Cat. No 4-546

DIAGNOSTIC KIT FOR DETERMINATION OF D-DIMER CONCENTRATION

HC – D-DIMER

INTRODUCTION

FDPs (Fibrin and Fibrinogen Degradation Products) are generic name for several degradation products that are formed as the result of plasmin mediated, proteolytic degradation of fibrin and fibrinogen. FDP assay become important test to diagnose or monitor fibrinolytic disorder, especially disseminated intravascular coagulation (DIC). But FDP assay also detects the degradation products of fibrinogenolysis. D-dimer assay is more specific for fibrinolysis because it can only be produced as the result of plasmin mediated, proteolytic degradation of fibrin.

METHOD PRINCIPLE

This D-dimer assay is a turbidimetric assay that utilizes antibody coated latex particles, in the presence of D-dimer, the particles aggregate to form larger aggregates and light scattering increases. The increase in scattered light is proportional to the amount of D-dimer in sample.

REAGENTS

Package

1-Reagent	1 x 58 ml
2-Reagent	1 x 19 ml
D-Dimer Diluent	2 x 40 ml

Buffer (1-Reagent), latex (2-Reagent) and D-Dimer Diluent stored at 2-10°C are stable until expiry date printed on the package. The reagents are stable for 4 weeks on board the analyser at 2-10°C. Do not freeze the reagents. Protect from light and contamination!

Concentrations in the test

Tris(hydroxymethylo)aminomethane	0.38 mol/l
suspension of latex particles sensitized with anti-D-Dimer antibodies (mouse)	0.2 w/v%

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products from human source have been tested for the HbsAg and antibodies to HCV and HIV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- Allow the reagents to equilibrate at the room temperature before use.
- Swirl the latex reagent (2-Reagent) well before use.
- Do not mix different lots of reagent.
- Do not add new reagent to the remaining reagent.
- Pay attention not to contaminate cuvettes with dust or detergents.
- Sometimes turbidity appears in buffer reagent (1-Reagent) but it has no influence on assay results.
- Immunoassay cannot deny non-specific reaction and rarely occurs prozone effect when assay samples containing unusually high D-dimer level.

SPECIMEN

Plasma.
Nine volumes of fresh blood are collected in one volume of 0.11M trisodium citrate, followed by centrifugation at 3000 x g for 10-30 minutes. Use supernatant as plasma sample.
Samples containing more than 20 µg/ml D-dimer should be re-assayed, using a 1:10 sample dilution with D-Dimer Diluent.
If the measurement is done after 8 hours since separation of plasma from blood, the samples should be kept in refrigerator for up to 4 days. After 4 days the samples should be kept in freezer for up to 2 months.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [1]

plasma	< 0.5 µg/ml

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY D-DIMER CONTROLS (Cat. No 4-459) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY D-DIMER CALIBRATOR (Cat. No 4-259) is recommended.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Hitachi 912, BS-400 and TBA80FR. Results may vary if a different instrument is used.

- **Sensitivity:** 0.3 µg/ml.

- **Linearity:** up to 20 µg/ml.
  For higher concentrations dilute the sample with D-Dimer Diluent in the ratio of 1:10 and repeat the assay. Multiply the result by 11.

- **Specificity / Interferences**
  Haemoglobin up to 4.6 g/dl, conjugated bilirubin up to 19.6 mg/dl, free bilirubin up to 18.4 mg/dl, RF up to 500 IU/ml do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.67	0.02	0.80
level 2	9.53	0.13	1.39

Reproducibility (day to day) n = 80	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.60	0.11	4.38
level 2	8.99	0.48	5.36

- **Method comparison**

A comparison between CORMAY kit (y) and another commercially available kit based on latex turbidimetric assay (x) using 54 samples gave following results:
y = 0.991 x + 0.028 µg/ml;
R = 0.9989 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE
1. Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 332 (2006).

Date of issue: 05. 2012.

MANUFACTURER

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05/12/05/12