

BLOOD BORNE DISEASE

STANDARD Q HIV 1/2 Ab 3-Line

WHO PQ
approved

| | |
|--------------------------|---|
| Test type | Professional Use Only |
| Intended use | Detection of specific antibodies to all isotypes of HIV-1/2 |
| Specimen type | Whole blood, Serum, Plasma |
| Specimen volume | Whole blood: 20µl, Serum/Plasma: 10µl |
| Testing time | 10-20 mins |
| Storage condition | 2 – 40°C / 36 - 104°F |



» **Test Performance** in accordance with CTS

| STANDARD Q HIV 1/2 Ab 3-Line Test | | | |
|-----------------------------------|-------------------------------------|-----------------------|---|
| Sensitivity [95% CI] | | Specificity [95% CI] | |
| Total | 99.8% [98.9-100.0%](500/501) | Total | 100.0% [99.8-100.0%] (1,900/1,900) |
| HIV-1 positive | 99.7% (360*/361) | EDTA plasma | 100.0% (1,000/1,000) |
| HIV-1 positive (non-B subtypes**) | 100.0% (40/40) | Whole blood | 100.0% (500/500) |
| HIV-2 positive | 100.0% (100/100) | Hospitalized patients | 100.0% (200/200) |
| | | Pregnant women | 100.0% (200/200) |

* The missed sample was collected from a patient receiving HAART very soon after seroconversion phase.

** non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

» **Ordering Information**

| Product | Contents | Pack Size | CAT No. |
|--------------------------|---|-----------|-----------|
| Q HIV 1/2 Ab 3-Line Test | Device/Assay diluent/Capillary Tube/Lancet/Alcohol swab | 25 Tests | 09HIV30D |
| | Device/Assay diluent | 25 Tests | 09HIV30DM |
| | Multi-Device/Assay diluent | 100 Tests | 09HIV30F |

HEPATITIS

STANDARD Q HAV IgM

CE

| | |
|--------------------------|---|
| Test type | Professional Use Only |
| Intended use | Detection of Hepatitis A virus IgM antibody |
| Specimen type | Whole blood, Serum, Plasma |
| Specimen volume | 10µl |
| Testing time | 15-20 mins |
| Storage condition | 2 – 40°C / 36 - 104°F |



» **Test Performance**

Reference : Internal evaluation

| Reference | Sensitivity | Specificity |
|-----------|--------------|------------------|
| CLIA | 100% (26/26) | 98.04% (450/459) |

» **Ordering Information**

| Product | Pack Size | CAT No. |
|----------------|-----------|----------|
| Q HAV IgM Test | 25 Tests | 09HAV10D |