



# SeroSelect<sup>TB</sup> *newsletter*



# 2023 at a Glance

- » Following pandemic-related delays in 2020-2022, the field trials progressed well in 2023. However, we continued to experience delays due to load-shedding in South Africa (programmed electricity black-outs of up to 10 hours a day), flooding due to extreme weather in Tanzania, and civil unrest that escalated to war in the Amhara Region of Ethiopia.
- » For safety reasons, the project activities in Ethiopia were moved to field sites in the Sidama Region in the south of the country.
- » As of 31 December 2023, a total of 1719, 2462, and 836 participants had been enrolled in South Africa, Tanzania, and Ethiopia, respectively.
- » The project lead visited Tanzania and Ethiopia in June following invitations from the Provost at KCMUCo and the Deputy Director General at AHRI, and South Africa in September.
- » The aim of the visits was to discuss project continuation with the teams, conduct a “mock” SeroSelectTB QC exercise, visit the field sites, and examine data entry in TB-registry books and REDCap.
- » Participant enrollment continues at field sites in South Africa, Tanzania, and Ethiopia. Refresher sessions addressing the clinical trial protocol, SeroSelectTB test procedure and interpretation of results, ethics, eCRF, REDCap, randomization app, and the Automatic QC Indicator Reporting System are held on a regular basis.
- » Community engagement activities are repeated at regular intervals. The Community Engagement materials designed especially for the SeroSelectTB project (found at [www.seroselecttb.org](http://www.seroselecttb.org)) are available at all field sites, and given to all persons who are invited to participate in the study and other persons seeking health care at the sites.





Accessing healthcare services can be a challenge during the rainy season in Tanzania.

# *Fieldwork update from Tanzania and Ethiopia*

Excellent progress was made in Tanzania during 2023. Almost all the 21 field sites are close to Moshi town, the furthest being less than an hour's drive from KCMUCo.

SeroSelect TB “mock” QC exercises were held in Tanzania and Ethiopia during June 2023.

The purpose of this exercise was to ensure that healthcare workers:

- 1) interpret SeroSelect TB results correctly, and
- 2) uncover the need for retraining where warranted.

The “mock” tests were prepared digitally by Lateral Flow Laboratories (South Africa).

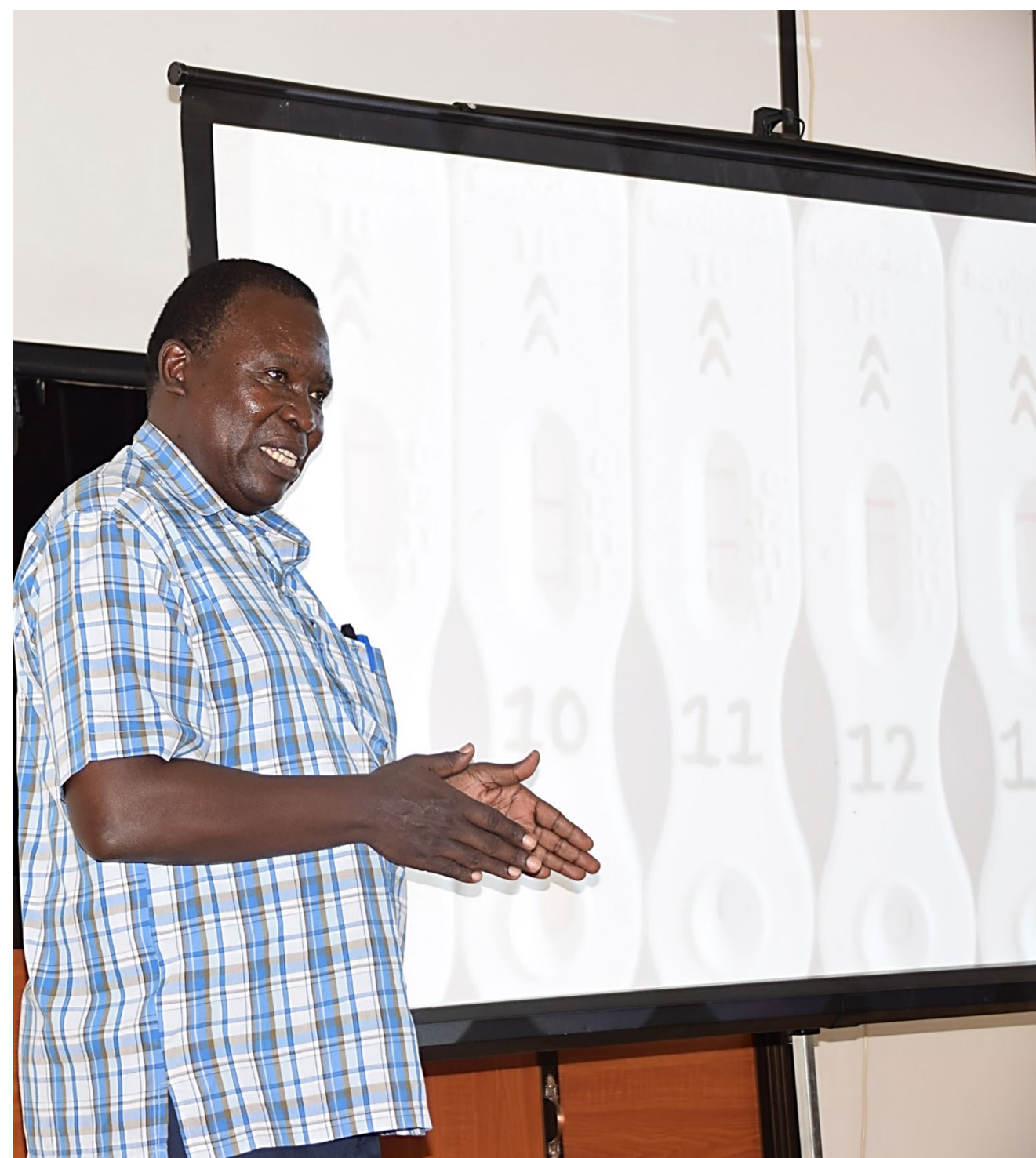
Healthcare workers from the field sites were invited to attend the exercises.

The “mock” tests were distributed to the participants, and the healthcare workers were asked to record the results (presence or absence of the I, T1, T2 and C bands on the SeroSelect TB “mock” tests) and their interpretation of the results on a prepared record sheet.



The PI, Dr Balthazar Nyombi, led a discussion in which the healthcare workers presented their results and interpretation.

The exercise was repeated several times, each attendee receiving a different “mock” test. The healthcare workers’ responses indicated an excellent understanding of the SeroSelect TB test. The “mock” test kits have since been used for training new healthcare workers and in refresher courses.



Dr Nyombi at KCMUCo in Tanzania.

A photo of the 16 “mock” tests was used as the key.



Photographs of the “mock” test results were available to aid the healthcare workers attending the exercise at the sites without electricity in Ethiopia.



The 16 test cassettes with digital results included the “mock” test kit.





“Mock” QC exercise at KCMUCo, Tanzania, with healthcare workers from the field sites.

Finger-prick whole blood sample collection and SeroSelectTB testing is performed at all field sites, dispensaries and health centers in Tanzania and health posts in Ethiopia.

### *Sample transport from the dispensary/health post to clinic level in Tanzania and Ethiopia was problematic in 2023.*

There are no sputum testing facilities at the dispensary/health post level. Therefore, sputum samples are sent to the next level of healthcare in Tanzania. In Ethiopia, participants are referred to the health clinic. At the health clinic level in Tanzania

and Ethiopia, routine AFB microscopy is required for all TB suspects according to national TB control program guidelines. Patients with positive AFB microscopy results should start TB treatment regime at once and before Xpert results are provided. This was not followed.

During the project lead's visits to Tanzania and Ethiopia, discussions were held with the district and regional health authorities. As a result, communication between the health facilities and district authorities improved, and AFB reagents are now available at all health clinics in Ethiopia and all dispensaries in Tanzania.

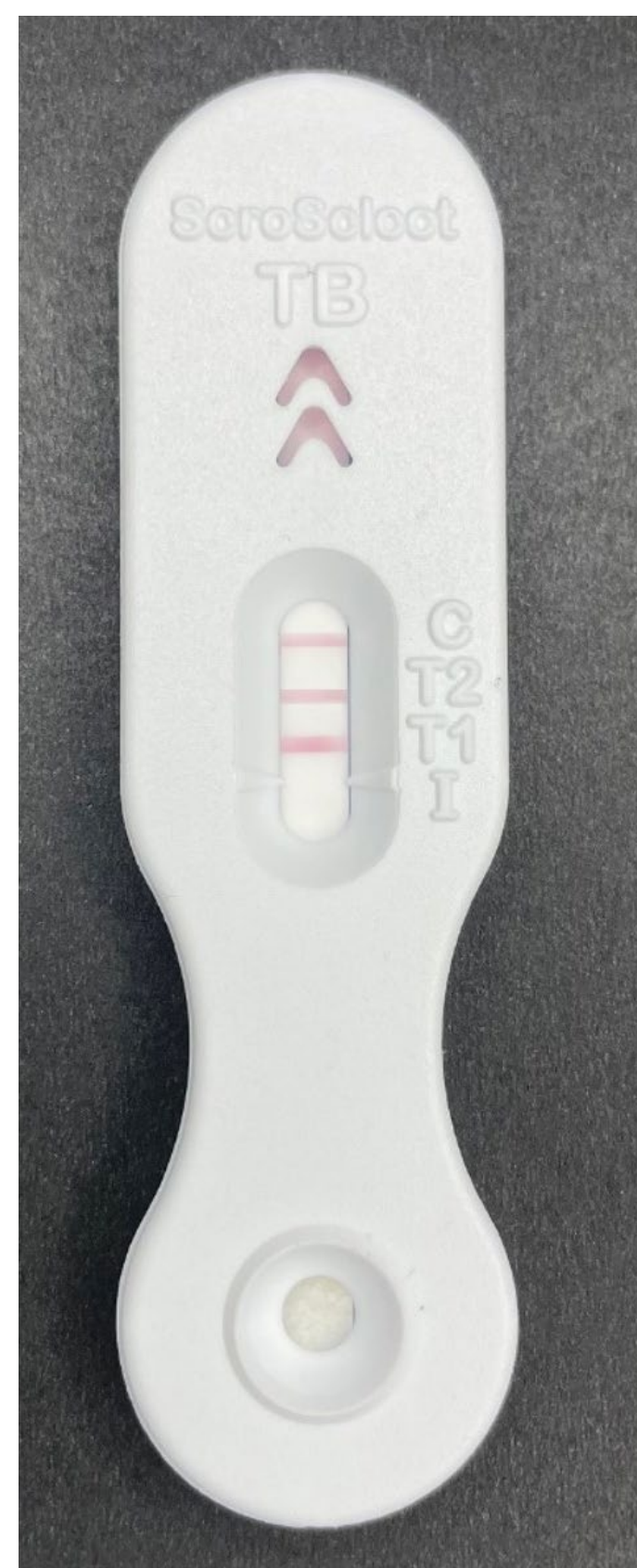


*For several reasons, project activities in Ethiopia were moved to field sites in the Sidama Region in the south of the country.*

Despite unforeseen challenges, the team from AHRI has done an admirable job. Community engagement meetings have been conducted and healthcare workers trained at the sites not included in the study during 2022.

Enrollment continued in the Bahirdar Zuria district, West Gojam Zone of the Amhara region, and activities expanded to other districts in the same zone. Our sites in the Amhara Region are a day's drive from AHRI in Addis Ababa. The distance required local TB coordinators to assist the team from AHRI.

It became evident in early 2023 that the prevalence of TB in the West Gojam Zone was far lower than indicated by previous epidemiological studies on which we based our calculations. Therefore, new sites in the Sidama region in southern Ethiopia, where the prevalence of TB is high, were included in the study.





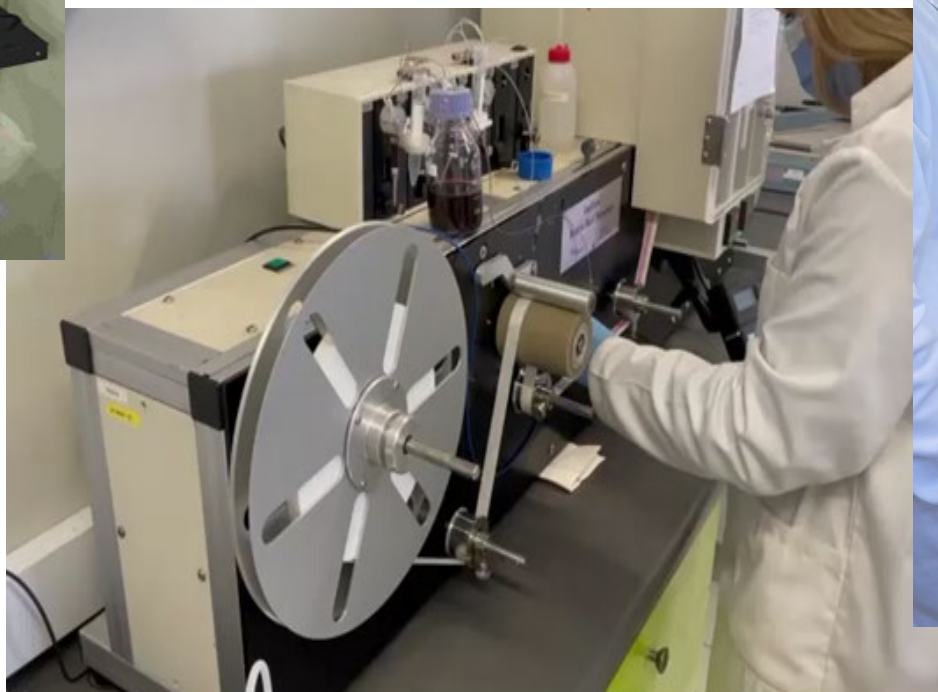
# Continued development of SeroSelectTB test

FIND (Foundation for Innovative New Diagnostics) and FEND-TB (Feasibility of New Diagnostic for TB in Endemic Countries, <https://www.fend-tb.org/>) have shown great interest in SeroSelectTB test since 2022 and requested to include the test in their ongoing bench-top and clinical evaluations.

An application to participate in the FEND-TB network was approved in September 2023 and evaluations began in South Africa, Uganda, and Vietnam in early 2024. These investigations will provide essential data for the SeroSelectTB WHO pre-qualification dossier.

Lateral Flow Laboratories will donate the test kits to FIND/FEND at no-cost.

Photos show the production facilities at Lateral Flow Laboratories.







In conclusion, after pandemic-related delays in 2020-2022, the field trials progressed well in 2023.

Some delays were experienced in South Africa due to load-shedding (programmed electricity black-outs of up to 10 hours a day), flooding due to extreme weather in Tanzania, and civil unrest that escalated to war in the Amhara Region of Ethiopia. For safety reasons, the project activities in Ethiopia were moved to field sites in the Sidama Region in the south of the country.

*Participant enrollment progressed well in 2023.*

As of 31 December 2023, a total of 1719, 2462, and 836 participants had been enrolled in South Africa, Tanzania, and Ethiopia, respectively.

To ensure statistically robust data, 123 active TB cases are required in each study arm. The number of participants needed to identify 123 active TB cases in each country was calculated using TB prevalence data from 2017.

South Africa and Tanzania will reach the required sample size. The prevalence of TB in the Sidama Region of Ethiopia is considerably higher than in the Amhara Region, and we thus believe that the required number of active TB cases will be identified in 2024.



Above: Health extension workers at a health post included in the SeroSelect TB evaluation in Ethiopia.

On the left: Dr Kidist Bobosha, the PI in Ethiopia, and Dr Solomon Yimer greeting patients waiting outside a health post.



- » The SeroSelectTB team members worked diligently to compensate for pandemic-related delays and meet project aims during 2023.
- » We are very grateful for the 2-year no-cost extension granted by EDCTP2, which will enable us to successfully complete the project by the end of 2025.



Healthcare worker with TB Myths and Facts poster in Kiswahili at dispensary in Tanzania.

Newsletter graphic design and photo editing: M Savic  
 Text: C Holm-Hansen  
 Photo credits: M Savic/C Holm-Hansen/N Borain

