The first pilot of participants through the process of the study is shown in figure 2. There was good agreement between the participant contacted and read OFT ST and the researcher reading the same test as well as between the participant contacted and read OFT ST and researcher conducted OFT. Table 2.

![Image](https://via.placeholder.com/150)

**Figure 3: Participant flow through study protocol**

**RESULTS**

A total of 5,757 participants were recruited, 7,006 of whom were women and 66.8% had previously tested for HIV. Literacy levels were higher in the urban community and facility-based testers than in the rural community testers.

<table>
<thead>
<tr>
<th>Study Area</th>
<th>Total Participants</th>
<th>Rural Participants</th>
<th>Urban Participants</th>
<th>Facility Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (% previous testers)</td>
<td>No. (% previous testers)</td>
<td>No. (% previous testers)</td>
<td>No. (% previous testers)</td>
</tr>
<tr>
<td></td>
<td>5,757 (99.9)</td>
<td>3,152 (98.0)</td>
<td>2,605 (98.3)</td>
<td>1,576 (99.8)</td>
</tr>
</tbody>
</table>

- **Total participants:** 5,757 (99.9)
- **Rural participants:** 3,152 (98.0)
- **Urban participants:** 2,605 (98.3)
- **Facility participants:** 1,576 (99.8)

**Table 2:** Comparison of OFT between urban and professional users.

**Sensitivity**

The sensitivity of OFT-ST was 94.2% (95% CI: 91.5-95.9) when compared to RDT, with a specificity of 97.1% (95% CI: 96.9-97.3) and 96.8% (95% CI: 96.5-97.1) when compared to the gold standard laboratory algorithm.

**Table 3:** Comparison of OFT between urban and professional users.

**CONCLUSION**

This study provides robust evidence of the sensitivity and specificity of the OraQuick® self-retrieval HIV self-test kit, with prior demonstration, in the hands of intended users in urban and rural Zambia, and is likely to be generalizable to other settings. Pilot studies of this test in rural communities indicate that it is a promising tool for use by lay people in Zambia and elsewhere. Additional analysis of the data in the study will be needed, at least until widespread familiarity with the test develops, in order to obtain definitive results.

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