PROJECT TITLE

VALIDITY OF ICT WHOLE BLOOD TEST FOR THE DIAGNOSIS OF INFECTION IN BANCROFTIAN FILARIASIS

> **ID NO** EM (WHO /TDR 970878)

INVESTIGATORS <u>SPP</u>, SLH, AE, JY, RL & KDR

PERIOD OF STUDY

1 YEAR (December 1997 to December 1998)

OBJECTIVE

To determine the sensitivity and specificity of ICT whole blood test for detection of *W. bancrofti* infection

STUDY DESIGN

SUBJECTS

KNOWN ENDEMIC LOCALITY:189 PERSONSKNOWN NON-ENDEMIC LOCALITY :189 PERSONS

METHODS

NIGHT CONVENTIONAL BLOOD TEST (60 MICRO-LITRE) NIGHT VENOUS BLOOD MEMBRANE FILTRATION (1 ML) DAY-TIME WHOLE BLOOD ICT CARD TEST

RESULT

Table 2

Sensitivity, specificity, positive and negative predictive value of the ICT Card Test, compared to thick smear examination and membrane filtration technique

| | ICT card Test in comparison to | | |
|------------------------------|-----------------------------------|----------------------------------|--|
| | Thick smear examination | Membrane filtration technique | |
| Sensitivity | 98.5 % | 71.9 % | |
| Specificity | 100.0 % | 100.0 % | |
| Positive predictive value | 100.0 % | 100.0 % | |
| Negative predictive value | 99.5% | 88.3 % | |

CONCLUSIONS

The specificity ICT card test was 100% and its sensitivity was comparable to conventional night blood smear examination (98%).

Therefore, the day time ICT card test can replace the

• Conventional test, provided cost - benefit ratio is high,

• Compared to the conventional test in endemic locality the ICT card test could detect an additional 17% of cases, who were antigenemia positive but mf negative by conventional method.

• The sensitivity of ICT card test was only 72% in comparison to the microfilaremia by membrane filtration.

SENSITIVITY & SPECIFICITY CRITERIA

SENSITIVITY

For the purpose of the study, the sensitivity of the ICT test is defined as its ability to detect filarial antigen in persons who are microfilaremic according to results of night blood examination. Hence sensitivity will be estimated by percentage of proven microfilaremics who are positive by ICT card test during day time (10 a.m. to 3 p.m.).

A total of 100 carriers to be tested from a own endemic area

SPECIFICITY

The specificity of ICT card test is defined as its ability to exclude persons who are not infected with *W. bancrofti.* The specificity will be estimated by the percentage of non-infected persons (proven amicrofilaremics), who have negative by ICT card test

A significant number of people who are infected with *W. bancrofti* may not have demonstrable microfilariae in their blood and night blood examination cannot be used to identify persons who are definitely non-infected. Instead, individuals should be selected from non-endemic areas should be carefully selected. Only persons who have been born and resident all their lives in the non-endemic area should be included in the study.

A total of 200 apparently healthy persons from a non-endemic area to be tested for specificity.

Additional testing: (Optional)

100 amicrofilaraemics from the same endemic community may be tested for filarial antigenaemia by ICT card test during day time. area. These additional results shouls be analysed separately. As it will not be known with certainty who is infected or not among the mf negatives, these results will only provide an comparison of prevalence of infection as determined by ICT card test and night blood microfilaraemia.

It will help in estimating the true prevalence of infection. For example the prevalence of microfilaraemia is 20% and among the amicrofilaremics the ICT card positivity is 50 %, then the true

Recommended method for night bloodmicrofilaraemia was Knotts technique 1 ml venous night blood.

Table1Results of ICT Card Test in different groups of individuals

| Locality | Test Method | Groups | No. of Persons | ICT Card tes Positive (%) | st results Negative (%) |
|--------------------------------|--------------------------------------------|----------------|----------------------|---------------------------------|-------------------------------|
| Non- Endemi c (n=189) | Conventional and Membrane Filtration | Mf Positive | 189 | 0 (0.0%) | 189 (100%) |
| Endemi c (n=189) | Conventional Night blood survey | Mf Negative | 124 | 17 (13.7%) | 107 (86.3%) |
| | | Mf Positive | 65 | 64 (98.6%) | 1 (1.4%) |
| | Membrane filtration | Mf Negative | 100 | 17 (17%) | 83 (83%) |
| | | Mf Positive | 89 | 64 (71.9%) | 25 (28.1%) |

Table 2

Sensitivity, specificity, positive and negative predictive value of the ICT Card Test, compared to thick smear examination and membrane filtration technique

| | ICT Card Test in comparison to | | |
|------------------------------|-----------------------------------|----------------------------------|--|
| | Thick smear examination | Membrane filtration technique | |
| Sensitivity | 98.5 % | 71.9 % | |
| Specificity | 100.0 % | 100.0 % | |
| Positive predictive value | 100.0 % | 100.0 % | |
| Negative predictive value | 99.5% | 88.3 % | |

Table 3

The results of ICT test in relation to micro filarial count as determined by the membrane filtration technique.

| mf count (membrane filtration) | Total no. tested (n) | ICT Carc No. of ICT positive (% of n) | I Test No. of ICT negative (% of n) |
|-----------------------------------|-------------------------|---------------------------------------------|-------------------------------------------|
| 1-4 | 22 | 7 (31.8) | 15 (68.2) |
| 5-9 | 8 | 3 (37.5) | 5 (62.5) |
| 10-24 | 4 | 4 (100.0) | 0 (0.0) |
| 25-49 | 1 | 1 (100.0) | 0 (0.0) |
| 50-99 | 9 | 8 (88.9) | 1 (11.1) |
| 100-199 | 13 | 11 (84.6) | 2 (15.4) |
| 200-399 | 14 | 12 (85.7) | 2 (14.3) |
| >400 | 18 | 18 (100.0) | 0 (0.0) |
| Total | 89 | 64 (71.9) | 25 (28.1) |

Table 4

Comparison of sensitivity, specificity, positive and negative predictive values of ICT test card between original readings and those of three independent observers

| ICT Card Readers | Sensitivity % | Specificity % | Positive predictive value % | Negative predictive value % |
|---------------------------|------------------|------------------|-----------------------------------|-----------------------------------|
| Original reading | 71.9 | 100.0 | 100.0 | 83.3 |
| Independent observer 1 | 70.6 | 99.4 | 98.4 | 86.8 |
| Independent observer 2 | 72.9 | 99.4 | 98.4 | 88.4 |
| Independent observer 3 | 69.3 | 100.0 | 100.0 | 87.1 |

Age specific results of ICT Card Test in Endemic normal individuals (n = 100)



Result of ICT Card Test according to microfilarial count (Membrane filteration)







Mf count wise ICT test Results