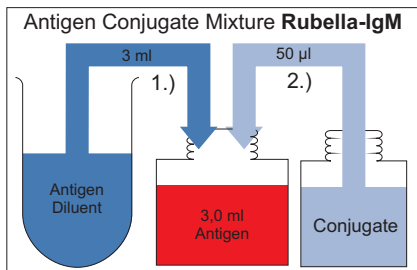
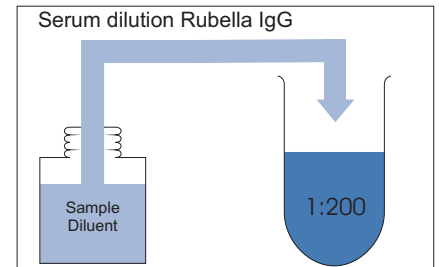
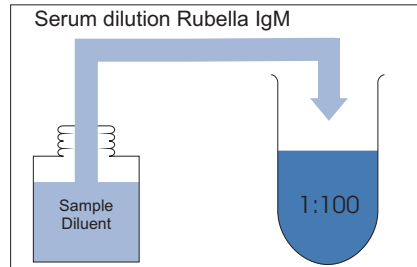
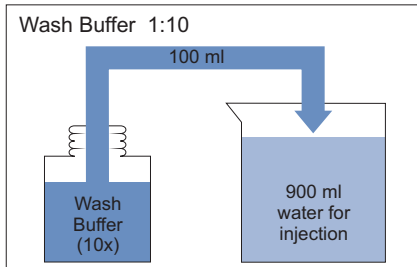
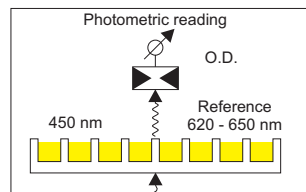
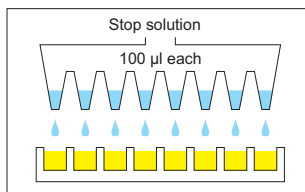
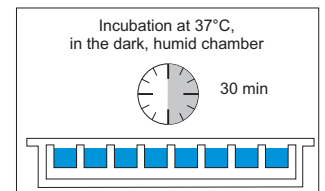
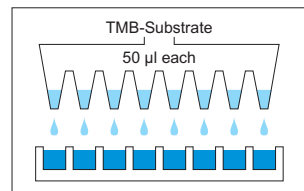
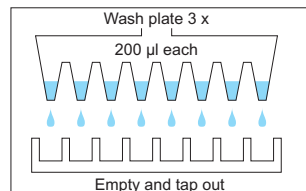
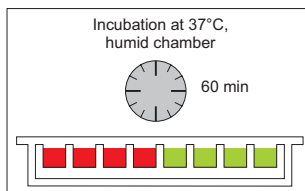
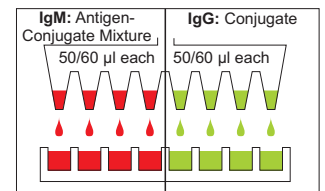
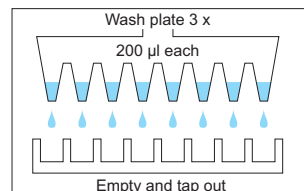
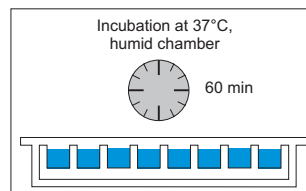
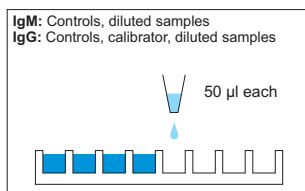


## Preparation of the reagents:



## Test run:



For test valuation and interpretation of results see overleaf

## Test valuation:

- The photometric reading is performed at 450 nm as measuring wave length (620-650 nm as reference wave length).
- The OD of the blank (well A1) is subtracted from all OD values.
- The mean OD value of the **negative control has to be < 0,100**.

### Rubella-IgM:

- The mean OD value of the **positive control has to be > 0,800**.
- **Serum cut-off = Mean OD of the negative control + 0,320**.
- **Grey zone = Cut-off ± 10%**.

### Rubella-IgG:

- The mean OD value of the **calibrator** has to be above the lower OD limit and the unit value of the **positive control** has to be within the nominal range indicated in the **lot specific data sheet**.

- **Correction of the results:**

$$OD_{\text{corrected}} = \frac{\text{Nominal OD value of the calibrator}}{\text{Measured OD of the calibrator}} \times OD_{\text{measured}}$$

- **Quantification of the results:**

$$\text{Concentration [IU/ml]} = b / \left( \frac{a}{OD_{\text{corrected}}} - 1 \right)$$

- **The cut-off for immunity is = 15 IU/ml.**

- **Grey zone = cut-off ± 20% (= 12 - 18 IU/ml).**

## Interpretation of the results:

- Samples with OD values below the grey zone are reported as **NEGATIV**
- Samples with OD values within the grey zone are reported as **BORDERLINE**.
- Values within the grey zone should be controlled for titer movement by testing second serum samples after 14 days in parallel with the initial serum samples.
- Values with OD values beyond the grey zone are reported as **POSITIVE**.
- Samples with IgG values exceeding the upper limit of the grey zone are reported as **POSITIVE** with regard to immunity.