# Finecare™ D-Dimer Control

*The* Finecare™ *D-Dimer controls are supplied at 3 levels, level 1 (REF: W812; W812-L), 2 (REF: W812-N) and 3 (REF: W812-H). Target value and range of level 1 to level 3 is corresponding to Low (L), Normal (N) and High (H).*

***Caution: This instruction for use applies to this lot of product only.***

## INTENDED USE

The Finecare™ D-Dimer Control is intended for use as an assayed quality control to monitor the precision of D-Dimer in laboratory testing procedures for Finecare™ D-Dimer Rapid Quantitative Test.

*For in vitro diagnostic use only. For professional use only.*

## SUMMARY AND PRINCIPLE

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. The test is based on the fluorescence immunoassay technology using a sandwich immunodetection method.

## PRECAUTIONS

1. This product is for in vitro diagnostic use only. Do not swallow.
2. Do not mix components from different control lots.
3. Do not use control beyond the expiration date.
4. Tests should be applied by professionally trained staff working in certified laboratories.
5. Do not use the control if the vial is damaged or not well sealed.
6. The operation should be conducted strictly according to the instruction.
7. The Finecare™ D-Dimer Control is supplied lyophilized. Carefully reconstitute each vial of exactly with 0.5ml of distilled water. The control should be return to room temperature before reconstitution.
8. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam.
9. If an expected value is not obtained. Please check whether the test device is expired or the operation is improper. If not, please use another new control to retest.
10. If there is agglomeration or floccule after reconstituting, the product may be overheating or frozen. Discard it and use another new control.
11. The human source material used to manufacture this control was tested and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source materials for which there are no approved tests. All human source material should be considered potentially infectious and handled with the same precautions used with patient specimens. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.

## MATERIAL

### Material Provided

1. Control (lyophilized): 0.5ml×1
The controls mainly contain D-Dimer recombinant antigen, human serum, glycine and 0.02% sodium azide as preservative.
2. Leaflet with instructions for use

### Material Required But Not Provided

1. Finecare™ series FIA instruments
2. Finecare™ D-Dimer Rapid Quantitative Test
3. Transfer Pipette Set
4. Distilled water
5. Timer

## STORAGE AND STABILITY

1. Store at 2～8℃ up to the expiration date.
2. If removed from refrigerator, allow the test for 15 minutes to return to room temperature before testing.
3. Reconstituted vials are stable for 8 hours at room temperature.

## TEST PROCEDURE

1. Take out the D-Dimer control from refrigerator and balance it at room temperature for 15 minutes before testing.
2. Open the vial very carefully, avoiding any loss of material.
3. Reconstitute each vial exactly with 0.5ml of distilled water.
4. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam.
5. The D-Dimer control reconstituted should be treated the same as serum/plasma specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used.

## VALUE ASSIGNMENT

The target value and range were derived from replicate analyses and are specific for this lot of product. The tests were performed by using manufacturer supported reagents and a representative sampling of this lot of product.

**Value:**

| Level | Target value | Range |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |

## INTERPRETATION OF RESULTS

The test values must be within the acceptable ranges. Those outside the range may indicate unsatisfactory performance. The causes for such discrepancy may be variation in techniques, instruments, reagents etc., which should be evaluated by the laboratory.

## LIMITATIONS OF PROCEDURE

1. This product is applicable for Finecare™ D-Dimer Rapid Quantitative Test only.
2. This product is not intended for use as a calibrator or a standard.

## PERFORMANCE CHARACTERISTICS

### Precision

***Intra-Vial Precision***

Within-run precision has been determined by using 10 replicates of one vial control for each of three lots on the Finecare™ D-Dimer Rapid Quantitative Test. C.V. is ≤15%.

***Inter-Vial Precision***

Between run precision has been determined by using 10 different vials of controls for three lots on the Finecare™ D-Dimer Rapid Quantitative Test. C.V. is ≤15%.

## BIBLIOGRAPHY OF SUGGESTED READING


[1] Palareti G. Fibrinogen/fibrin Degradation Products: Pathophysiology and Clinical Application, Fibrinolysis. 1993; 7: 60-61.

[2] Gaffney PJ. The Occurrence and Clinical Relevance of Fibrin Fragments in Blood, Annals New York Academy of Sciences. 1983; 407-423.

[3] Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Public Health Service, 5th Edition, 2007.


## INDEX OF SYMBOLS

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|---|---|---|---|
| IVD | In Vitro Diagnostic Use | | See Instruction for Use |
| REF | Catalog # | | Manufacturing Date |
| LOT | Batch Number | EC REP | Authorized Representative |
| 2℃ 8℃ | Store between 2～8℃ | | Expiry Date |
| | Keep away from Sunlight | | Keep Dry |
| | Manufacturer | CONTROL | Control |


Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China

EC REP
Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel, Belgium


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Version: 04/05/2016


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