



# Hong Kong: Diagnostic Test Products

Rose Mak and  
Elizabeth Cheng  
07/2008

## Summary

Hong Kong is entirely dependent on imported diagnostic test products. The total value of imported diagnostic test products in 2007 was US\$1 billion, but re-exports totaled US\$986 million, with a large percentage entering the China market. Imports from the U.S. were valued at US\$314 million (31% of total imports). Japanese, Chinese, German and Swedish products had a 15%, 14%, 9% and 5% market share, respectively.

The Hong Kong market for the diagnostic test products is highly competitive. Industry representatives expect a modest 2% growth in Hong Kong for the next two years, but they predict over 10% growth in China.

## Market Demand

Hong Kong will continue to demand test diagnostic products from abroad. Hong Kong is reliant on imports, as there is no domestic production, and with the SARS (Severe Acute Respiratory Syndrome), avian (H5N1) flu and influenza outbreaks in the last decade, there is a growing demand for reagents and test instruments to conduct diagnostic tests. Additionally, as China's population becomes more affluent, they are looking for higher end care. Hong Kong re-exports of diagnostic products to China grew 25% from the preceding year (from US\$606 million in 2006 to US\$753 million in 2007) and is forecasted to increase. The U.S. is generally regarded as a reputable source of the latest technology. A medical professional commented the U.S. has a strong competitive edge in high-end innovations, with a relative commercialization of medical products. For these reasons, U.S.-made diagnostic test products have good marketability in the Hong Kong Market.

Using 2007 Hong Kong Merchandise Trade statistics, diagnostic test products are divided into instruments and reagents categories for the total imports amount of US\$1 billion. U.S.-made test diagnostic products represented the largest share of imported products to Hong Kong, accounting for US\$314 million, 31% of the total imports (refer to Table 1).

In the instruments category (see Table 4), Hong Kong imported a total of US\$794 million worth of test diagnostic instruments, with the U.S. representing the largest share with 29% (US\$227 million). Following the U.S. is Japan (20%), China (18%), Germany (8%) and Sweden (5%). The instrument which has the highest value imported to Hong Kong in 2007 was Instruments and Apparatus for Physical or Chemical Analysis (HS90278000) at US\$268 million.

Hong Kong imported a total of US\$217 million worth of diagnostic test reagents in 2007. U.S.-made diagnostic reagents again dominated the largest imports share with 40% (US\$87 million). Next were Germany (13%), Sweden (9%), Japan (2%) and China (2%). See Table #5. The Hong Kong Merchandise Trade statistics also showed the most imported test diagnostic reagents to Hong Kong are Composite Diagnostic or Laboratory Reagents (HS 38220090) for the total amount of US\$191.

In 2007, the monetary amount of imports for instruments was US\$794 million while the monetary amount of imports for reagents were US\$217 million. It is possible the amount of imports will not increase significantly in subsequent years because newly purchased instruments will continue to be used, while

the amount of test diagnostic reagents will most likely increase as reagents can not be re-used and new reagents must be imported.

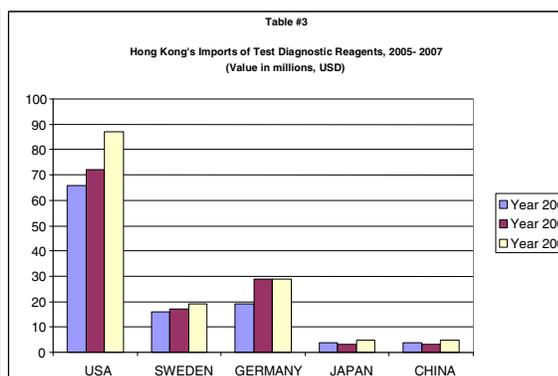
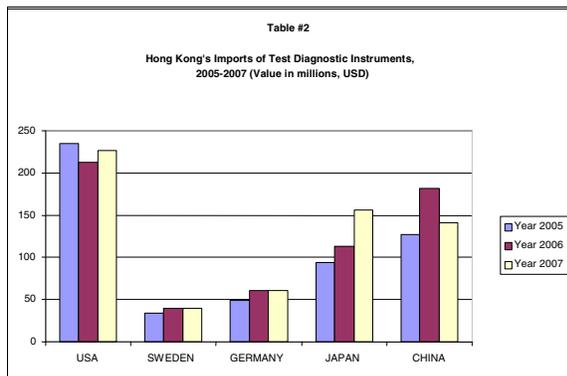
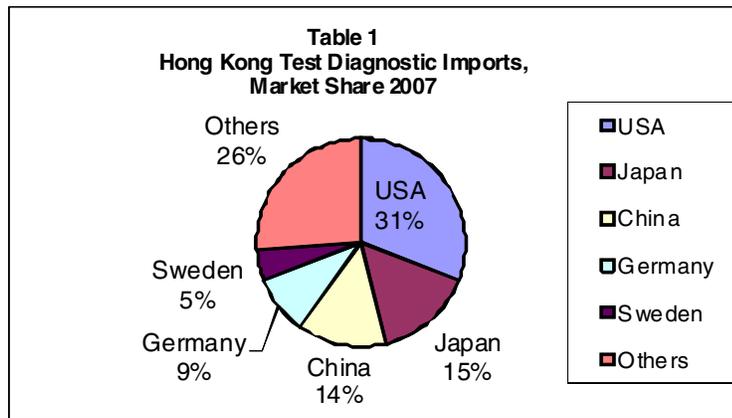
**Market Data**

STATISTICAL DATA FOR DIAGNOSTIC TEST (MEDICAL)

	2005	2006	2007	Est. Ave. Ann Real Growth Next 2 Yrs % Gain/Loss
Import Market	831	919	1,011	+3
Local Production	-0-	-0-	-0-	-0-
Total Re-Exports	814	899	986	+2%
Total Market	17	20	25	+2%
Imports from U.S.	301	284	314	+3%

Note: All values are in US million  
 Source: Hong Kong Census & Statistics Department and CS Hong Kong Estimates.  
 Exchange Rates 7.80  
 Estimated Future Inflation Rate: 6%

2007 Market Share: USA 31% Japan 15% China 14% Germany 9% Sweden 5%



## Best Prospects

Best prospects include: HIV/AIDS test, Enzymic Immunology Assay (EIA) test, chip test, DNA, hepatitis and research products. Other prospects are fast-kits for H5N1, influenza virus, pregnancy, diabetes, breath-test for H.pyloric and Severe Acute Respiratory Syndrome (SARS).

Other key prospects include health and research centers. The Research Center for Emerging Infectious Diseases is the first-ever national level "State Key Laboratory" outside Mainland China. The China Ministry of Science and Technology approved the research on emerging infectious diseases, which was completed on September 30, 2004, at the University of Hong Kong (HKU). The lab was designed and constructed to Physical Containment Level 3 (PC-3) with animal holding facilities for research to be done with live animals. The Lab is the first facility of this kind in Hong Kong and the only one focusing on emerging infectious diseases. Another Infectious Diseases Center at the Princess Margaret Hospital was completed in October 2005.

The Hong Kong Center for Health Protection was established in May 2003 by the Department of Health in the aftermath of the SARS (Severe Respiratory Syndrome) outbreak in Asia that claimed the lives of over a hundred Hong Kong citizens.

## Key Suppliers

Hong Kong will continue to rely entirely on imports of diagnostic test products. There are no legal or trade barriers for imported diagnostic test products, no import duties, and virtually no regulations on the sale of diagnostic products. Dade Behring, Randox, Oxoid, Dia Sorin, Virgo, Becton Dickson (BBL) and BioMerieux have local distributors; while Beckman-Clinical, Ortho-Clinical Diagnostic, Roche Diagnostic, Bayer Diagnostic, Abbott Laboratory, and Bio-Rad, have offices in Hong Kong.

The market in Hong Kong is competitive: competition to sell diagnostic test products to the public healthcare providers and private end-users is fierce. There are 20-30 distribution companies selling diagnostic test products in Hong Kong. There is, however, a niche market for small and medium companies wanting to enter in Hong Kong.

Hong Kong-based U.S. companies have a long history in Hong Kong and most their products are sold to the Government. U.S. diagnostic test products enjoy an excellent reputation with Hong Kong laboratory technologists. They consider the U.S. diagnostic test products to be accurate and innovative, an impression attributable to the U.S. Government's strict regulations on diagnostic kits and products. FDA Certification gives Hong Kong end-users confidence in using U.S. diagnostic products. The U.S. (31%) leads in supplying diagnostic test products to Hong Kong, followed by Japan (15%), China (14%), Germany (8.5%), and Sweden (5%).

According to industry sources, small laboratories prefer European suppliers of diagnostic test products. They consider European products to be comparable with those from the U.S. European products are also CE Standard-approved. The Europeans are reportedly more flexible on payment terms, stock support, and give free samples for evaluation. They also build up brand names (important to the new-to-the market companies). Some European firms even loan the diagnostic devices to the local SME laboratories. For example, according to a Hong Kong distribution company, a major European supplier loaned their diagnostic device "vidas" to local SME laboratories that could not afford to buy a comparable U.S.-made fully-automatic immunoanalyzer. These laboratories eventually purchased the diagnostic test products from this European supplier.

## Prospective Buyers

Hong Kong's medical and healthcare standards are among the best in the world. Hong Kong's 7 million population can access a comprehensive range of healthcare from 44 public hospitals, 50 government specialist clinics, 12 private hospitals, and two medical universities. Hong Kong's 32,145 beds include 29,243 beds in Hospital Authority hospitals and 2,902 in private hospitals. Over 128 private laboratories and 2,513 laboratory technologists provide diagnostic test services to Hong Kong people.

There are basically four categories of "consumers" for diagnostic test products: the Government (93%), private hospitals (3%), universities (1%), and independent medical laboratories (3%). Since the government purchases 93% of Hong Kong's diagnostic test products, it is imperative that companies wanting to enter this market understand the procedures of selling to the Hong Kong Government. Another potential end-user for diagnostic test products is the School of Chinese Medicine at the Hong Kong Baptist University.

Beside the SARS outbreak in 2003, Hong Kong lists 26 statutory noticeable infectious diseases (listed in Table #4), including three quarantinable diseases, namely cholera, plague and yellow fever. In 2007, Hong Kong reported 24,788 cases of noticeable infectious diseases of which 22 per cent were due to tuberculosis. The cumulative number of HIV (Human immunodeficiency Virus) infection and AIDS (Acquired Immune Deficiency syndrome) cases reported from 1984 to 2007 exceeded 3,612 and 934, respectively. According to Department of Health, there are about 200 new cases of HIV infection diagnosed each year.

TABLE #4 Infectious Diseases Notified 2005-2008

Disease	2005	2006	2007	April 2008
Amoebic dysentery	2	4	4	3
Bacillary dysentery	129	140	67	23
Chickenpox	11,943	14,415	17,947	3483
Cholera	5	1	3	0
Dengue fever	31	31	58	7
Food poisoning: Outbreaks	1,095	621	94	972
Persons affected	4,147	1,992	325	3541
Legionnaires' disease	11	16	11	0
Leprosy	4	6	2	0
Malaria	32	40	33	1
Measles	65	106	88	16
Meningococcal infections	4	6	2	0
Mumps	145	184	180	38
Paratyphoid fever	33	39	28	3
Rubella	53	34	38	10
Scarlet fever	177	230	224	82
Tetanus	0	2	1	0
Tuberculosis	6,160	5,856	5,545	1,371
Typhoid fever	36	46	46	7
Typhus	24	18	2	38
Viral hepatitis	234	210	59	203
Whooping cough	32	21	31	12
<b>Total</b>	<b>24,362</b>	<b>24,018</b>	<b>24,788</b>	<b>9,810</b>

Sources: Department of Health, HKSAR

## Market Entry Strategies

One of the best ways for American SEM suppliers to sell diagnostic test products in Hong Kong/Chinese market is through agents or distributors because it is cost effective to minimize the initial investment of setting up a representative office in the market. Virtually anything that both sides can agree to and put into a written contract is acceptable and enforceable, including restrictions on territory and a grace period for termination of the agreement.

For companies with a reliable agent/distributor or those that have set up a representative office, marketing diagnostic test products should focus on government tenders. The biggest end-user in Hong Kong is the Hospital Authority and Department of Health. Beckman, Orth-Clinical, Roche, Bayer, Abbott, and Bio-Rad dominate the public sector. Successful, new-to-market U.S. firms should have reliable and experienced Hong Kong agents or distributors, competitive prices, and provide strong marketing and material support. These Hong Kong diagnostic product agent/distributor companies typically have established good relationships with the private hospitals and laboratory technologists. In addition, they have experience with submitting applications for government tenders. New-to-the-market companies should also look at direct sales to medical universities, private hospitals and private laboratories.

The China market has tremendous potential for diagnostic test products, due to its large population and growing purchasing power. After China's accession to World Trade Organization, import tariffs have decreased to 17% as of 2007. U.S. small and medium diagnostic companies may find that working with a reliable Hong Kong agent/distributor can also open doors in China. As Chinese citizens become more affluent, more people can afford top-end, Western medical care. In addition, both the standard of living as well as the age of the population continues to increase, creating demand for innovative medical and health care products and services. An inefficient distribution system and a complex regulatory environment, however, make China a challenging market.

Hong Kong medical agent/distributors often have established a great network and excellent relationships with the medical industry in China. They often have extensive experience in working with China and share a common cultural heritage, excellent language skills, knowledge of the products, capability of providing logistics and after-sale services, and a strong reputation for marketing know-how in China. Some larger Hong Kong trading firms have offices in Beijing, Shanghai, Guangzhou, and Chengdu to cover the China market. Furthermore, the involvement of Hong Kong traders in this market is a major factor in the large re-export market for these products.

## Market Access Issues & Obstacles

In Hong Kong, there are three categories of diagnostic test products: in vivo, in vitro, and radioactive. In vivo diagnostic test products are classified "poisonous," (poison means a substance specified in the Poisons List that is prescribed by regulations) that requires registration with the Pharmacy and Poisons Ordinance. The Pharmacy and Poisons Ordinance's complete list of "poisons" can be viewed at: [www.info.gov.hk/pharmser/Reg\\_ir/download\\_pharm.htm](http://www.info.gov.hk/pharmser/Reg_ir/download_pharm.htm).

### Licenses

In vitro product registration is exempted with the Pharmacy and Poisons Board; they require, however, an import license from the Department of Health at the following address:

Department of Health  
Pharmaceuticals Registration & I/E Control Section, Pharmaceutical Service  
3/FI., Public Health Laboratory Center, 382 Nam Cheong Street, Kowloon, Hong Kong  
Tel: 852-2319-8458; Fax: 852-2803-4962  
Web site: [www.info.gov.hk/pharmser](http://www.info.gov.hk/pharmser)

Radioactive diagnostic test products require registration with the Radiation Health Unit, which works under the direction of the Radiation Board (RB). RB is the Government's adviser on radiation matters, including contingency measures, and safeguards the public against ionising radiation by means of licensing and inspections of premises where radioactive sources or equipment are used. Radiation licenses are issued to the proprietors in accordance with the Radiation Ordinance and Regulations. Contact information is:

Radiation Health Unit, Department of Health  
3/FI., Sai Wan Ho Health Center, 28 Tai Hong Street, Sai Wan Ho, Hong Kong  
Tel: 852-2836-3536; Fax: 852-2834-1224  
Web site: [www.info.gov.hk/dh-rhu](http://www.info.gov.hk/dh-rhu)

Hong Kong is a duty-free port. As such, the Hong Kong Government (HKG) levies no import tariffs on diagnostic products. The HKG pursues a free enterprise and free trade policy based upon a philosophy of minimum interference with market forces and a low, standard rate of taxation. There are no legal or trade barriers on import diagnostic products and virtually no regulations on the sale of healthcare supplies. Diagnostic products made to American standards should have no problem selling in Hong Kong.

#### Labeling and Registration Requirements

There are few requirements in labeling and marketing test diagnostic products. Test diagnostic reagents are required to label products with expiration dates. As of August 2008, registration of test diagnostic instruments is only voluntary but that may soon change with the passage of the "Regulation of Medical Devices."

Although listing is currently voluntary, once the Regulation of Medical Devices passes in the Hong Kong Legislative Council, registration of medical products imported to Hong Kong will be required, which would affect test diagnostic instruments. For more details, please contact:

Medical Device Control Office, Department of Health  
18/F, Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong  
Tel: 852-2961-8788; Fax: 852-3157-1286  
Email address: [mdco@dh.gov.hk](mailto:mdco@dh.gov.hk) (<http://www.mdco.gov.hk/>)

#### Trade Events

Medical & Health Care Fair, August 14-18, 2008  
Hong Kong Convention and Exhibition Center  
[www.hkdtc.com](http://www.hkdtc.com)

CMEF, Suzhou, October 29-November 1, 2008  
Suzhou International Expo Center  
[en.CMEF.com.cn/](http://en.CMEF.com.cn/)

#### Resources & Contacts

Research Center for Emerging Infectious Diseases  
Dr. Thomas Tsang, Controller (The Center for Health Protection)  
21<sup>st</sup> Floor, Wu Chung House, 213 Queen's Road East, Wan Chai, Hong Kong  
Tel: 852-2961-8889; Fax: 852-2573-0585  
Email: [enquires@dh.gov.hk](mailto:enquires@dh.gov.hk)  
Website: <http://www.info.gov.hk/dh>

Infectious Disease Center, The Princess Margaret Hospital  
Dr. Danny Tong Wah-Kun, Senior Nursing Officer  
2-10 Princess Margaret Hospital Road, Lai Chee Kok, Kowloon, Hong Kong  
Tel: 852-2990-2867; Fax: 852-2990-2875  
Email: hatongwk2@ha.org.hk

Professor KY Yuen, Director, Research Centre of Infection and Immunology and State Key Laboratory of Emerging Infectious Diseases  
c/o Dept of Microbiology, Pathology Department  
Queen Mary's Hospital, Pokfulam Road, Hong Kong  
Tel: 852-2855-4382; Fax: 852-2855-1241  
Email: hkumicro@hkucc.hku.hk

### **For More Information**

The U.S. Commercial Service in Hong Kong can be contacted via e-mail at:  
[Rose.Mak@mail.doc.gov](mailto:Rose.Mak@mail.doc.gov); Phone: 852-2521-7173; Fax: 852-2845-9800; or visit our website:  
[www.buyusa.gov/hongkong](http://www.buyusa.gov/hongkong)

### **The U.S. Commercial Service — Your Global Business Partner**

With its network of offices across the United States and in more than 80 countries, the U.S. Commercial Service of the U.S. Department of Commerce utilizes its global presence and international marketing expertise to help U.S. companies sell their products and services worldwide. Locate the U.S. Commercial Service trade specialist in the U.S. nearest you by visiting <http://www.export.gov/>.

*Disclaimer: The information provided in this report is intended to be of assistance to U.S. exporters. While we make every effort to ensure its accuracy, neither the United States government nor any of its employees make any representation as to the accuracy or completeness of information in this or any other United States government document. Readers are advised to independently verify any information prior to reliance thereon. The information provided in this report does not constitute legal advice.*

*International copyright, U.S. Department of Commerce, 2008. All rights reserved outside of the United States.*