

## Qualisa HIV 4.0

### Fourth generation ELISA for the detection of antibodies to HIV 1/2 & O subtypes and p24 antigen in human serum or plasma

**Intended Use:** \_\_\_\_\_

Qualisa HIV 4.0 is intended to be used for the detection of antibodies to HIV-1 & HIV-2 & O subtypes and p24 antigen in human serum or plasma.

**Qualisa HIV 4.0 kit components:**

|                          |   |
|--------------------------|---|
| <b>Coated microwells</b> | Microwells are coated with monoclonal anti p-24 antibodies and recombinant antigens representing both HIV-1 and HIV-2 |
| <b>Positive control</b>  | Inactivated and stabilized human serum reactive for HIV-1 with preservatives  |
| <b>Negative control</b>  | Inactivated and stabilized human serum non reactive for HIV-1, HIV-2, HBsAg and HCV                                   |
| <b>Conjugate</b>         | Antigen-HRP conjugate (50x). To be diluted 50 times with conjugate diluent  |
| <b>Antibody reagent</b>  | Biotinylated monoclonal anti-p24 antibody. Ready to use   |
| <b>Conjugate diluent</b> | Buffered solution containing stabilizing proteins and preservatives   |
| <b>Sample diluent</b>    | Buffered solution containing stabilizing proteins and preservatives   |
| <b>Substrate</b>         | Solution containing Tetramethyl benzidine (TMB) and hydrogen peroxide. Ready to use                                   |
| <b>Wash buffer</b>       | Buffer containing surfactants (20x). To be diluted 20 times with distilled water or deionized water                   |
| <b>Stop solution</b>     | Diluted sulphuric acid. Ready to use  |
| <b>Other Accessories</b> | Microwell holder, Instructions for use, ELISA protocol sheet, Plate sealer and Package Insert                         |

**Performance Characteristics:**

|                          |                            |
|--------------------------|----------------------------|
| <b>Sensitivity:</b> 100% | <b>Specificity:</b> 99.71% |
|--------------------------|----------------------------|

| FEATURES                                      | BENEFITS   |
|---|--|
| <b>High p24 antigen sensitivity: 20 pg/ml</b> | Excellent detectability and specificity  |
| <b>High S/CO</b>                              | Higher OD values in low titre samples and 'grayzone' reactions are highly in true positive samples                           |
| <b>DHS<sup>3</sup> technology</b>             | High detectability particularly in low titre samples<br>High antibody sensitivity<br>High thermal stability<br>Long-use life |
| <b>High specificity</b>                       | Good correlation with other licensed ELISAs  |
| <b>Early detection within 2 weeks</b>         | Serves to contain the spread of infection, by timely detection   |

| Storage / Stability | Temperature | Duration  |
|---------------------|-------------|-----------|
| Unopened kit        | 2-8°C       | 12 Months |
| Opened kit          | 2-8°C       | 8 Months  |

| Available Pack Sizes |           |
|----------------------|-----------|
| 96 Tests             | 192 Tests |
| 480 Tests            |           |