



Field evaluation of Standard Q Filariasis Antigen Test for Lymphatic Filariasis during a pre-transmission assessment survey in Sierra Leone, 2022.

#7025

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Background

As part of a multi-country evaluation, the SD Biosensor STANDARD™ Q Filariasis Ag Test (QFAT) was compared with (the currently used) Abbott Bioline™ Filariasis Test Strip (FTS) for classifying lymphatic filariasis (LF) prevalence at a population level and for ease of use in field conditions in Sierra Leone.

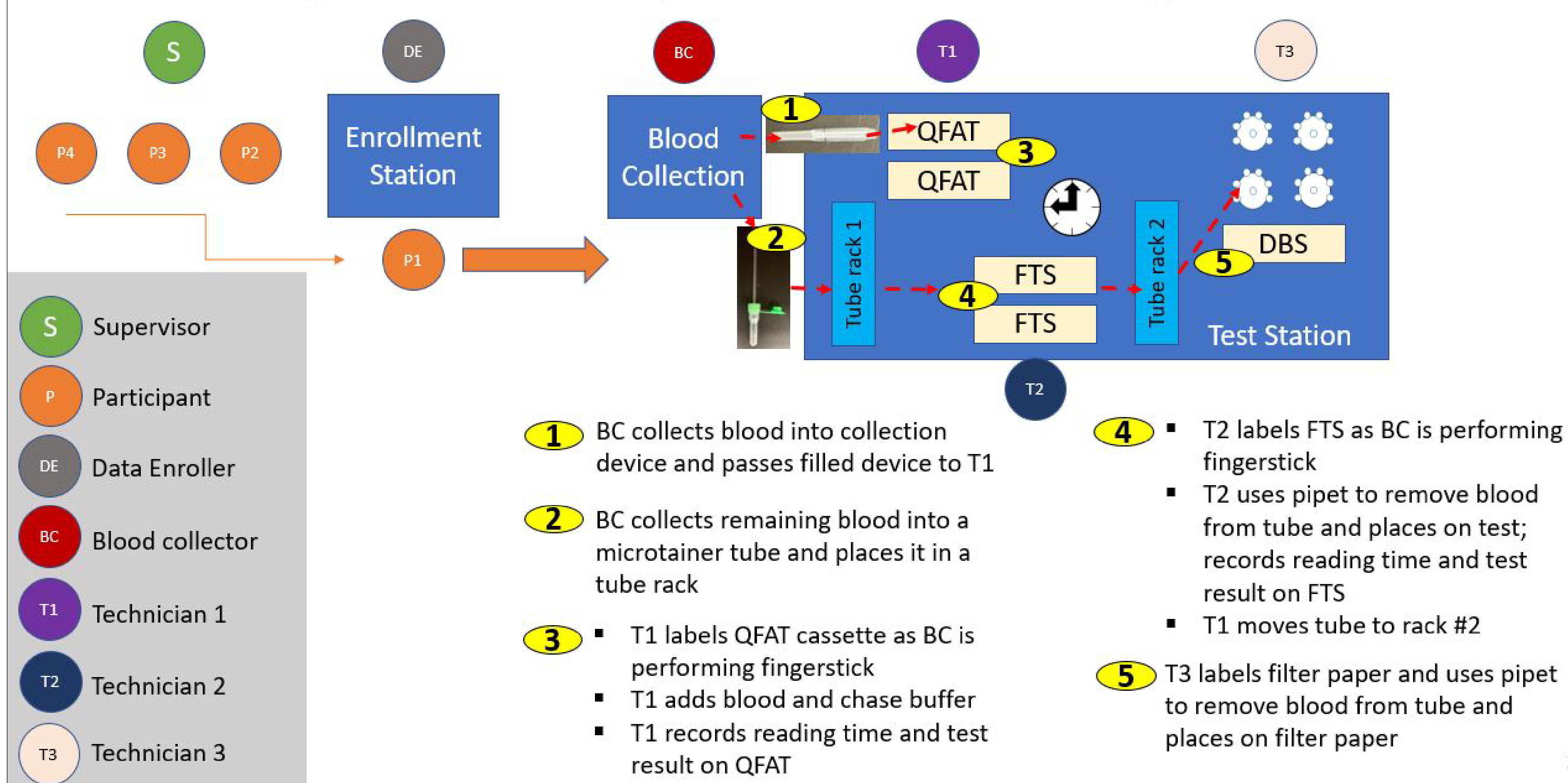
The evaluation was done in two districts, Bombali and Karene, where repeat pre-transmission assessment surveys (pre-TAS) were planned. Two sites with high LF antigen (Ag) prevalence in 2020 (4.1% in the village of Kagbo and 7.7% in the village of Makorba Yelimi) were chosen.

Field plan and Methods

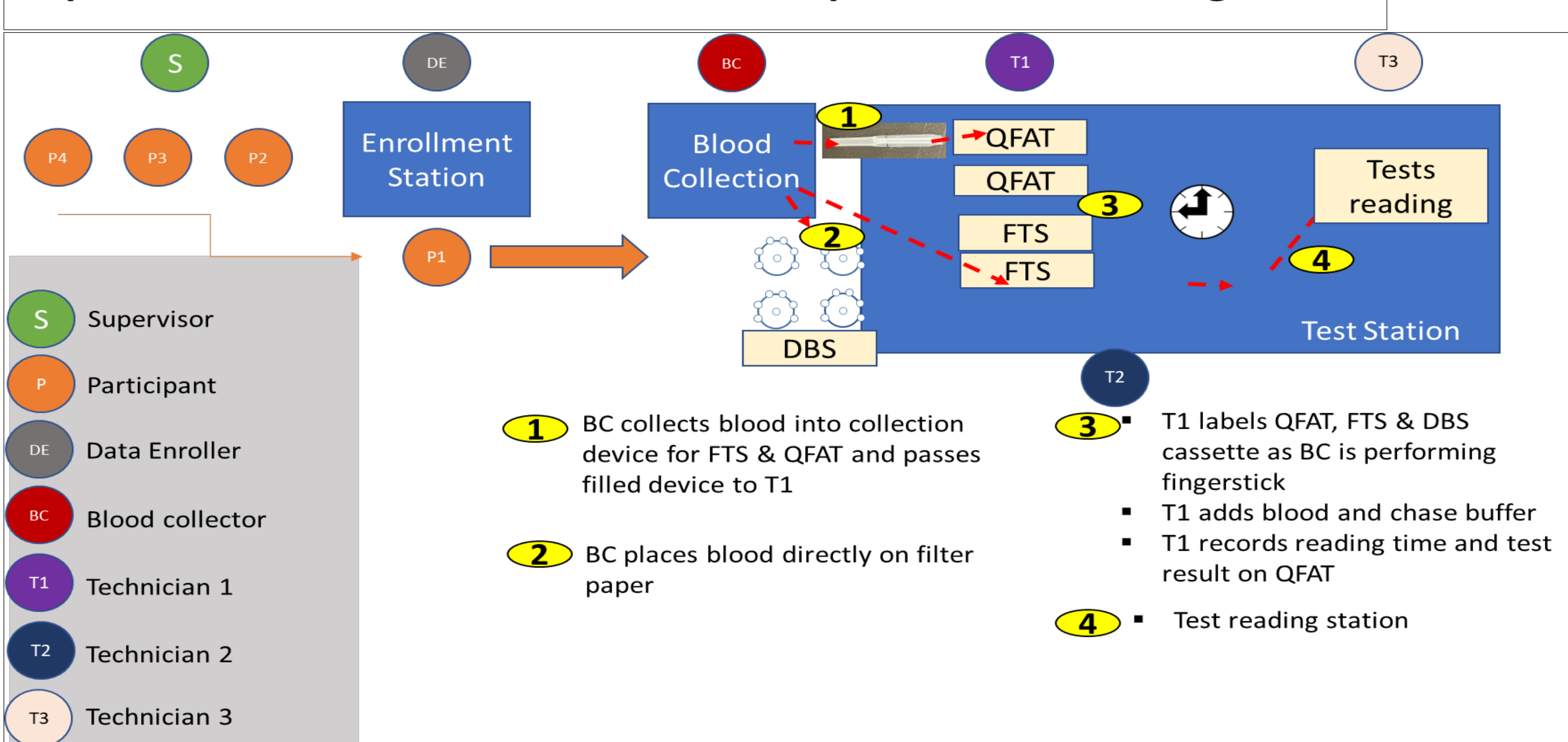
Convenience sampling was used to recruit 350 community members ≥5 years in each site. Blood was collected by fingerstick (20µl for QFAT and 75 µl for FTS). The reading time of the results for both tests was 10 minutes. For all positive or invalid results, a repeat test was performed.

Night blood smears were performed for all the positive participants. Slides were read by qualified laboratory technicians in Freetown.

Option 1: QFAT performed from fingerstick



Option 2 Makorba site: QFAT, FTS & DBS performed from fingerstick



Results

FTS and QFAT result distribution by age group

In total, 728 participants (5 - 91 years) were tested by QFAT and FTS. The positive rate was 4.8% (17/357) and 3.5% (13/367) for FTS and 3.4% (12/357) and 4.1% (15/367) for QFAT in Kagbo and Makorba Yelimi, respectively. None of the positive participants had circulating microfilariae. Nearly half (14/30) of those who tested positive with FTS during this survey also tested positive with FTS during the re-pre-TAS in 2020.

FTS and QFAT results distribution by sex

FINAL RESULT	Filariasis Test Strips			QFAT		
	female	male	Total	female	male	Total
Indeterminate	3	1	4	1	2	3
Negative	366	328	694	370	328	698
Positive	14	16	30	12	15	27
TOTAL	383	345	728	382	345	728

Among all participants, 4.1% (30/728) tested positive using FTS whereas 3.7% (27/728) tested positive using QFAT. A total of 0.01% of results were indeterminate using either test kits. More positive cases were recorded among those ≥20 years regardless of the type of test kit used.

There was no significant difference between participants who tested positive using FTS versus QFAT.

Test performance based on the method option used

Option 1	Final result FTS			Option 2	Final result FTS		
FINAL RESULT QFAT	positive	negative	Total	FINAL RESULT QFAT	Positive	negative	Total
positive	12	0	12	positive	10	4	14
negative	5	340	345	negative	1	349	350
TOTAL	17	340	357	TOTAL	11	353	364

Using the same method (option 2) QFAT registered three more positives than FTS (14 versus 11).

Discrepancy results between two tests

Results	FTS positive	FTS negative	FTS Indeterminate	Total
QFAT positive	22	4	1	27
QFAT negative	6	689	3	698
Indeterminate QFAT	2	1	0	3
Total	30	694	4	728

In cases where a second test was required for the positive result, both tests recorded four and three indeterminate results for FTS and QFAT, respectively.

Using the FTS results as the gold standard, the sensitivity and specificity of the QFAT was 78.6% and 99.4%, respectively. The Cohen's Kappa is 0.81. That all Ag positive cases were negative for microfilariae is not uncommon in individuals who have received treatment.

Invalid result for two tests

Results	FTS invalid 1er test	FTS invalid 2nd	FTS result
QFAT positive	1	1	2
QFAT negative	4	0	4
Invalid QFAT	0	0	0
Total	5	1	6

Six FTS were invalids, five in the first test and one in the confirmatory test. Zero QFAT tests were invalid. Among the two invalid tests for FTS with QFAT positive result, one was positive with FTS and one negative with FTS. In either option used, QFAT did not register any invalid tests.

Conclusions

In field conditions, QFAT was easy to handle and recorded zero invalid tests compared to FTS (six invalids). Using the FTS results as a reference standard, the sensitivity and specificity of the QFAT was 78.6% and 99.4%, respectively. The concordance between FTS and QFAT was 0.81 (Cohen's Kappa). The discrepancy found between the two tests in terms of positive tests was not statistically significant (P value=0.78). The results suggest that the QFAT is a credible LF diagnostic test when compared to the routinely used FTS; use of either test would result in the same programmatic decision.

Acknowledgment



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Discordant pairs



QFAT positive test