Fibrinectin Assay Kit (FN)

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GS8651M	R1:1×60 ml R2:1×20 ml	For Hitachi 7170/7180& Olympus AU640/400/600
GB8650M	R1:1×60ml R2:1×20ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GX8651M	R1:1×60ml R2:1×20 ml	For Beckman

INTENDED USE
For the *in vitro* quantitative determination of Fibronectin in serum.

CLINICAL SIGNIFICANCE
Fibronectin is a high-molecular weigth (440kDa) glycoprotein of the extracellular matrix that binds to membrane spaning receptor protein called integrins.Fibrinectin that functions as a reticuloendothelial mediated host defense mechanism and is impaired by surgery, burns, infection, neoplasia, and disorders of the immune system.

ASSAY PRINCIPLE
Fibronectin in sample reacts with antibody specific for human fibronectin. The formation of the antibody-antigen complex results in an increase in turbidity at 340nm. By constructing the standard curve, the concentration of fibrinectin can be determined.

REAGENT COMPOSITION

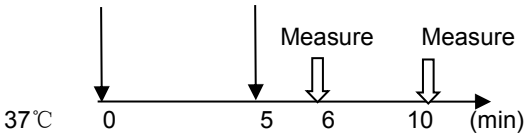
Contents	Concentration of Solutions
Reagent 1 (R1)	
NaH_2PO_4-Na_2HPO_4 buffer	10mmol/L
NaCl	0.15 mmol/L
Reagent 2 (R2)	
NaH_2PO_4-Na_2HPO_4 buffer	100mmol/L
Anti fibrinectin	10-30%

SAMPLE COLLECTION AND PREPARATION
Serum sample.
The sample can be stable for 6 days at 2-8℃

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃

ASSAY PROCEDURE
Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: 2 Point End 16-34
Wave length (sub/main): 800/340nm

Sample 7 µl
R1: 180µl R2: 60 µl



1. Mix 7 µl sample with 180 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 60 µl R2 into cuvette, mix and incubate for 1 minute at 37℃.
3. Read initial absorbance A_1 and incubate for another 1.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION
Recommend using Gcell calibrator (Cat .No. GC-FN).

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of FN in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL
For quality control, use Gcell calibrators (Cat .No. GQ-FN) as daily quality control and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum:>250mg/L
It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
The linearity is up to 630mg/L, when the linear correlation coefficient r ≥ 0.990. If the concentration is above 630 mg/L,please dilute the sample.Multiply the factor to calculate the result.

PRECISION
The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(mg/L)	129.20	248.85
SD	2.84	4.66
CV(%)	2.20	1.87

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CE version 2014

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/L)	133.2	130.6	130.2
$\bar{x}$	131.33		
(Xmax-Xmin)/$\bar{x}$	(133.2-130.2)/131.33*100=2.30%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Vitamin C: up to 100mg/dl
Bilirubin: up to 40 mg/dl
Hemoglobin: up to 1000mg/dl
Intralipid: up to 200mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

References

1. Ni H,Yuen PST，Papalia JM，et al．Plasma fibronectin promotes thrombus growth and stability in injured arterioles[J]．Proc Nad Acad Sci uSA，2003，100(5)：2415-2419

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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