

## D-Dimer Quality Control

**Lot:** Please refer to the label

**Expiry Date:** Please refer to the label

### Product name

Generic name: D-Dimer Quality Control

Trade name: D-Dimer QC

### Package Specification

2× 0.5 mL/bottle    REF: 52105018

### Intended Use

This product is used for quality control of D-Dimer on quantitative immunofluorescence analyzer.

### Main Components

Recombinant D-Dimer protein.

### Storage and Stability

UNOPENED: the QC is stable for 18 months (see the label for specific date) at -25°C to 8°C.

OPENED: the reconstituted QC is stable for 6 days at -20°C or 6 days at 2-8°C in the shade.

Note: Avoid freezing and thawing reconstituted QC repeatedly.

### Test Methods

1. Bring the quality control to room temperature (18-30°C) before use.
2. Carefully open the bottle cap to avoid spurting of the contents.
3. Add 0.5 mL of purified water.
4. Cover the bottle cap and leave at room temperature for 15 minutes, gently shake the bottle to fully dissolve the dry powder.
5. After the dry powder is fully dissolved, use it as a sample.

### Precaution

1. Only used for in vitro diagnostic, please refer to the Operation Manual.
2. Do not use the expired reagents.
3. Do not use reagents of different batches together.

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## Target Values

The quality control products produced in each batch will be submitted to several reference laboratories, and the evaluation will be completed after reliable results are obtained by these laboratories. With each batch, a quality control range is provided for each parameter and each parameter method. The quality control range is equal to the assigned mean  $\pm$  3SD. This can produce extremely accurate values, which can be used by laboratories to ensure the accuracy of their methods.

| Range   |      |                              |                              |                              |
|---------|------|------------------------------|------------------------------|------------------------------|
| Analyte | unit | Target                       | low                          | high                         |
| D-Dimer | mg/L | Based on the batch<br>number | Based on the batch<br>number | Based on the batch<br>number |

### MANUFACTURER



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