilities.

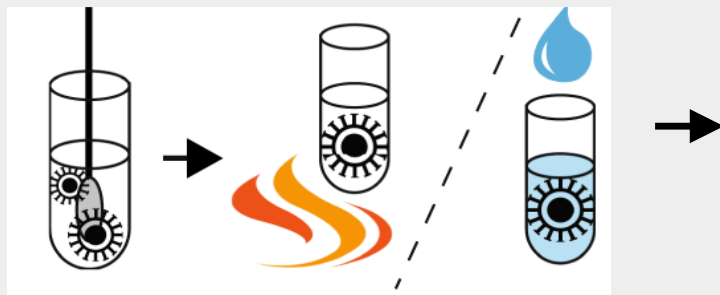
Specific objectives

1. Optimize and validate the specificity and sensitivity of the SARS-CoV-2 LAMP assays.
2. Determine the feasibility of using lyophilized LAMP reagents in the tropics.
3. Determine the cost effectiveness of the rapid assays for testing COVID-19.
4. Build capacity of technical staff at health-care facilities across the country to detect COVID-19.

Extraction-free LAMP-PCR assay

LAMP= Loop-mediated isothermal **amplification**

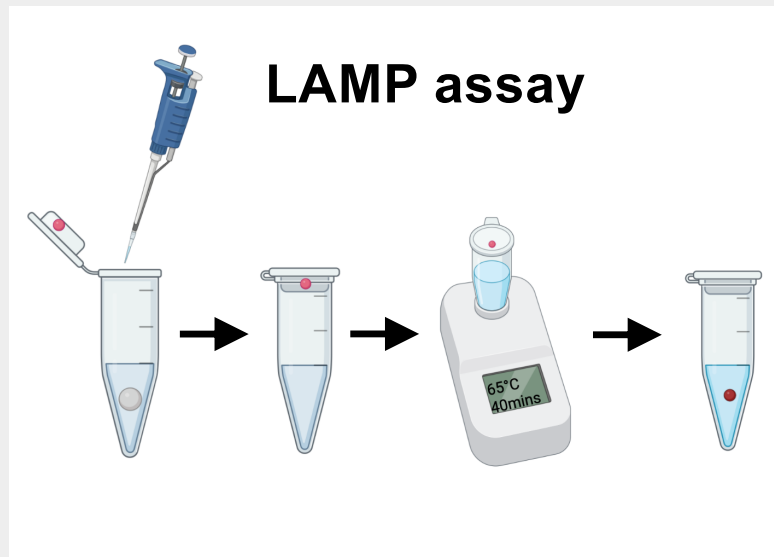
Sample preparation



Swab in
sterile
water

Heat
@98°C,
5mins

Cool on ice



LAMP assay

Incubate

Invert to
mix dye

Results



Neg Pos

Objective 1: Assay validation

- 362 swab samples collected in sterile water.
- Of these 80 (22.1%) and 43 (11.9%) were detected as positive using the RT-qPCR and LAMP assays, respectively

	RT-qPCR		
LAMP	Positive	Negative	Total
Positive	31	12	43
Negative	50	269	319
Total	81	281	362

Sensitivity= 38.3%; Specificity= 95.7%
 Positive predictive value (PPV)= 72.1%;
 Negative predictive value (NPV)= 84.6%

Accounting for samples that showed RT-qPCR Ct values >32.

	RT-qPCR		
LAMP	Positive	Negative	Total
Positive	31	12	43
Negative	32*	269	302
Total	63	281	345

Sensitivity= 49.2%; Specificity= 95.7%
 Positive predictive value (PPV)= 72.1%;
 Negative predictive value (NPV)= 89.4%

Objective 1: Assay validation

Improving sample preparation with Glass milk extraction

- Of these 12 (13.5%) and 14 (15.7%) were detected as positive using the RT-qPCR and LAMP assays, respectively

	RT-qPCR		
LAMP	Positive	Negative	Total
Positive	0	14	14
Negative	12	63	75
Total	12	77	89

Sensitivity= 0%; Specificity= 81.8%

Positive predictive value (PPV)= 0%

Negative predictive value (NPV)= 45%

Objective 2: Lyophilized LAMP reagents

- Store the reagents at different temperatures (4-30°C)
- Discovered:
 - Reagents stored at room temperature lose their efficiency
 - **Only cold chain recommended**

Objective 3: Cost comparison

Item	Gold standard (RT-qPCR)	LAMP
Cost of assay reagents (without primers) per sample	\$4-6	\$2
Time spent on viral isolation for a full plate of 96 samples	120-140mins (vacuum extraction) 5-6hrs (manual extraction)	12-15mins
Test run time	90mins	60mins
Equipment	\$10K-90K	\$300-350

Objective 4: Build capacity in LAMP

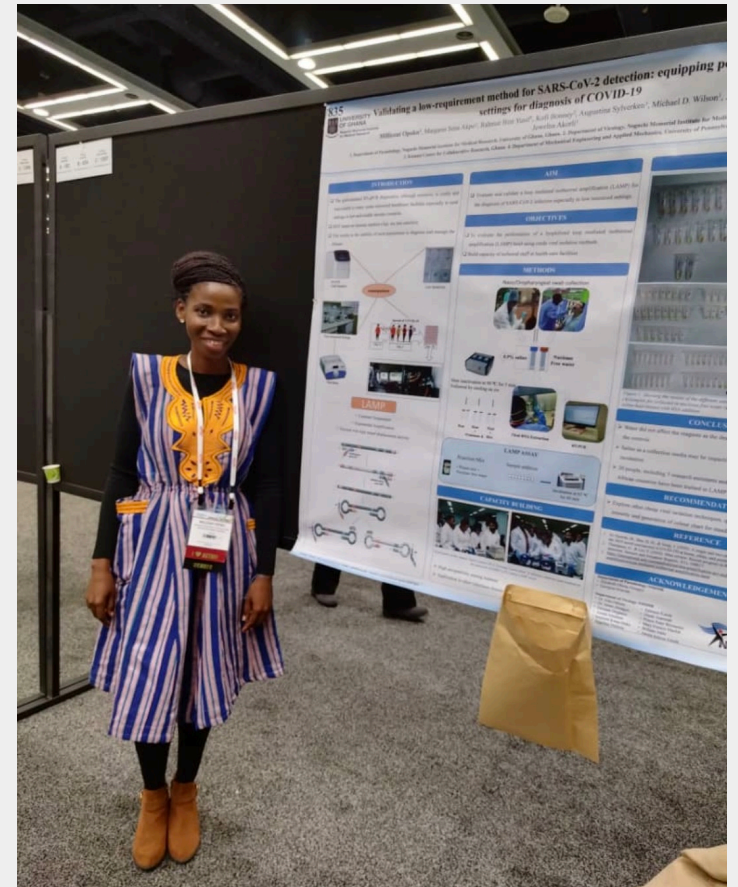
- Included in the training module for a diagnostic course for infectious diseases organized and hosted at the Noguchi Memorial Institute for Medical Research, University of Ghana.
- Trainees are selected from 10 countries across West and Central Africa.
 - Accepted the concept of LAMP assay
 - Willingness to adapt for other infectious diseases

Challenges

- Disease dynamics over the project period
 - Late start of project (May 2021 instead of Jan 2021)
 - Reduced cases
- Low population positivity
 - Peak in June-July 2022 still wasn't enough
- Sub-optimal test results

Opportunities

- Leveraged on existing projects at NMIMR to obtain samples.
- Presented results at ASTMH 2022
- Oral microbiome related to SARS-CoV-2 in an African population
 - Prelim results presented at ASTMH 2022
 - Selected for Young Investigator Award, ASTMH 2022
 - Manuscript drafted for publication



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THANK YOU

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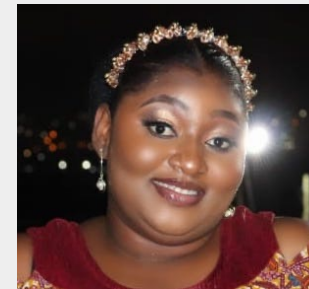
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