

Enhanced Chemiluminescence Immunoassay System



ECLIA



China Medical
Technologies



We Make Life Healthier ...

About Us



China Medical Technologies, Inc. is a China-based medical device company that develops, manufactures and markets advanced in-vitro diagnostic ("IVD") products using Enhanced Chemiluminescence ("ECLIA") technology and Fluorescent *in situ* Hybridization ("FISH") technology, to detect and monitor various diseases and disorders, and innovative therapeutic products using High Intensity Focused Ultrasound ("HIFU") for the treatment of solid cancers and benign tumors.

The company was listed on the NASDAQ Global Select Market on August 10, 2005 and trades under the ticker symbol "CMED". Our two major products, ECLIA and HIFU, are operated through our wholly-owned subsidiary Beijing Yuande Bio-Medical Engineering Co., Ltd. (YDME) in China. YDME was established in 1999 and its headquarters and manufacturing facilities are located in the Beijing Economic-Technological Development Area. The company was awarded ISO 9001 certification in 2001 and ISO 13485:2003 certification in 2006.

We acquired our FISH business in March 2007 and operate it through our other wholly-owned subsidiary, Beijing GP Medical Technologies, Ltd., which was established in 2006. We launched our FISH imaging analysis system and probes in June 2007. The acquisition is expected to expand and diversify our existing product portfolio and complement our existing ECLIA diagnostic products by providing proprietary tests for the diagnosis of prenatal and postnatal disorders as well as various cancers that arise from genetic mutations. The new business aims to further strengthen China Medical's leading position in the rapidly-growing area of advanced diagnostic testing in China.

Our first ECLIA analyzers and reagents were launched in 2004. In light of our extensive research in chemiluminescence technology, we believe we are one of the first China-based companies to successfully develop these products, and more importantly, the first to offer an integrated platform including self-developed analyzers and reagents. We manufacture both the equipment and reagents that detect and monitor various diseases and disorders that arise from the human immune system. We currently offer more than 70 reagent kits that can analyze blood, urine or other body fluids through laboratory evaluation. Our non-invasive HIFU tumor therapy system was approved for sale by the Chinese State Food and Drug Administration ("SFDA") in 1999 for the treatment of a wide variety of cancerous and benign solid tumors including: liver, breast and kidney tumors, and tumors in the pelvic cavity. Our HIFU tumor therapy system has been used in over 40,000 cases in China.

China Medical Technologies is managed by an experienced team of professionals and scientists. Our dedicated R&D team is committed to the continuous development of innovative products, both internally and through collaboration with leading research institutions such as the China Academy of Science and Peking University. Our well-established sales and customer service networks put us in a competitive position in both Chinese and international markets. Our innovative products, strict quality control and comprehensive after-sales service have created a solid foundation for our continued success.

About ECLIA

Enhanced chemiluminescence immunoassay (ECLIA) is a non-radioactive immunoassay technology which has been rapidly developing worldwide for a decade. Its principle is to apply luminescence to magnify the signal and directly determine the immunobinding in vitro by its luminous intensity. Compared with radioimmunoassay (RIA) diagnostics, ECLIA avoids radioactive contamination risk. It is also easier to operate and generates the results as fast as the enzyme-linked immunosorbent assay (ELISA). Most important of all, ECLIA is safe in operation without application of harmful reagents. Furthermore, ECLIA also has other advantages including stable reagents, long life period and wide scope of detection. Replacing radioactive immunoassay and common enzymatic immunoassay is a key objective of ECLIA development.

Benefits of ECLIA System

- **Easy to Operate, Explicit Monitoring Process and Shows Clear Results**

Regarding the operating platform, we apply highly-integrated immunoassay data management software which conforms to the most updated international standards.

Its features include:

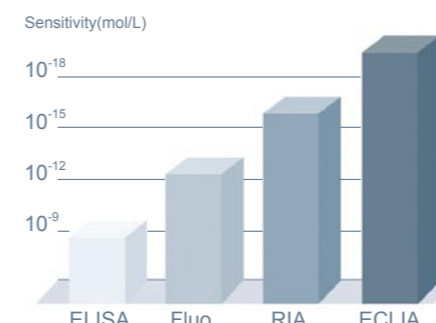
- Input and management of patients' information
- Automatic input and management of the kit parameters by an IC Card
- Automatic calibration and data analysis
- Flexible management of quality controls and test reports
- Automatic print of reports, laboratory sheets, QA/QC reports and tables
- Automatic data search and analysis
- Internet upgradeable and Intranet compatible

In the data analysis system, we apply proprietary integrated circuit card (IC Card) input technology, which simplifies the input and management of information and parameters, thus reducing other operating errors.

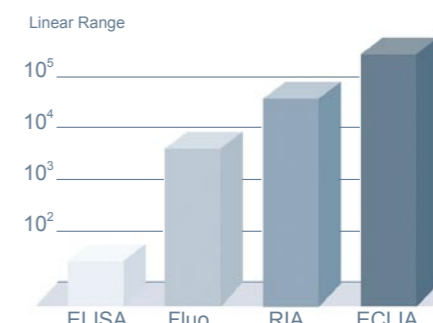
- **High Sensitivity, Accurate Detection Result**

Our enhanced chemiluminescence immunoassay system takes the lead in advanced technology, including techniques such as partition enhancement, co-enhancement and plateau extension. These advances in technology improve the sensitivity and linearity of the diagnostic test compared to other similar technologies. At the same time, we have developed a photoelectric calibrating illuminant and double circuit photon counter for the diagnostic instruments which significantly improve the reliability and linearity of the luminometer.

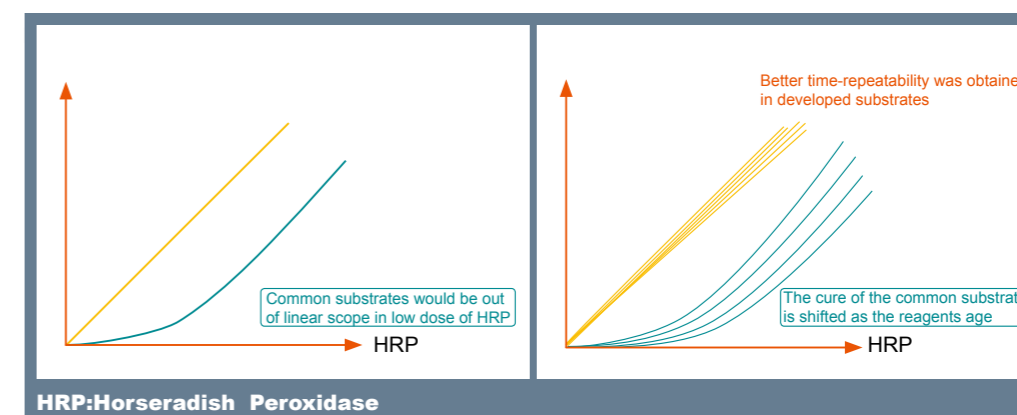
Performance Comparison on Sensitivity



Performance Comparison on Linear Range



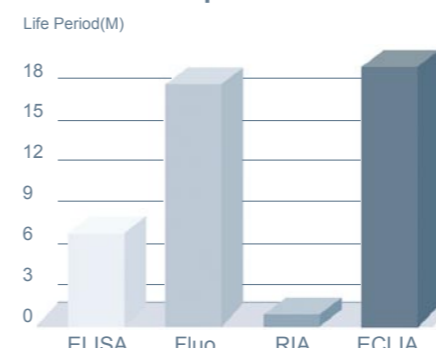
This technology yields a linear response at nearly eight magnitudes and overcomes the curve shift and slope dropping problems which typically occur in enzymatic luminescence, resulting in a new generation of detection systems with high precision and stability.



- **Stable Reagent, Long life Period**

With a patent for "enhanced sensitive enzymatic chemiluminescence substrate", we have developed a technology with a stable signal that extends light emission and maximizes substrate validity through antibody vitrification. The validity and stability of reagent kits have reached international standards.

Performance Comparison on Life Period



Performance Comparison on Cost



- **Full Customer Support and Service**

The integrative solution ensures effective maintenance of the system and prompt supply of the reagent kits.

Performance Comparison on Current Technology

No.	Type of Method	Conjugator & Luminescence System	Advantages	Weaknesses
1	Chemiluminescence	Enzymatic	Simple measurement, Low cost, High sensitivity	Time dependent curve shifting, Non-linear slope variation
		Non-Enzymatic	Simple measurement, High sensitivity	High cost, Complex measurements, Expensive device and maintenance cost
2	Enzyme-Linked Immunosorbent Assay (ELISA)	Acridine ester, Hydrogen peroxide	High sensitivity	Low sensitivity, Only applicable to qualitative or semi-quantitative detection
3	Radioimmunoassay (RIA)	Peroxidase, Alkaline phosphatase	Low reagent cost, Easy to operate	Radioactive contamination, Complex to operate, Short effective period
4	Time Resolved Fluorescence (Time Delayed Photo luminescence)	Radioactive element	Low reagent cost, High Sensitivity	High cost, Complex measurements, Expensive device and maintenance cost, Disturbances from backgrounds of similar elements
5	Electrochemiluminescence (Electroluminescence)	Pulsed light activation by chelate complexes: Europium (Eu), Dysprosium (Dy), Europium (Eu), etc. Pulsed field activation by chelate complexes of Ruthenium (Ru)	High sensitivity & Stability	



ECLIA Analyzer — Model MPC-1

The MPC-1 is YDME's first generation of semi-automatic microplate readers. Its high sensitivity and linear range make it more stable and technologically mature. In addition, it is more accurate and safer to use than radioimmunoassay and enzymatic testing. The semi-automatic ECLIA System achieves results comparable to more expensive, fully-automatic systems provided by international players, but at a lower cost.

ECLIA Analyzer — Model MPC-1

Components

- ◆ Microplate Single Photon Counter
- ◆ PC and Monitor
- ◆ IC Card Reader

Parameters

Detection Mechanism	ECLIA
Substrates	Enhanced Sensitivity Enzymatic Chemiluminescence Substrate
Sensitivity	10^{-19}
Linearity Scope	500 - 1.8×10^6 RLU/Sec*
Stability	CV \leq 3%
Repeatability	CV \leq 3%
Voltage	AC 230V 50/60HZ
Power	220VA
Size (L x W x H)	455mm x 340mm x 195mm
Weight (Main Frame of Luminescence Instrument)	12 Kg
Background Noise	\leq 100RLU/Sec
Operating Environment	a) Temperature: 5°C - 40°C b) Relative Humidity: < 80°C c) Warming Up: \leq 20min

*RLU (Relative Luminescence Unit): 1 RLU is equal to 10 photons

Features

- ◆ Integrated Solution
- ◆ Friendly Bright Genius™ Software
- ◆ Easy Operation
- ◆ Intuitive Interface
- ◆ Unique Detection Technologies
- ◆ High Sensitivity and Accurate Results
- ◆ Improved Safety



ECLIA Analyzer — Model JETLIA-96/2

The JETLIA-96/2 requires minimal counter space. Its compact design makes the system ideal for physician office laboratories, work stations for small hospitals, diabetes and specialty testing. The JETLIA is automated with substrate access. The analyzer uses IC card to reduce errors and minimize technologist time.

Components

- ◆ Microplate Photoncounter Luminometer with built-in Auto Injector & Computer
- ◆ Monitor
- ◆ IC Card Reader



Parameters

Detection Mechanism	ECLIA
Substrates	Enhanced Sensitivity Enzymatic Chemiluminescence Substrate
Sensitivity	10 ⁻¹⁹
Linearity Scope	500 - 1.8 × 10 ⁶ RLU/Sec*
Stability	CV ≤ 3%
Repeatability	CV ≤ 3%
Voltage	AC 230V 50/60HZ
Power	250VA
Size (L × W × H)	600mm × 400mm × 285mm
Weight (Main Frame of Luminescence Instrument)	16 Kg
Background Noise	≤ 100RLU/Sec
Operating Environment	a) Temperature: 5°C - 40°C b) Relative Humidity: < 80°C c) Warming Up: ≤ 20min

*RLU (Relative Luminescence Unit): 1 RLU is equal to 10 photons

Features

Unique Two-Channel Pump Design

- ◆ Automatic substrate injecting

Innovative Detachable Microplate

- ◆ Strong compatibility

Built-in Calibration Illuminant

- ◆ Feathering self-calibration ability

Double-Circuit Super Linearity Photon Counter

- ◆ To enhance the detectable scope

Unique IC Card Design

- ◆ Provides clearer guidance for users
- ◆ More convenient to operate

Comprehensive Assay Group

- ◆ Large menu of over 70 available assays with proven performance

Operation Process of JETLIA-96/2



***** ECLIA Laboratory Sheet				Sample No.:1
Case No.:1	Name: luly	Gender: Female	Age: 25	Sample: No
Bed No.: 12	Sample Type: Serum	Manifestation:		Department:
Test List	Result	Unit	Normal	
CA19-1TY (CA19-1)	<0.27	kU/L	>38.36	
APKY (CEA)	24.56	ng/L	<60	
Sender: Wang Auditor: Li Tester: Zhang Collect D: 2007-8-8 Test D: 2007-8-8				
Reminder: Current results only correspond to this assay of specimen.				

Report





ECLIA Analyzer — Model AUTOLIA-12/48 (In Development)



Features of Model AUTOLIA -12/48

Efficient Patient-Oriented Output

- ◆ Maximum speed up to 48 tests/hour

Capacity

- ◆ Simultaneous 12-assay loading capacity
- ◆ Strong anti-interference capacity
- ◆ Background noise: ≤ 40 RLU/second

Proven Performance

- ◆ Unique design of 3-in-1 tray integrating incubation medium, reagents and reaction samples
- ◆ Compact all-in-one kit cartridges, no supplementary manual operation needed
- ◆ Full random access design with ready-to-test chamber for emergency samples

Unique Technical Features

- ◆ Minimum sampling volume is 1 μ L (usually 10 or 20 μ L)
- ◆ Unique fully-automated cleaning of sampler ensuring cross-contamination rate less than 10^{-15}

True Result Integrity

- ◆ Unique design of IC Card, by which manual errors may be minimized

Comprehensive Assay Group

- ◆ Large menu of over 70 available assays with proven performance



Disease-state Assays

Infectious Disease

Hepatitis

HBsAg (Quant.)
HBsAg (Qual.)
HBsAb (Quant.)
HBsAb (Qual.)
HBeAg (Quant.)
HBeAg (Qual.)
HBeAb (Quant.)
HBeAb (Qual.)
HBcAb (Quant.)
HBcAb (Qual.)
HBcAb IgM (Qual.)◆
HBcAb IgM (Quant.)◆
PreS2 (Qual.)◆(Hepatitis B PreS2 Antigen)
PreS2 (Quant.)◆
HCVA◆ (Antibodies to Hepatitis C virus)

Other viruses

CMV IgM (Anti-Cytomegalovirus IgM)
CMV IgG
Rubella IgM
Rubella IgG
Toxoplasma IgM
Toxoplasma IgG
Herpes I IgM
Herpes I IgG
Herpes II IgM
Herpes II IgG

SARS

SARS-CoV

Reproductive Endocrinology

Down Syndrome

Free-β-hCG
PAPP-A (Pregnancy Associated Plasma Protein A)

Other hormones

Progesterone
Testosterone
Estradiol
Prolactin
FSH (Follicle Stimulating Hormone)
LH (Luteinizing Hormone)

Oncology / Tumor Markers

CA 125 (Cancer Antigen 125)
CA 15-3
CA 19-9
CA 50
PSA (Prostate Specific Antigen)
Free PSA
HCG
AFP
CEA
NSE (Neuron Specific Enolase)

Infertility Disorder

AHCG IgG (Anti-HCG IgG)
AHCG IgM
ASA IgG (Anti-Sperm IgG)
ASA IgM
ASA IgA
AOA IgG (Anti-Ovary IgG)
AOA IgM
AZP IgG (Anti-Human Zona Pellucida IgG)
AZP IgM
AZP IgA
ACA IgG (Anticardiolipin IgG)
ACA IgM
ACA IgA
ATB IgG (Anti-Human Trophoblast IgG)
ATB IgM
AEA IgM (Anti-Human Endometrium IgG)
AEA IgG

Thyroid

Total T3
Free T3
TSH
Total T4
Free T4
TPOA (Anti-Thyroid Peroxidase)
TGA (Anti-Thyroglobulin)

Kidney Function

UALB◆ (Urea Abumin)
α1-MG◆ (α1-Microglobulin)
β2-MG◆ (β2-Microglobulin)

Liver Fibrosis

LN (Human Laminin)
Col IV (Human Collage Type IV)
HA (Hyaluronic Acid)
PIIINP (Procollagen III N-Terminal Peptide)

Metabolic Function (including diabetes)

GADA (Glutamic Acid Decarboxylase Autoantibody)
IAA (Insulin Antigen Autoantibody)
C-Peptide
Insulin

Cardiac

Digoxin
cTnI◆ (Cardiac Troponin I)
CK-MB◆ (Creatine Kinase-MB Isoenzyme)
Myoglobin◆
FABP◆ (Fatty Acid Binding Protein)
CRP◆ (C-Reactive Protein)
N-hANP* (N-Terminal-Human)

Growth Disorder

Growth Hormone

Anemia

Ferritin

HIV

HIV◆
P24◆ (Protein 24)

Allergy

tlgE◆ (Total IgE)

Components of Reagent Kit

The first domestic ECLIA kit approved by SFDA for the Chinese market
The first SARS kit available in the global market



Components

- ◆ Coated microplate
- ◆ Enzyme conjugate
- ◆ Calibration materials/negative and positive controls
- ◆ Luminescent substrates
- ◆ IC Card

Features

- ◆ Excellent quality
- ◆ Stable reagents with long expiration

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**China Medical
Technologies**

China Medical Technologies, Inc.

Address: Beijing Fortune Plaza A-701
No. 7 Dongsanhuan Zhong Road
Chaoyang District
Beijing 100020
People's Republic of China
Tel: +86 10 65308833
Fax: +86 10 65309733
E-mail: globalsales@chinameditech.com
Website: www.chinameditech.com

Beijing Yuande Bio-Medical Engineering Co., Ltd.

Address: No. 24 Yongchang North Road
Economic-Technological Development Area
Beijing 100176
People's Republic of China
Tel: +86 10 67871166
Fax: +86 10 67889588
E-mail: yuande@yuande.com
Website: www.chinameditech.com