



Chemiluminescence Immunoassay (CLIA) System

OUTSTANDING TECHNOLOGY

Chemiluminescence Immunoassay (CLIA) System

CLIA uses two important technologies, one is label technology which determines reactive mode and the other is separation technology which determines the sensitivity, accuracy and precision of the reagents.

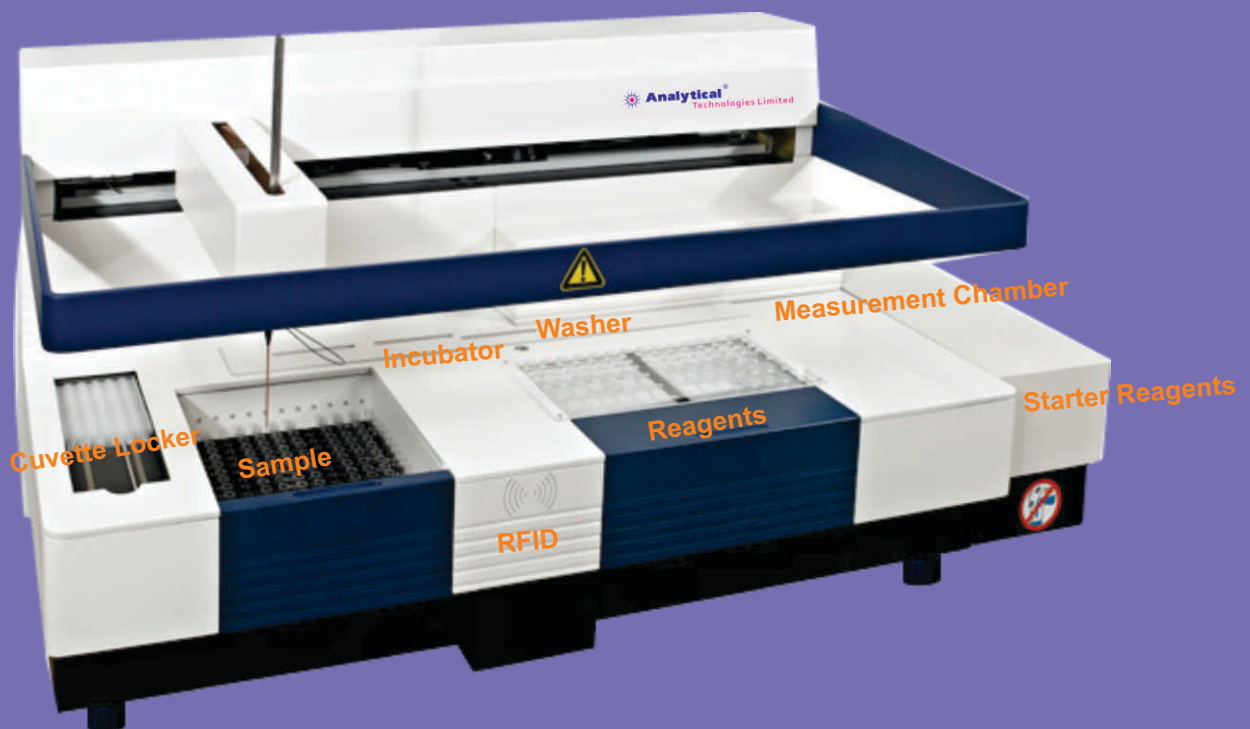
Labeling Technology :

Two types of labeling technologies are commonly used. One contains enzyme labels and other non-enzyme small molecule labels. Enzyme label reagents are not so stable and are easily affected by the change of storage conditions. Analytical system applies ABEI labels. ABEI is a small non enzyme molecule with special molecular formula to enhance stability in acid and alkaline buffer. As fast chemiluminescence, ABEI chemical reaction with sodium hydroxide (NaOH) and double oxygen water (H_2O_2) finishes the process in 3 seconds.

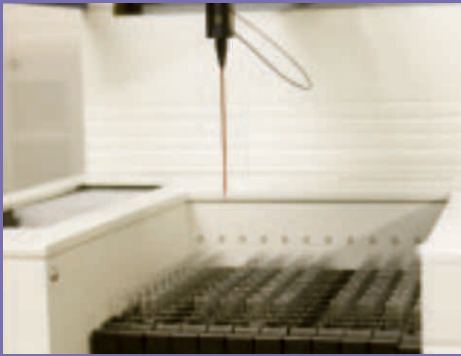
Separation Technology :

Analytical uses Nano Magnetic Micro beads. As separation technology, nano magnetic micro beads has been widely used in the field of CLIA. Compared with traditional separation technologies, it has four major advantages:

1. It helps in enlarging the reaction area of antigens and antibodies to shorten the reaction time.
2. Better and faster capture of the antigens and antibodies to enhance the sensitivity.
3. As liquid separation platform, it mixes thoroughly with the reagents to significantly reduce inter - or intra - assay discrepancies.
4. Absorbs the antigens or antibodies through chemical reaction to enhance the accuracy.



- Flash chemiluminescence ABEI label
- Nano magnetic micro beads solid phase
- Throughput : Maximum 120 tests / h
- Sample and reagent continuous loading
- On board capability : up to 144 samples
- Random access or batch mode, STAT
- 2-point calibration, stable for 4 weeks
- 1 Titanium needle for sample and reagent
- Refrigerated reagent area
- On board capability : 15 analytes
- Reagent recognition : RFID reader



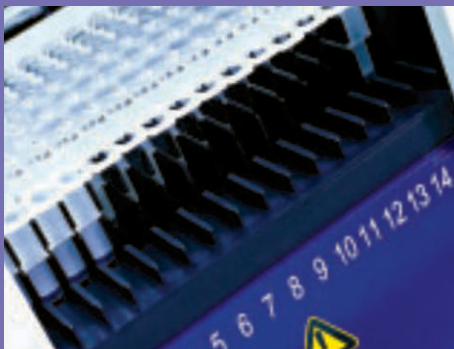
Pipetting Needle

- ◆ 1 needle for reagent and sample
- ◆ Washed internally and externally
- ◆ Needle tip coated with Teflon
- ◆ Level sensor and clot detection
- ◆ Titanium needle for crashproof



Sample Area

- ◆ Up to 144 primary tubes
- ◆ continuous loading
- ◆ optional ratio for sample dilution
- ◆ auto dilution for high titer sample
- ◆ Random, batch and STAT function



Reagent Area

- ◆ Reagent cooling (8-15°C)
with independent power switch
- ◆ On board capability : 15 analytes
- ◆ Continuous loading of reagent integrals
- ◆ RFID tag, fast speed, high reliability
- ◆ Magnetic microbeads suspension system



Cuvette Leader

- ◆ Continuous loading during testing



Incubator

- ◆ Incubate 16 places of cuvettes (96 tests) $37^{\circ}\text{C} \pm 0.01^{\circ}\text{C}$



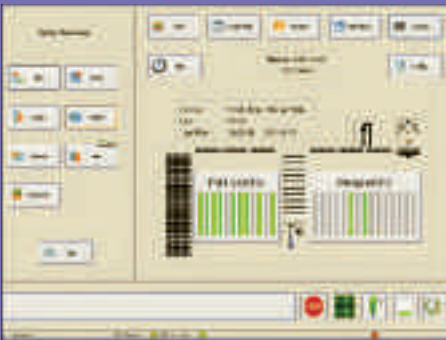
Washer Station

- ◆ Ferromagnetic permanent magnet component for separation
- ◆ 3 pairs of washing needles anti-overflow



Chamber Station

- ◆ High sensitivity low noise photomultiplier tube
- ◆ 3 pairs of washing needles anti-overflow



Software

- ◆ Complete software for operation of testing sample, calibrator, control, BGW and light check
- ◆ Intelligent alarm function



Reagent Kit

- ◆ Integrated reagent kit, ready to use
- ◆ RFID tag stored all information of reagent easy and fast for adding and updating new assay
- ◆ 2-point calibration adjust master curve

Consumables



Reaction Module

- ◆ Disposable plastic module with 5 cavities for 6 tests where the reaction and dilution happen



Starter 1 + 2

- ◆ Starter 1 and starter 2 used for each test to generate the chemiluminescence signal



Light Check

- ◆ A system test checking the dispensing performance of analyzer



Wash / system Liquid

- ◆ Concentrated liquid in bottles used to wash the pipetting needles and microbeads



Waste Bag

- ◆ Plastic bag to contain the used reaction modules to prevent contamination and protect environment

Test Menu

TUMOR MAKERS

AFP
CEA
Ferritin
TPA
PAP
PSA
F-PSA
CA 125
CA 15-3
CA 19-9
CA 50
CYFRA 21-1
CA 242
CA72-4
NSE
Sangtec 100
SCCA
Pepsinogen I
Pepsinogen II

CARDIAC

Troponin I
Myoglobin
CK-MB
A I
AII
NT- proBNP
Aldosterone

DRUG MONITORING

Digoxin
Cyclosporine A
FK 506

INFLAMMATION MONITORING

PCT
CRP

FERTILITY

FSH
LH
Prolactin
Estradiol
Progesterone
Testosterone
Free Testosterone
HCG/ β -HCG
Free β -HCG
FE₃
PAPP-A
DHEA-S

GLYCO METABOLISM

C-Peptide
Insulin
Pro Insulin
IAA
GAD65
IGF-1

HEPATIC FIBROSIS

Hyaluronic Acid
PIIIP N-P
Collagen IV
Laminin
CG, Glycocholic Acid

OTHERS

GH
Cortisol
ACTH

THYROID

TSH
T3
T4
Free T3
Free T4
Reverse T3
TG
TGA
TMA
TRAb
Anti-TPO

HEPATITIS

HbsAg
HbsAb
HbeAg
HbeAb
HbcAb
HCV IgG

PRENATAL SCREENING

AFP
Free β -HCG
PAPP-A
FE₃
HCG/ β -HCG

ANEMIA

Ferritin
FA
VB₁₂

KIDNEY FUNCTION

β_2 -MG
H-ALB

TORCH

Toxo IgG
Toxo IgM
Rubelia IgG
Rubelia IgM
CMV IgG
CMV IgM
HSV-1/2 IgG
HSV-2 IgM

EBV

EBV EA IgA
EBV EA IgG
EBV NA IgG
EBV VCA IgA
EBV VAC IgG
EBV EA IgM

IMMUNOGLOBIN

IgG
IgM
IgE
IgA

BONE METABOLISM

BGP, Osteocalcin
Calcitonin
PTH

SYSTEM FEATURES

Principle of Luminescence

- Non-enzyme involved flash chemiluminescence, long stability of reagents.
- ABEI label, very stable in acid and alkaline buffers.
- Starter reagents consists of NaOH and H₂O₂, not affected by storage conditions.

Main Features

- Throughput :, up to 120 tests/h
- 24 hours ready to use
- Time to first result : 17 minutes

Modes of Operation

- Random, Batch and STAT function

Sample Loading

- up to 144 primary tubes
- Continuous loading, STAT available
- analyzer auto numbered
- Lis connection

Reagent Loading

- 15 reagents on board
- Continuous loading
- RFID read all info of reagents
- Refrigerated reagent area

Reagent Features

- Integrated kit, ready to use, no pretreatment required
- Integrated kit include calibrator
- use superparamagnetic microbeads
- RFID tag stored all info of reagent
- RFID tag with built in master curve
- 2-point calibration to adjust master curve
- calibration stability : max 4 weeks

Other Features

- Clot detection
- Monitor for liquid level of reagent
- Optional ration for sample dilution
- Auto dilution for high titer sample
- Constant 37°C incubation
- 15-30°C room working temperature

Interconnection

- Connection to LIS via COM or network card
- Direct operation on LIS system to test

Dimensions / Weight

- 133 x 66 x 63 cm, 90 kg



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