D-Dimer
Multi-Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Catalogue No.	*Quantity*	*Reagent*	*Storage*
GL198DD	1 x 40ml	D-D Reagent 1	2 – 8 °C
	1 x 15ml	D-D Reagent 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of fibrinogen / fibrin degradation products (D-Dimer) in human plasma on automated and semi-automated analysers. Measurement of D-Dimer is used as an aid in detecting the presence of intravascular coagulation and fibrinolysis.

SUMMARY AND EXPLANATION:

Thrombus formation is normally followed by an immediate fibrinolytic response. The resultant generation of plasmin causes the release of fibrin degradation products (predominantly containing D-Dimer) into the circulation. Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC).

PRINCIPLE OF THE TEST:

This D-Dimer Assay is based on a latex enhanced immunoturbidimetric assay. D-Dimer proteins in the sample bind to the specific anti-D-Dimer antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of D-Dimer in the sample.

WARNINGS AND PRECAUTIONS:

In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Contains Sodium Azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide build-up. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Refer to relevant user's manual or laboratory internal practice for routine maintenance procedures. Instrument settings are available upon request.

COMPONENTS:

Component	*Ingredients*	*Concentration*
Reagent 1	Tris Buffer (pH 8.2)	100 mM
Reagent 2	Suspension of anti-human D-Dimer mouse monoclonal antibody coated latex particles	0.2 %

REAGENT PREPARATION AND STABILITY:

Reagent 1 is ready for use. Mix R2 reagent gently before use and once weekly thereafter.
If stored and handled properly, unopened components are stable at 2-8°C until expiry date stated on the label.
Once opened, reagents are stable for 1 month on-board the analyser at 2-8°C. Avoid contamination.

TYPE OF SPECIMEN:

Plasma samples with 0.109 Molar (~3.2%) Na Citrate concentration can be used for the D-Dimer assay. Mix the sample by gentle inversion prior to centrifugation. Centrifuge and separate plasma as soon as possible after collection. Samples can be stored at 2-8○C, if analysed within 4 days, and 3 months when stored at -20°C. When thawing frozen samples, thaw at room temperature and mix thoroughly before use. Once thawed, a sample may not be refrozen for analysis.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalogue No.*	*Description*	*Catalogue No.*
D-Dimer Controls	GQC198	Analyser & Consumables	N/A
D-Dimer Calibrators	GL9198	General Laboratory Equipment	N/A

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

Calibration:
Using the recommended calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part.
- When Quality Control results are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program:
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Q.C. laboratory programme.

REFERENCE RANGE:

The reference interval was established to be < 0.50 µg/mL FEU. However, each laboratory is recommended to establish a range of normal values for the population in their region. Results are printed out in µg/mL. The Glenbio D-Dimer Assay result unit is µg/mL FEU (Fibrinogen Equivalent Units).

LIMITATIONS:

1. Glenbio D-Dimer Assay is not intended to be used for exclusion of VTE.
2. Glenbio D-Dimer Assay has not been established in pediatric subjects.
3. For assays employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. Glenbio D-dimer Assay has been formulated to minimize this interference; however, specimens from patients who have been routinely exposed to animals or to animal serum products may contain heterophilic antibodies which may cause erroneous results.
4. As with any latex turbidimetric immunoassays, Glenbio D-Dimer Assay runs should be followed with appropriate and thorough wash steps. Please consult instrument manuals for further information.
5. D-Dimer Assay reagents, calibrators, and controls should be stored at 2-8°C. DO NOT FREEZE.

PERFORMANCE CHARACTERISTICS

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values

Linearity:
This assay is linear from 0.15 to 8.0 µg/mL FEU.

Interfering substances:

Bilirubin:	Up to 40 mg/dL
Bilirubin Conjugated:	Up to 40 mg/dL
Haemoglobin:	Up to 500 mg/dL
Triglycerides:	Up to 1000 mg/dL
Rheumatoid Factor:	Up to 100 IU/mL
Ascorbic acid:	Up to 176 mg/dL
Heparin:	Up to 1.5 IU/mL
HAMA:	Up to 490 ng/mL

LOB, LOD, LOQ:
LOB was determined to be 0.06 µg/mL FEU.
LOD was determined to be 0.09 µg/mL FEU.
LOQ (lowest concentration for which CV is less than a target of 20%) is 0.15 µg/mL FEU.

Precision:

Within Run N = 240	*Mean (µg/mL FEU)*	*SD*	*% CV*	*Between Run N = 240*	*Mean (µg/mL FEU)*	*SD*	*% CV*
Level 1	0.97	0.03	2.9	Level 1	0.97	0.04	4.4
Level 2	2.99	0.05	1.6	Level 2	2.99	0.08	2.8
Level 3	7.47	0.11	1.4	Level 3	7.47	0.27	3.6

Method Comparison:
Using 128 samples (with D-Dimer ranging from 0.17 to 7.95 µg/mL FEU), a comparison between this D-Dimer test (y) and another commercially available test (x), gave the following results:

Parameter	**Total of 3 sites**
Slope	0.979
95% CI	0.909 to 1.060
Intercept	-0.106
95% CI	-0.260 to 0.026
R^2	0.939

The bias around the medical decision point is -0.12 µg/ml FEU.

BIBLIOGRAPHY:

1. BJH GUIDELINE. BRITISH JOURNAL OF HAEMATOLOGY. 124, 15-25.
2. ALAN H.B. WU. TIETZ CLINICAL GUIDE TO LABORATORY TESTS. FOURTH ED. SAUNDERS ELSEVIER, 11830 WESTLINE INDUSTRIAL DRIVE, ST. LOUIS, MISSOURI 63146. 2006; 328-329.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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