What's New in China

IVD markets in China will grow to more than US$1.5 billion in 2009, making China the world's #6 IVD market. Over the last few years, annual market growth has been in the 15-20% range, putting China on track to pass Italy and France by 2012 and Germany by 2015. The IVD business in China is never easy; with all the lean local competitors, end-user commissions, spotty distribution channels, and the recent reigning in of reimbursement. Still, there are more reasons than ever for IVD companies to redouble their efforts in China in 2009.

Just as we were finishing this report **China's State Council announced a major new health care spending program** to bring some minimum standard of medical insurance coverage to 90% of both the urban and rural population, while also upgrading hospitals. The central government has committed 850 billion yuan ($US123 billion) to the task, which is mainly meant to pay for lots of drugs and doctors fees, though surely not all, which will open the gates for plenty of back and forth over how much from which pockets.

A big part of the government's motivation is clarified by remarks by Bai Zhongen, chairman of the economics department at Tsinghua University's School of Economics and Management in Beijing, who said that establishing universal health care with government-financed insurance would increase general consumer spending. He said the school did a survey in 2007 about the effect of rural health insurance on consumer behavior and "found that in government-sponsored health insurance areas, people are spending more." So getting people to save less and spend more is no small part of the government's motivation for the new largesse.

IVD companies should note that the plan also aims to improve health centers in rural and remote areas as well as equalize health services between urban and rural areas. We expect this to lead to a once-in-a-career boom in small instrument placements at the country's 200,000+ clinics and 40,000+ health centers. China is already the world's #2 market for automated IVD instrumentation, having absorbed well over 4,000 new chemistry systems, 9,000 hematology systems, and 3,000 new immunoassay systems *during each* of the last few years. Now a significant but completely new market for smaller, more robust instrumentation appears likely to take shape.

Another gradual but significant change has been **the strengthening of the yuan, which keeps making imports more affordable**. When we did our 2004 report, the exchange rate was still at the long-standing peg of 8.28 to the US dollar. In 2006 the rate was 7.90, an increase of almost 5% and for this report we are using an exchange rate of 6.80 to the dollar. The direction is clear, and as the Chinese currency continues to strengthen, imported IVD products will continue to look better to Chinese buyers.

There is no laboratory consolidation in China; new hospitals continue to open at the rate of ≈575 per year. In addition, the Ministry of Health is expanding their Centers for Disease Control laboratories. They are in the process of opening 1,000 new epidemiological laboratories throughout the country.

COUNTRY SUMMARY

What's New in China

The government has also announced a plan to open 22,000 primary health care clinics in the countryside by 2010. These would be entirely outpatient facilities, and would include laboratories with automated chemistry instruments doing ≈200 tests/hour, 3-part differential cell counters, EIA readers and urinalysis instruments.

Private laboratories are beginning to be a part of the IVD market. While it is still uncommon for specimens to be sent outside of hospitals, private labs are making inroads in getting specimens from hospitals and health checkups as well as for esoteric testing. At least three Chinese lab groups are trying to become national chains of private labs; KingMed of Guangzhou, Adicon of Hangzhou and Lawke of Beijing.

Private medical practices are also beginning to appear, mainly practiced by. by retired physicians, as hospitals will not allow their staff to do private practice on the side.

The market continues to grow at 15-18% annually, but those rates will be hard to sustain without substantial trickle-down from the big bang announced by the government on January 22. Over the last four years the government has started to reduce the reimbursement rates. And it is hard to know how the current global financial crisis will alter China's economy and the IVD market. But today, the macro-economic indicators are still good for the IVD industry. Even with the current world economic problems, China's economic growth is estimated by non-government sources to be even higher than the official ≈10% reported by the government. The country is urbanizing and modernizing faster than any other has in history, and their foreign exchange reserves are over the $1 trillion level. With greater levels of prosperity, the citizens of China will continue to seek better health care and better diagnostics. Even at our current estimate of the market, China spends around $1.00 per person each year on diagnostics. When you compare this with the $22-28 per capita that is spent in Europe and the US, it is clear that China's IVD markets have a great future.

Local manufacturing is booming. The number of companies we report on continues to increase. Four years ago we listed 87 local manufacturers. This report profiles 132 local manufacturers, with more companies entering the market all the time. Chinese manufacturers are getting more aggressive with their export efforts. There were 16 Chinese companies exhibiting at the 2005 AACC meeting. In 2006 there were 20, in 2007 there were 23, and in 2008 there were 31 Chinese firms exhibiting. Watch out - pretty soon they'll be hurting you in your own backyard.

<u>The Healthcare System in China</u>

Total healthcare expenditures in China are estimated to be 5-6% of GDP with that share growing at a relatively slow pace. The volume of these expenditures is approximately $70b or $50-$55 per person. The proportion of these expenses born by individuals has been steadily growing and is now over 50%. Healthcare is one of the fastest growing segments of household budgets in China. Today the Chinese consumer pays nearly triple for healthcare what they paid in 1994.

We have pages like this on all the major international competitors

MANUFACTURER PROFILE:	**ABBOTT**
Company:	Abbott Laboratories
Office in Hong Kong	Abbott Laboratories Diagnostics Division 20/F, AIA tower, 183 Electric Road, North Point Hong Kong Phone: 852-2566-8711 or 2806-4209 Fax: 852-2806-1389 e-mail: kh.to@abbott.com raymond.fung@abbott.com
Office in Beijing:	Room 1709-1716 Canway Building #66 Nan Li Shi Road Xi Cheng District Beijing 100045 Phone: 86-10-6802-8080 Fax: 86-10-6802-7788 e-mail: lucy.wang@abbott.com
Office in Shanghai:	37/F Ciro's Plaza 28th Floor, Xian Le Si Square 388 Nanjing W. Road Shanghai 200003 Phone: 86-21-3302-4777 Fax: 86-21-6334-6331
Office in Guangzhou:	Room 1905-07, Guangzhou International Electric Tower No. 403, Huan Shi Dong Road Guangzhou 510095 Phone: 86-20-8732-0188 Fax: 86-20-8732-0445
Local Contacts:	Mr. King-Hon To - Area Divisional VP (Hong Kong) Mr. Raymond Fung – Business Development & Marketing Director Ms. Lucy Wang – Country Manager, China, Abbott Molecular (Beijing) Ms. Libby Xu - Area Manager (Guangzhou) Mr. Sam Liao – Area Manager (Hangzhou) Mr. James Fong – Manager, Point-of-Care Division Mr. James Zheng – Hematology Product Specialist Ms. Cynthia Chen – Government Affairs
Staff:	• Diagnostic Total 75
Products Sold:	Chemistry, immunochemistry, hematology and diabetic testing systems

We have pages like this on all the major international competitors

MANUFACTURER PROFILE:	**ABBOTT**
Company:	Abbott Laboratories
Comments:	Abbott's headquarters for China is in Hong Kong. They also have offices in Beijing, Shanghai, Guangzhou, Qingdao, Hangzhou and Chengdu. Abbott has moved its pharmaceutical and nutritional business management from Hong Kong to Shanghai, and expects to eventually move the diagnostic division as well. In chemistry, Abbott has placed ≈60 high-throughput Aeroset systems in China and ≈200 Architects. Of these ≈50 are the "ci" configuration that also does immunochemistry testing. They also have ≈300 low-throughput Alcyon systems. Their chemistry reagent share is ≈3%. In critical care chemistry, Bio-Asia is now the iSTAT distributor. Abbott has ≈4% of the hematology systems working in China and ≈5% of the 5-part differential systems. These include ≈3 Sapphires which are demos. So far they have not introduced either the Ruby or Pearl. Abbott sells ≈5% of the hematology reagents consumed in the country. Abbott has an immunochemistry market reagent share of ≈13%. This comes from a total of ≈1,500 closed instruments, only ≈500 of which are from the IMx/TDx era. This includes ≈800 AxSYMs, as well as ≈200 Architect units that do immunochemistry. In addition to their closed systems, Abbott is the only foreign company that has approvals for all three main screening tests.. In molecular testing they offer the m2000sp for sample preparation and the m200rt for real-time testing. They have a small number of these, mostly with the CDC focusing on HIV viral loads, though these also do HBV and HCV testing. Abbott is also one of the main two competitors in China's florescent *in situ* hybridization (FISH) market. They sell the ThermoBrite slide processor, Xmatrix automated slide stainer, high volume VP 2000 slide processor and Vysis AutoVysiion System microscope, camera, PC workstation and software. Much of their focus will be prenatal screening.

We have pages like this on the most important local dealers

DISTRIBUTOR PROFILE:	**GENE COMPANY**
Office in Hong Kong:	Gene Company Unit 806, 8/F, Shell Industrial Building 12 Cheung Lee Street Chai wan, Hong Kong Phone: 852-2896-6283 e-mail: johny_zjl@genecompany.com
Shanghai Office:	Gene Company Ltd. 6^{th} Floor, #25 Building #69 Guejing Road Shanghai 200233 Phone: 86-21-6495-1899
Beijing Office:	Beijing Northern YiTao Trade Company Ltd. 4/F, South Building #18 Baiguang Road, Xuanwu District Beijing 100053 Phone: 86-10-5166-5161
Local Contacts:	Mr. Chang Tao – President Mr. John Zhou – General Manager, Mainland China Mr. Johny Zhang - Business Manager, Reagents(Shanghai) Mr. Li Zhe – Product Specialist, Marketing Dept.
Staff:	• Diagnostic Total: 30 • Company Total: 220
Companies Represented:	**Dako** (Denmark) – Immunohistochemistry and flow cytometry reagents **Abbott** (US) – Molecular diagnostic products **Applied Biosystems (ABI)** (US) – PCR instruments **Qiagen** (US) – Molecular testing products **CombiMatrix** (US) – Molecular diagnostic products **ThermoFisher** (US) – Centrifuges and consumables
Comments:	Gene Company was founded in 1992. Their headquarters is Hong Kong, but their mainland business is managed from their Shanghai office. They have an additional five offices around the country. Their focus is on the life science/research markets of China. Applied Biosystems (ABI) (see profile) is the leader in molecular instrument sales in China. Gene Company is their exclusive for PCR instruments and StepOne systems, which they describe as an "entry-level" real-time PCR system. Several other companies distribute ABI's reagents and disposables. CombiMatrix makes DNA microarrays that can test for breast cancer, leukemia and prenatal genetic defects. They are considering registering these products, but at this point they could only be used in China if some portion of the array was made in house.

We have pages like this on the most important local manufacturers

DOMESTIC MANUFACTURER:	**MINDRAY MEDICAL ELECTRONICS**
Company:	Mindray Medical Electronics
Headquarters:	Mindray Medical Electronics Mindray Building Keji 12th Road South High-tech Industrial Park, Nanshan Shenzhen 518057 Phone: 86-755-2658-2888 or 2658-2896 Fax: 86-755-2658-2800 e-mail: intl-market@mindray.com mhcheng@mindray.com.cn ray@mindray.com.cn jie.liu@mindray.com.cn jbtang@mindray.com.cn Internet: www.mindray.com.cn
Beijing:	Phone: 86-10-6833-2021 Fax: 86-10-6834-6086
Local Contacts:	Mr. Hang Xu – Chairman and CEO Mr. Minghe Cheng - VP of Strategic Development Mr. Jie Liu – Chief Operating Officer Mr. Ray Xiang – International Marketing Department Mr. Tang Jingbo – Director, Laboratory Products Mr. Wang Jin Zhao - Sales, Beijing
Staff:	• Company Total:3,700 (worldwide)
Products Manufactured:	Hematology and chemistry systems, urine strip readers, EIA readers
Comments:	Shenzhen Mindray Medical Electronics has been in business since 1991 and was listed on the New York Stock Exchange in 2006. They have 29 offices around the country and work through ≈100 distributors. In addition to making patient monitors and medical imaging systems, they manufacture full line of hematology analyzers, including the 5-part differential BC-5500 and three 3-part differential instruments, the BC-3200, BC-3000Plus and the BC-2800. They also make a semi-automated cell counter, the BC-2300. In July of 2003, they introduced their BS-300, an automated chemistry instrument and in 2006 added the BS-200 (the numbers refer to their throughput). Since then they have added the BS-400 and the BS-120. They also make a semi-automated chemistry instrument, the BA-88. Their sales in 2007 were $306 million and net income was $92 million. Mindray has distributors in nearly every major international market. In 2006 their export sales exceeded their sales in China.

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Market Total; Hematology

Sales in hematology appear to be:

Hematology Instrument	Units Placed	Units Rented	Units Sold	Average Unit Price in RMB	Average Unit Price in US $	Total Market in RMB	Total Market in US $
5-Part Diff Systems	1,500	200	1,300	292,400	$43,000	380,120,000	$55,900,000
3-Part Diff-Imported	3,300	0	3,300	102,000	$15,000	336,600,000	$49,500,000
3-Part Diff-Domestic	4,700	0	4,700	68,000	$10,000	319,600,000	$47,000,000
Semi-Auto Systems	700	0	700	20,400	$3,000	14,280,000	$2,100,000
Instrument Total	10,200	200	10,000			1,050,600,000	$154,500,000
Hematology Reagents						530,400,000	$78,000,000
Exchange Rate	6.80						
Hematology Total						1,581,000,000	$232,500,000

Adding in flow cytometry and coagulation total sales for this market segment appear to be:

Hematology Segment:		Market Value in RMB	Market Value in US $
Hematology (from above)		1,581,000,000	$232,500,000
Flow Cytometry		79,900,000	$11,750,000
Coagulation		461,720,000	$67,900,000
Total		2,122,620,000	$312,150,000
Exchange Rate	6.80		

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Market Total; Hematology

The tables on the prior page list the current annual market for hematology, flow cytometry and coagulation systems in China.

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Since the year of 2000, the number of laboratories and level of hematology automation in China appears to have changed as follows:

Number of Labs	2000	2002	2004	2006	2009
Automated	≈8,000	≈10,700	≈13,400	≈15,000	17,500
Semi-auto	≈2,500	≈2,500	≈2,500	≈2,000	1,500
Manual	≈5,500	≈4,000	≈2,500	≈1,700	1,000
Total	≈16,000	≈17,200	≈18,400	≈18,700	20,000

When we did our 2000 study, the reimbursement lists in China allowed for no additional compensation for running a 5-part differential, and there were just over 300 instruments in the country doing these unrewarded differentials. This had changed by 2002, with an additional reimbursement, and the market responded. The graph below on the 5-part differential instrument market share page shows the rather remarkable growth in this market segment.

Mindray is the only domestic company competing in the 5-part differential market, and their BC-5000 series instruments makeup only ≈6% of the installed base. The balance of the market is supplied by imported instruments. We expect this segment of the market to remain strong for at least the next two years. We are predicting that ≈1,500 5-part differential systems will be placed in China in each of the next two years, with a small portion; perhaps 10-15%, placed on reagent rental.

The markets for 3-part and 5-part differential systems are very different. A large part of the 3-part market is done by government tender, and price is almost the only factor taken into account. So this market segment is very price-sensitive. Quality is taken into account in the 5-part segment of the market. But the 3-part differential market is much more of a commodity market.

Domestic companies are very important in the 3-part differential portion of the market, with 55-60% of the installed base. They are gaining in this sector and we expect them to continue to expand their share at the expense of imported brands. We also expect to see continued strong sales of 3-part differential cell counters, with ≈4,700 domestic and ≈3,300 imported instruments sold in each of the next two years. There is some reagent rental of these systems, but it comes from the distributors not the manufacturers.

The market for semi-automated cell counters is declining, but still exists. Labs benefit from the lower initial cost, lower maintenance and the use of finger-stick blood. We expect ≈700 semi-automated cell counters to be sold in each of the next two years.

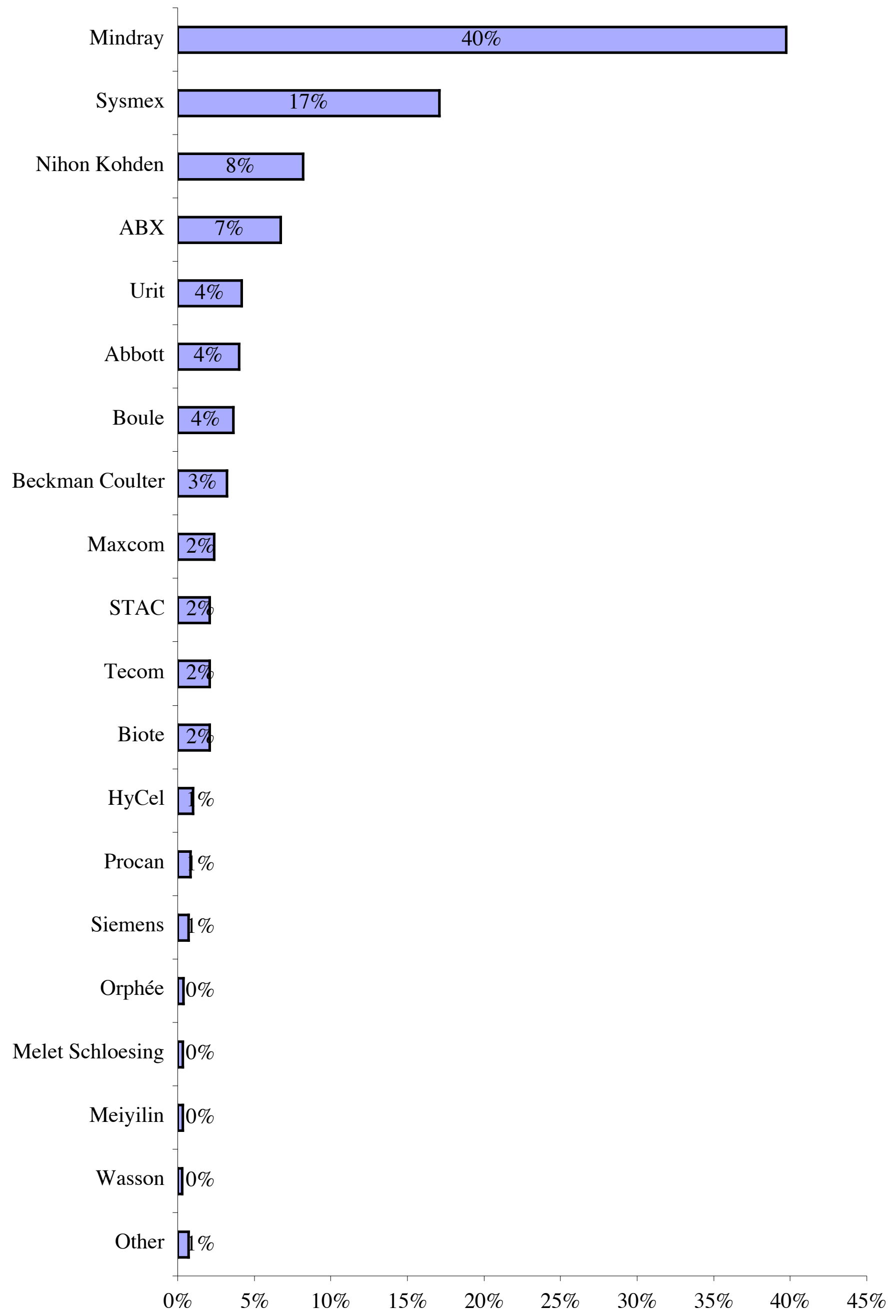
In total, the hematology market in China is growing in the 15-17% range.

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Instrument Market Shares

The market leaders in all automated hematology instrumentation appear to be:



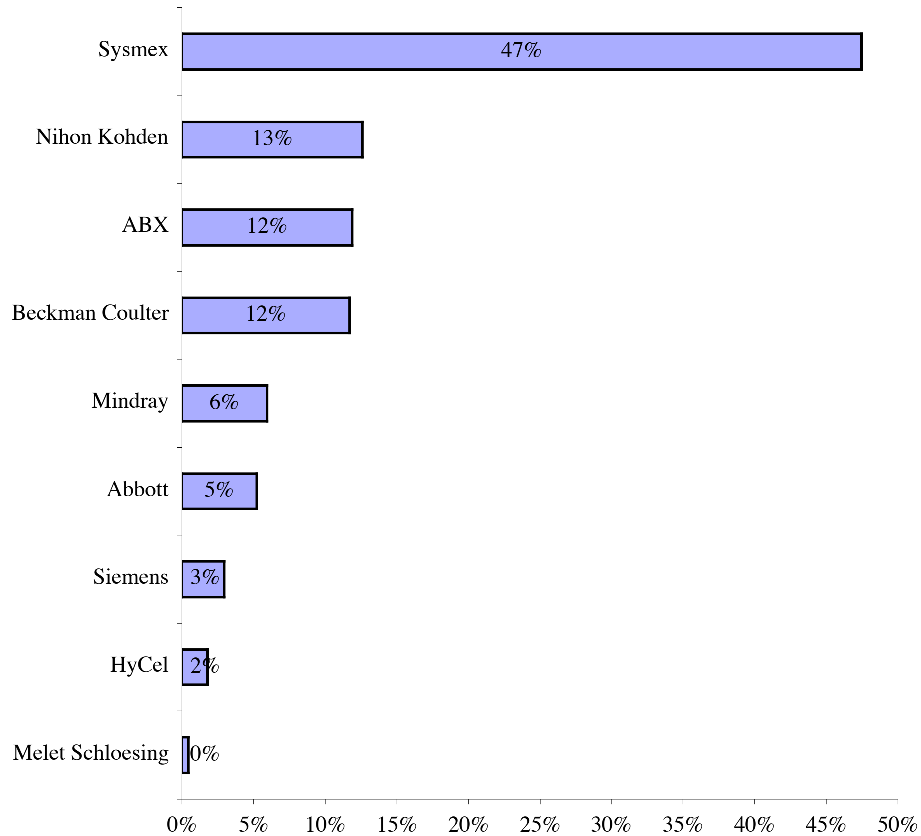
Over half of China's hematology analyzers come from local manufacturers. This is a slight increase from the just under half which were locally made when we did our 2006 report.

We also have pages like this on chemistry, immunochemistry & NAT markets.

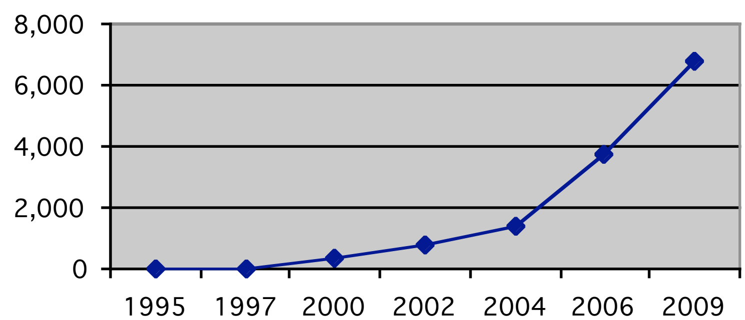
SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Instrument Market Shares

The market leaders in automated 5-part differential hematology instrumentation appear to be:



Over the years that we have been reporting on the market in China, the installed base of 5-part differential systems in China has grown from ≈30 in 1997 to the current level of just over 6,700.

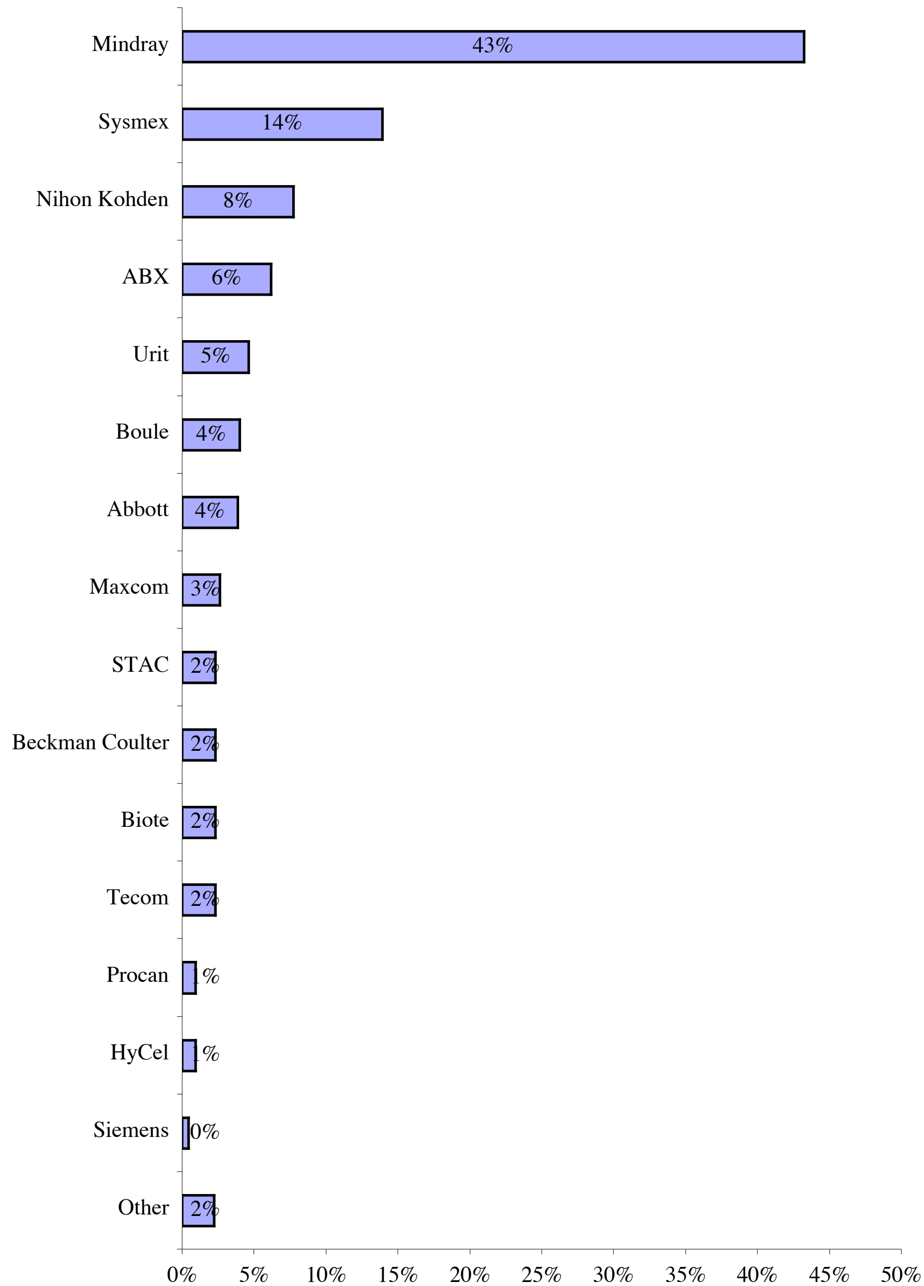


We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Instrument Market Shares

The market leaders in automated 3-part differential hematology instrumentation appear to be:



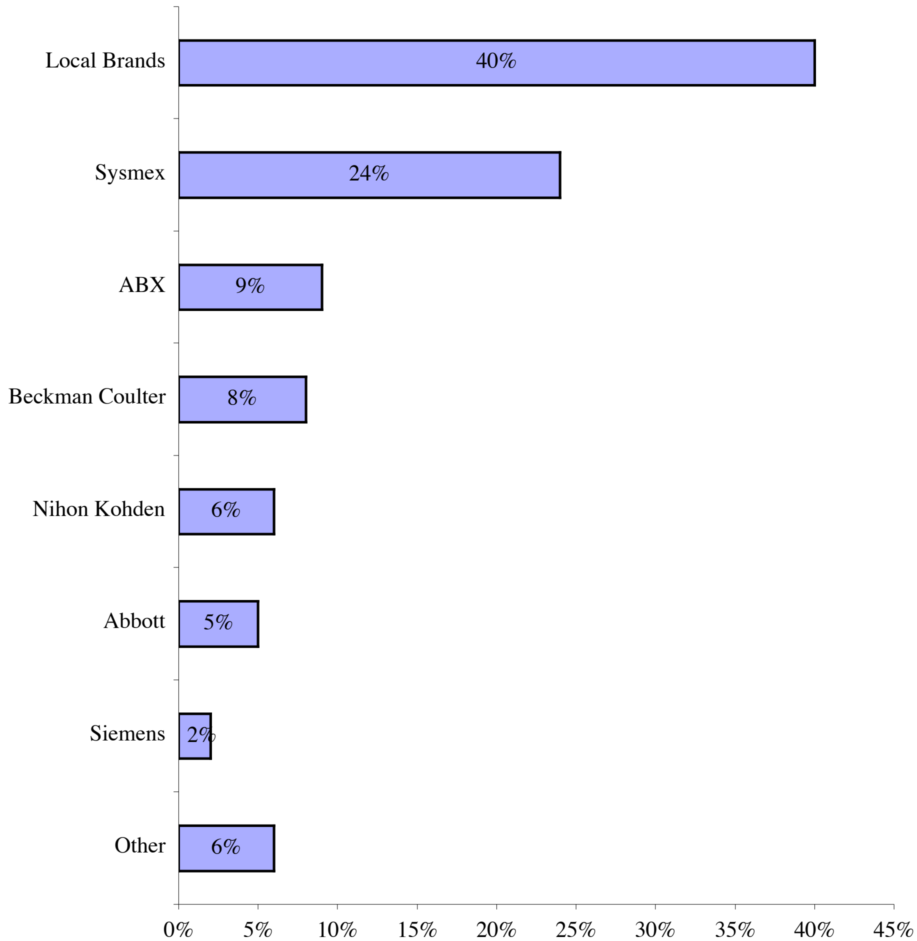
Mindray is the most common 3-part differential cell counter in China, with 40-45% of the total systems placed in the country.

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Reagent Market Shares

The market leaders in hematology reagents appear to be:



By value, a little over a third of the hematology reagents consumed in China are from local suppliers. The other two thirds are foreign brands, but most of these reagents are made in China. Most of the key hematology companies make their 3-part differential reagents locally and import the 5-part differential products.

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The installed base of automated hematology instrumentation in China is listed below.

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Automated Hematology Instrumentation

Instrument	Total	5 Part Diff	3 Part Diff
Country Totals			
• **Automated Systems**	**≈71,473**	**≈6,743**	**≈64,730**
Mindray			
• BC-5500/5300/5380	**≈400**	400	
• BC-3200/3000/2800	**≈28,000**		28000
Total	**≈28,400**		
Sysmex			
• 5 part differential systems	**≈3,200**	3200	
• 3 part differential systems	**≈9,000**		9000
Total	**≈12,200**		
Nihon Kohden			
• Celltac F/E	**≈850**	850	
• 3-Diff Systems	**≈5,000**		5000
Total	**≈5,850**		
ABX			
• Pentra 120/80/60	**≈800**	800	
• Micros/MCRP	**≈4,000**		4000
Total	**≈4,800**		
Urit Medical (Guilin Medical)			
• Botest 3100/Urit 3000 Series	**≈3,000**		3000
Abbott			
• Cell-Dyn Sapphire	**≈3**	3	
• Cell-Dyn 3000 series	**≈350**	350	
• Cell-Dyn 1800 to 1200	**≈2,500**		2500
Total	**≈2,853**	353	
Boule/Medonic/Swelab			
• Swelab AC 970/920 EO	**≈1,800**		1800
• Medonic CA 620/530	**≈800**		800
Total	**≈2,600**		2600
Beckman Coulter			
• LH 700 Series	**≈100**	100	
• LH 500 Series	**≈10**	10	
• HmX	**≈130**	130	
• Gen•S	**≈50**	50	
• Other 5 Diff	**≈500**	500	
• 3 Diff Systems	**≈1,500**		1500
Total	**≈2,290**	790	
Maxcom			
• MC-600/300	**≈1,700**		1700

We also have pages like this on chemistry, immunochemistry & NAT markets.

SECTOR ANALYSIS: HEMATOLOGY AND COAGULATION

Commentary

The prior page lists the international companies that are active in China's hematology market.

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Looking first at the international companies with local offices in China....

Sysmex is based in Shanghai, and also has offices in Beijing, Chengdu, Shenyang, Guangzhou and Xi'an. Sysmex has been active in China since the 1970s. They started with semi-automated instruments years before our first market study in 1995. In that study we observed that the Sysmex model F-800 was common enough that it has almost become a generic term for "hematology instrument" in China. Sysmex still sells a substantial number of the semi-automated F-820 instruments each year. While Mindray has more 3-part differential instruments working in China, the dominance of Sysmex in the 5-part differential systems, where they have almost half the placements in the country, makes Sysmex China's leading company in hematology. Over the past two years, Sysmex has increased their base of 5-part differential systems from ≈1,800 to the current level of ≈3,200. Sysmex is also the leading international brand in hematology reagents with ≈24% of the market. Sysmex makes all of its hematology reagents for the local market through its subsidiary, Jinan Sysmex Medical Electronics.

ABX/Horiba opened their offices in Shanghai in May 2005. They also have an office in Beijing. ABX has ≈7% of the hematology instruments working in China, but ≈12% of the 5-part differential systems. They have increased their installed base of 5-part systems from ≈600 in 2006 to ≈800 today. They rank second in international company reagent sales with ≈9% of the market.

Abbott's headquarters for China is in Hong Kong. They also have offices in Beijing, Shanghai, Guangzhou, Qingdao, Hangzhou and Chengdu. Abbott has moved its pharmaceutical and nutritional business management from Hong Kong to Shanghai, and expects to eventually move the diagnostic division as well. Abbott has ≈4% of the hematology systems working in China and ≈5% of the 5-part differential systems. These include ≈3 Sapphires which are demos. So far they have not introduced either the Ruby or Pearl. Abbott sells ≈5% of the hematology reagents consumed in the country.

Beckman Coulter previously managed their China business out of their office in Hong Kong but have moved that function to Shanghai. They also have offices in Guangzhou, Fuzhou and Suzhou. Beckman has just celebrated the tenth anniversary of their factory in Suzhou that makes hematology and chemistry reagents. The last two years have seen Beckman Coulter increase their 5-part differential placements by ≈70%, from ≈465 in 2006 to the current level of ≈790. This includes the placement of ≈110 LH systems. Beckman Coulter also sells ≈8% of the hematology reagents consumed in China.