

# InTec HIV Rapid Test Assay Evaluations

## International Red Cross -Germany

**Summary:** The ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) test had an overall specificity of 100.0% (calculated with all data from blood donors, patients, serum/plasma-comparison (not spiked) and cross contamination tests; N=2,215 samples tested). The sensitivity in spiked samples was 100% for HIV-1 and HIV-2. Specificity fulfils the criteria of the common technical specification (CTS) 2009/886/EC. No cross-reactivity with other virus antibodies was detected and the assay can be used for plasma, serum and whole blood samples.

Test	Sensitivity	Specificity
InTec HIV 1&2 Rapid Test	<b>100%</b>	<b>100%</b>

## Charing Cross Hospital-UK

**Summary:** InTec ADVANCED QUALITY™ ONE STEP HIV 1&2 test showed superior performance compared to SD Bioline RDT by detecting lower antibody titres, meaning shorter window of detection, resulting in earlier detection of HIV antibodies. Further study will be underway in order to provide more precise interpretation of evaluation results. InTec ADVANCED QUALITY™ ONE STEP HIV (1&2) test was even able to detect some P24 antigen positive sample. (A Cox, D Muir)

Test	Sensitivity	Specificity
InTec HIV 1&2 Rapid Test	<b>98.5%</b>	<b>99.7%</b>
Abbott - SD Bioline	96.7%	99.5%

## Institute of Tropical Medicine-Belgium

**Summary:** The ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) test is colloidal gold enhanced rapid immunochromatographic test for qualitative detection of antibodies to HIV-1 and 2 in human whole blood, serum or plasma. The ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) test showed on a panel of 600 HIV positive samples (260 HIV-1 positive, 40 HIV-1 non-B positive, 100 HIV-2 positive and 100 paired fresh HIV-1 whole blood/plasma samples) a sensitivity of 100%. The assay showed 100% specificity for all HIV negative potentially cross-reactive samples.

The ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) test was able to detect 49 out of 117 seroconversion panel members; the third-generation reference assay (Enzygnost Anti-HIV ½ plus or Genscreen HIV ½ v2) detected 42 out of 117.

Test	Sensitivity	Specificity
InTec HIV 1&2 Rapid Test	<b>100%</b>	<b>100%</b>