

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

#K032419

B. Analyte:

Fibrin degradation product (D-Dimer)

C. Type of Test:

Quantitative

D. Applicant:

Instrumentation Laboratory Co.

E. Proprietary and Established Names:

quantex D-DIMER; Fibrin Degradation Products Assay (D-Dimer)

F. Regulatory Information:

1. Regulation section:

CFR 864.7320

2. Classification:

Class II

3. Product Code:

DAP, GHH

4. Panel:

Hematology (81)

G. Intended Use:

1. Intended use(s):

The Instrumentation Laboratory Co. (IL) quantex D-DIMER is a latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on automated clinical chemistry analyzers.

2. Indication(s) for use:

Quantex D-DIMER is a latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on automated clinical chemistry analyzers.

3. Special condition for use statement(s):

N/A

4. Special instrument Requirements:

The automated ILab 600 Clinical Chemistry System (#K980757)

H. Device Description:

The IL quantex D-DIMER Kit consists of Latex Reagent, Phosphate Buffer, Calibrator and Controls I/II. The Latex Reagent is a suspension of polystyrene latex particles of uniform size, coated with a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. The Calibrator and Controls are solutions of partially purified D-Dimer from human fibrin digested with human plasmin. The quantex D-DIMER turbidimetric immunoassay measures the decrease in transmitted light caused by aggregates formed by latex particle agglutination in the presence of D-Dimer.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Instrumentation Laboratory Co. IL Test D-Dimer
2. Predicate K number(s):
#K972696
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Assay type	Latex enhanced immuno-assay	SAME
Monoclonal anti-body (MAB)	MA-8D3	SAME
Test principle	Turbidimetric agglutination	SAME
Buffer	Phosphate buffer	SAME
Calibrator/Controls	Lyophilized solution of partially purified D-Dimer, from human fibrin digested with human plasmin.	SAME
Storage	2 - 8° C.	SAME
Differences		
Item	Device	Predicate
Instrumentation	Automated clinical chemistry analyzers	Automated coagulation analyzers
Preservatives for Calibrator and Latex Reagent	0.02% Bronidox	< 0.1% Sodium azide
Linear range	150 – 3200 ng/mL	200 – 1050 ng/mL
Calibrator target value	3200 ng/mL	1000 ng/mL

J. Standard/Guidance Document Referenced (if applicable):

N/A

K. Test Principle:

Polystyrene latex particles are coated with a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. When plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer included in the quantex D-DIMER Kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample. The concentration is determined by measuring the decrease in light transmitted when the particles agglutinate in the presence of D-Dimer.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Controls I/II (N=60) were run on the ILab 600 Clinical Chemistry System, according to NCCLS EP5-T2 document. Results are as follows:

	<u>Level I</u>	<u>Level II</u>
Mean	301.6 ng/mL	636.8 ng/mL
Within-run	3.99% CV	2.17% CV
Between-run	2.78% CV	0.00% CV
Total	5.75% CV	2.83% CV

b. *Linearity/assay reportable range:*

Calibrator/saline dilutions (12 levels) were tested in triplicate, over (2) separate runs. They generated values over a range of 154 – 3212 ng/mL. The regression study of expected vs reported values yielded this equation: $y = 1.01x + 0.1663$; $R^2 = 0.9997$

c. *Traceability (controls, calibrators, or method):*d. *Detection limit:*

77 ng/mL

A saline study was performed, using (3) assay reagent lots (20 replicates). The mean +3SD (2 calibrations/lot) was calculated. The maximum value obtained was determined to be the detection limit.

e. *Analytical specificity:*

Interference testing demonstrated no significant interference as follows:

Unfractionated heparin (UFH) - < 1.5 IU/mL

Low molecular weight heparin (LMWH) - < 1.5 IU/mL

Bilirubin - < 18mg/dL

Hemoglobin - < 500 mg/dL

Triglycerides - < 1280 mg/dL

f. Assay cut-off:

198 ng/mL

The upper limit (UL) of normal (mean of 92 ng/mL + 2SD of 53 ng/mL) was determined from a study performed on citrated plasmas from normal blood bank donors (N=125).

2. Comparison studies:

a. Method comparison with predicate device:

An in-house study was performed on duplicate citrated plasma samples (N=137), obtained from the emergency room, Hospital de San Paul in Spain. The samples ranged in value 17 – 24149 ng/mL. The quantex D-Dimer/ILab 600 combination was compared to the IL Test D-Dimer/ACL Futura (#K951891) combination. Regression results on the mean of duplicates were:

Slope – 1.059, Intercept – 50.2, $r = 0.987$

Singlet results were statistically similar:

Slope – 1.053, Intercept – 51.6, $r = 0.979$

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a and b are not applicable):

A field site study was performed at Hospital St. Joan de Reus, also in Spain, on patient plasma samples (N=112), comparing the quantex D-Dimer to the IL Test D-Dimer on the ACL 7000 (#K961991). Single determinations were made on these samples: ER (N= 44); DIC (N=30); DVT (N=20); PE (N=18). The study yielded these regression statistics:

Slope – 0.752, Intercept – 52.5, $r = 0.984$

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Mean = 92 ng/mL

The normal range study was performed on citrated plasma from normal blood bank donors, males and females (N = 125), ranging in age 18-66 years. Test results yielded a mean of 92 ng/mL; and a UL of normal of 198 ng/mL (mean + 2 SD). Five outliers were donor samples that tested above the UL; and (3) donor samples had insufficient quantities and could not be tested.

M. Conclusion:

The company provided performance data that was within acceptable analytical limits for this type of device. Based upon the data presented, this device may be found substantially equivalent to a legally marketed device.

