

Trends in Medical Technologies Innovation in China

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Background on E.A.S.E.-Medtrend

- Equal Access to Scientific Excellence
- Emphasis on Access
- We have been in China for over 10 years
- Our activities center around diagnostics

What is driving innovation in medical (diagnostic) technologies in China

- Health care needs of a large population
- Policy from the central government
- Industry and academia's response to these forces

Diagnostics Market Dynamics (China)

- There are more than 28,000 hospitals in China
Class III ~1,400 Class II~6,500 Class I ~8,000
Unrated ~12,000 Private hospitals>1,000
- IVD market size is US\$3 billion in 2013
- Growth in last 7 yrs: 25-30%
- Foreign companies dominate market (Roche, Seimens, J & J, Beckman/Danahar, Sysmex, bioMerieux, Thermo Fisher, Allere)
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Some challenges for hospitals

- Seeking medical care is a tedious, time-consuming and inconvenient process.
- Patients need to travel long distances in many cases.
- Hence the time required to make an accurate diagnosis is important because repeat/follow up visits present a heavy burden.
- Coupled with a large patient load, there is a therefore a strong demand for high throughput tests in most hospitals---much more than in advanced countries.

Influence of the government on medical technologies development

Government policy on coverage & “reimbursement rate” is currently dependant on location, but will be moving towards harmonized rate.

Remimbursement rate for diagnostic tests are also “method/technology” based, and also depends on whether the product is a domestically made or imported one (imported products are allowed a higher rate in most cases because traditionally they

Reimbursement rates and market factors

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Example of how profit influences different test use

- Test for Toxoplasma IgG and IgM (reimbursement is currently method based)

Cost of Tests	Reimbursement schedule	Hospital profit
ELISA 15RMB	15 RMB (Shanghai)	15 RMB
CLIA 30 RMB	60 RMB	30 RMB
ELISA 15 RMB	45 RMB	30 RMB
CLIA 30 RMB	45 RMB	15 RMB

Trends in Clinical Chemistry

- This is an area of clinical diagnostics which is most developed with regards to reagents and instruments. There are many players covering the entire spectrum of capabilities.

Trends:

- Dry chemistry for serum/blood based tests (urine chemistry already very well developed)
- Expansion of menu, with emphasis on domestic manufacturing
- Development of homogeneous immunoassay systems and reagents which can use clinical chemistry autoanalyzers
- Development of Reflex Testing capability

Trends in Immunoassay

- Development of high-throughput Random Access instruments with large on-board menus.
- Expansion of menu

(Even medium size hospital labs are demanding Continuous and Random Access and Stat capabilities, 200 Tests/hour with turn around time of 30 minutes or less, and 20+ on board test menu)

There are several manufacturers in China who are marketing such products and generally use magnetic beads as the solid phase because it can be handled by existing liquid handling systems.

The challenge is development of an instrument with these features using traditional microwell format, and to do this without being unwieldy and cost effectively. Since there is a large pool of existing tests, these can be imported directly into this system. (There is at least one company doing this)

Innovative trends in Microbiology

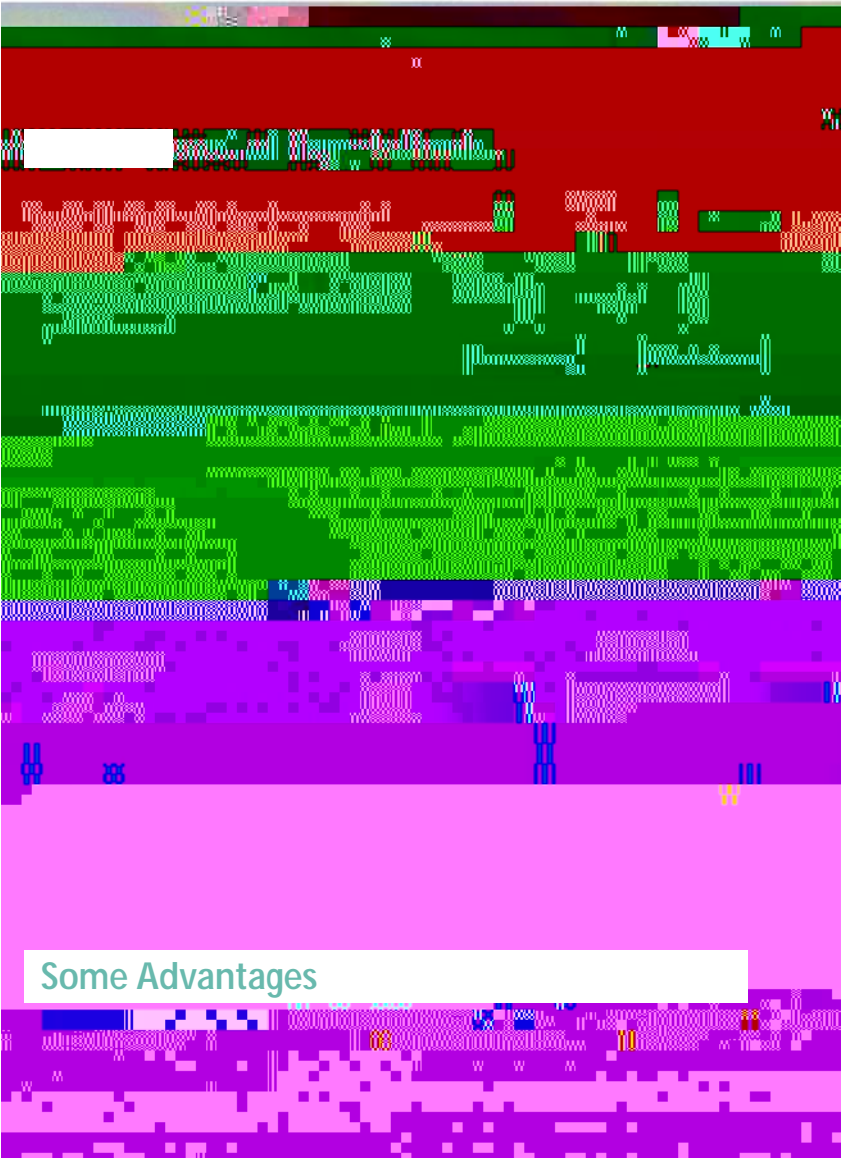
- One of the highest volume and expensive test in microbiology has been

Innovative trends in Rapid Diagnostic Tests (RDT/POCT) in China

- This is a high growth area with many players. It is easy to produce, easy to use, and easy to sell.
- Actual needs and market forces are driving the price down and also increasing the menu.
- There has been several major areas where advances have been made:
 1. Multiplexing (simultaneous determination of multiple analytes)
 2. Ability to use different specimen types (blood, plasma, serum, saliva, urine)
 3. Semi-quantitative and Quantitative read outs
 4. High-throughput instruments (for tests where there are distinct advantages of RDT over liquid chemistry)
 5. Profile tests for differential diagnosis and monitoring of patients

Trends in Nucleic Acid based testing in China

- Large numbers of small diagnostic companies have sprung up providing a large menu of tests for conventional and RT-PCR,





Microfluidics/Lab on a Chip

Over twenty universities and research institutes and commercial companies are actively engaged on various aspects of diagnostics using microfluidic techniques. The explosion in research in this area are witnessed by many recent symposia in China, Taiwan and Hong Kong.

Several factors have helped to accelerate research and development in this area:

1. Inexpensive photolithography/3D printing
2. Access to specialty polymers a relatively inexpensive price
3. Development in coating technologies and nanopumps in China
4. Collaborative efforts between the life science and engineering disciplines at academic institutions

The Challenges:

Business models for commercialization. Familiarity and acceptance of the methods.

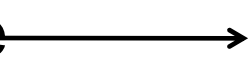
Smart Phone based testing

- An area which holds great promise is the development of test formats and devices which can interface with smart phones.

Front End Devices (eg. Scanners & Image Acquisition devices)



Smart Phone



Data analyzed on board with App



Data transmitted securely to
Cloud server for analysis

Making it work!

- EASE of use: minimum training and idiot-proof protocols
- Authentication: Type of test and relevant information on the test
(eg. Manufacturer, lot no. exp date, calibration etc.)
Time and location of performance and operator
(this is done automatically with device ID, GPS etc.)
- Security: Proper encryption of data and controlled access
- Efficiency: Ability to interface with different types of data acquisition devices. (Challenge is to have tests in a format amenable to be “read”)

Planned Applications in China

- Food Safety Monitoring (Testing by field inspectors)
- Epidemiological studies & Outbreak monitoring
- Diagnostic tests in remote areas (eg. Yunnan mountains)
- Home testing (eg. Diabetes, ovulation, kidney function etc. In addition to parameters such as heart rate, blood pressure)

Challenges to Industry:

Business Model: Open system or Closed system?

How to make money on such systems.

How to protect confidentiality of data.

Regulatory Trends

- There has been significant changes in CFDA concerning diagnostic device registration and production regulations in August 2014 which came into effect in October 2014.
- Some products have been moved from Class III to Class II.
- Products which can be proven innovative or is urgently needed will

Thank You !

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