Original Manufacturer Chemistry Reagents

Modular System

Hepatic	Renal	Cardiac	Inorganic &Anemia	Lipid	Immune protein	Diabetes	Rheumatism	Pancreatitis	Lung
ALT	CREA	CK	Mg	TC	C3	Glu	RF	AMY	ADA
AST	UREA	CK-MB	P	TG	C4	HbA1C	ASO	LIP	ACE
GGT	UA	a-HBDH	Ca	HDL-C	IgA	β-HB	CRP		
ALP	CO2	LDH	FER	LDL-C	IgG	FUN			
ALB	Cys-C	HS-CRP	Fe	Apo-A1	IgM				
TP	β2-MG	MYO	UIBC	Apo-B	IgE				
PA	RBP	D-Dimer	TRF	Lp(a)					
TBA	MALB		G6PD						
CHE	TPUC								
BIL-T									
BIL-D									
AFU									

HbA1C

ADA (American Diabetes Association) Endorses HbA1c for Diabetes Diagnosis

Advantages

Enzymatic method

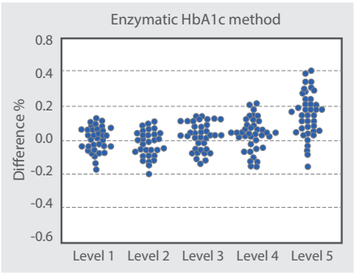
Wide measuring range:3~16%

Excellent sensitivity：Hb（15 μmol/L），HbA1C（3 umol/L）

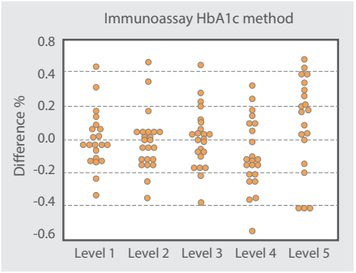
Excellent precision with intra CV value < 2.0%

Traceability to IFCC/NGSP/JCCL reference methods

Precision Contrast

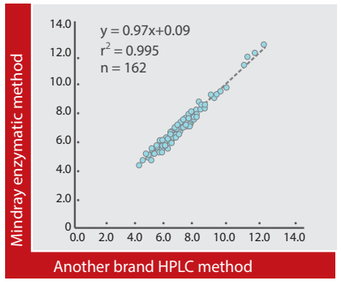


The bias value between the enzymatic HbA1c test results and the stated value : -0.2～0.4%

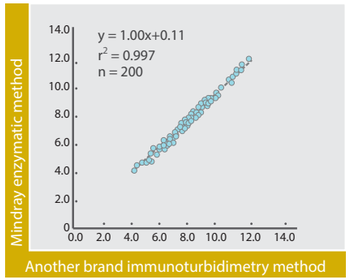


The bias value between the immunoassay HbA1c test results and the stated value : -0.5～0.6%

Method comparison

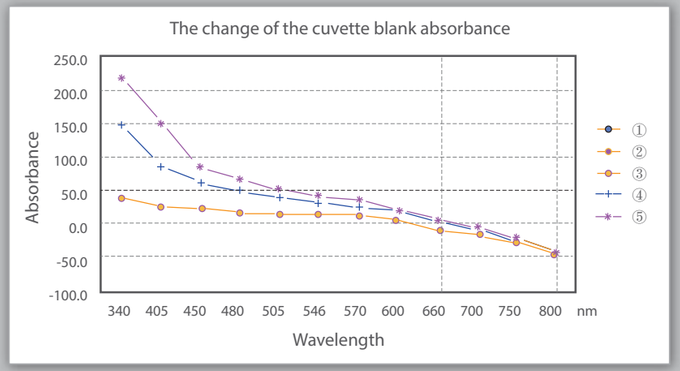


Correlation to HPLC method



Correlation to immunoturbidimetry method

Reagent contamination



Sampl①: 0.9% saline　Sampl②: hemolysis solution　Sampl③: hemolysis solution+ enzymatic HbA1c reagents

Sampl④: hemolysis solution+ immunoassay reagent Ⅰ　Sampl⑤: hemolysis solution+ immunoassay reagent Ⅱ

International standardization

International standardization certificates of HbA1c from NGSP.
More information refers to webstie.(http://www.cdc.gov)
NGSP(National Glycohemoglobin Standardization Program)

β-HB (β-Hydroxybutyrate)

ADA (American Diabetes Association)
Endorses β-HB for diagnosing and monitoring ketoacidosis

Enzymatic Colorimetric Method

Liquid ready-to-use reagent
Enzymatic Colorimetric Method for the measurement of β-Hydroxybutyrate, making automation easier
Wide measuring range with 0.03~5.5 mmol/L
Excellent sensitivity with minimal detection level as 0.03mmol/L
To test β-Hydroxybutyrate – the major ketone in the blood, making it a very reliable test
Measurement of ketones in serum rather than in urine helps eliminate the risk of false negatives due to insensitivity and false positives due to drug interference

Traditional diagnostic method

Sodium nitroprusside reaction(urine strip or tablet)

Qualitative result
False-positive results(Sulfhydryl drugs, including the ACE inhibitor captopril),false-negative results(High dosage of Vitamin C)
Not early period diabetic ketoacidosis diagnosis, for not testing β-HB
Misleads doctors for the increasing acetoacetate during treatment (β-HB oxidized into acetoacetate)

ADA (Adenosine Deaminase)

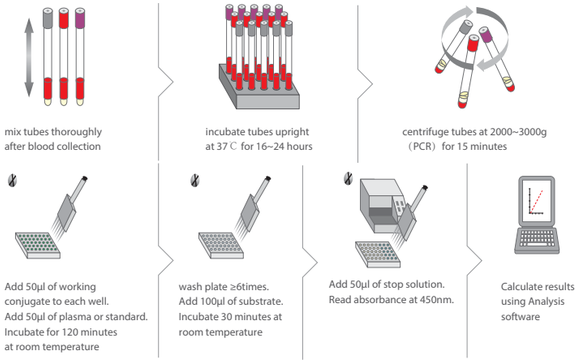
An Ideal Biomarker For Tuberculosis Screening

Advantages

High sensitivity: Measured Low limit of detection 1U/L
Wide linearity range: Measured 1~200 U/L
Excellent precision with low CV value.
Strong anti-interfering ability for lipemia, bilirubin, hemaglobin and ascorbic acid
Good correlation to reference method
Calibrators standardized to International Reference Material ERM-AD455/IFCC

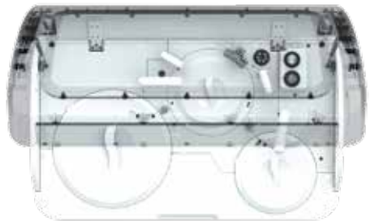
Comparison ADA assay with prevalent method

Interferon-γ Release Assays
Manual Operation
16-24 hrs(but longer if run in batches) to get results



Polymerase Chain Reaction(PCR)
Very expensive
Complicated operation

Adenosine deaminase Assay
Automatic chemistry method
Rapid test
Cost effective
Simple operation



G6PD (Glucose-6-phosphate Dehydrogenase)

An important parameter for G6PD deficiency screening

Advantages

- Liquid reagent, ready to use
- Wide linearity range: 0~3000 U/L.
- Excellent precision.
- Excellent on-board stability: 21 days.
- Long shelf life: 15 months.
- The sample type is the backlog red blood cells.
- There is no interfering for lipemia, bilirubin, drugs and so on.

The comparison with prevalent methods

Prevalent Diagnostic Method	Disadvantages
Methemoglobin Reduction Test Fluroescent Spot Test ELISA Method	Manual or semi-automatic operation Long time to get results (>3h) Short reagent stability (1 week ~ 1month)

Mindray G6PD reagent	Advantages
UV Enzymatic Method	Full-automatic Quantitative Fast Accurate Long stability

AFU (α-L-fucosidase)

A sensitive marker for diagnosing hepatocellular carcinoma (HCC)

Advantages

- Liquid reagent, ready to use
- High sensitivity and wide linearity range
- Excellent precision with CV< 2%
- Excellent stability
- Strong anti-interfering ability of ascorbic acid and intra-lipid.
- Calibrators standardized to International Reference Material ERM-AD455/IFCC.

The combined detection of AFU and alpha-fetoprotein (AFP) is better than AFP individual detection

- The combination test of AFP & AFU enzyme increases the diagnostic accuracy to 90% inspite of AFP alone.
- About58% patients with HCC negative for AFP could be diagnosed.
- In the HCC patients with tumor size < 3 cm, the concentration of AFP is very low and some of the results were negative. AFU is a good marker than AFP in the detection of early HCC.

	Sensitivity	Accuracy
AFP	52%	74%
AFU	70%	78%
APF+AFU	80%	90%