

# Virological validation of finger-stick whole blood HIV self-test Exacto® Test HIV

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## Abstract

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## Protocol

### Step 1.

In the inclusions sites. HIV self-test Exacto® Test HIV was carried out by participants and the results was read by healthcare professional. In parallel, Serological HIV testing was first carried out according WHO II algorithm for HIV testing using in series two test: Alere Determine™ HIV-1/2 (Alere Medical Co. Ltd., Matsudo-shi, Chiba-ken, Japan) as first test and Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd., Bray, Co. Wicklow, Ireland) as second confirmatory test.

### Step 2.

In the reference laboratory. All positive and indeterminate samples by initial WHO II algorithm screening were further re-tested on plasma with Alere Determine™ HIV-1/2 (Alere Medical Co. Ltd.) and Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd.) as first two HIV tests, followed by third HIV testing using recomLine HIV-1 & HIV-2® IgG (Biosynex), according to the 2012-revised, 2015-consolidated "WHO strategy for HIV testing. Finally, HIV viral load was assessed by molecular biology on plasma from all HIV-seropositive or indeterminate samples, and 1 out 2 HIV-seronegative plasmas randomly selected.