



Turkey: Clinical Laboratory Devices and Reagents Market

Ebru Olcay
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Summary

Turkey is at the crossroads of Europe, Middle East, and North Africa. With a population close to 75 million people, it has a significantly higher population growth rate compared to Western Europe. Median age is 29 years with 67% of the population between the ages of 15 to 64. Average life expectancy is 75 years. It has a fast-growing middle class that is willing to spend more on quality goods and services, and a democratically elected government which has historically invested in raising living standards for the masses. Turkey's GDP tripled in the last decade and is widely considered as one of the fastest growing economies in the world today.

Turkey has a public healthcare system with a \$20 billion federal budget for 2013 – an increase of 19% over 2012. Healthcare budget allocation in the national budget jumped from 2.25% in 2002 to 4.4% in 2012 while per capita healthcare spending grew from \$330 to \$780 in the same period. With OECD per capita spend average at \$2,386 in 2012, there is significant growth potential in this market thanks to Turkey's growing income and government programs. The Turkish government has made healthcare access and quality a priority. To improve healthcare access for its citizens, Turkey, in the last decade, invested \$4.7 billion in healthcare construction.

Market Demand and Data

85 % Turkey's population is covered under the '*Universal Health Insurance Plan*' which is provided by the Social Security Agency (SGK). Main source of income of this agency are the premiums paid by the insured throughout their working years.

Last year, 230 million visits were made to the approximately 1,250 public, private and university hospitals in Turkey. 800 of these are public hospitals operated by the Ministry of Health. Main patient base of the public hospitals are the people who are covered under the SGK plan. There are about 400 private hospitals and 50 university hospitals. Every inpatient serving hospital in Turkey has to have a clinical laboratory in its facility which means that there are at least 1,250 clinical laboratories established in these hospitals. On top of these laboratories, there are outpatient private laboratories whose number, at the time this report is being written, is not known. Ministry of Health, through a new licensing of the clinical laboratories project, is trying to identify the total number of clinical laboratories in Turkey.

Patients, with private healthcare insurance plan, usually prefer having their tests done at either private hospitals or at these private laboratories. There are approximately 2 million private insurance holders in Turkey. Patients holding SGK insurance-only can get their tests done at those private laboratories that have agreements with SGK over the reimbursement prices established by SGK.

According to Turkish Clinical Laboratories Directive, which has been in effect since August 2011, there are 5 types of clinical laboratories in Turkey:

- Basic Services Laboratories
- Comprehensive Services Laboratories
- Advanced Services Laboratories
- Reference Laboratories
- National Reference Laboratories

Basic Services Laboratories can be established in the premises of inpatient and outpatient healthcare facilities and following tests can be administered in these laboratories:

- Urine analysis
- Blood glucose
- Hemoglobin
- Erythrocyte sedimentation rate
- Hemotocrit
- hCG in urine

The rest of the laboratory types, listed above, require at least one medical staff or more specialized on infectious diseases, clinical microbiology, medical biochemistry, medical microbiology, medical pathology testings and some of them should be doing research and training alongside their testing business. These more advanced laboratories typically do tests in the following categories:

- Molecular biology
- Immunology
- Markers
- Panels and screening tests
- Serology
- Allergy
- Biochemistry
- Blood tests
- Drug levels
- Hormone levels
- Microbiology
- Hematology
- Genetics diagnosis tests
- DNA analyses

Clinical laboratory devices and reagents are imported into Turkey under the following HS Codes:

Clinical Laboratory Devices

HS Code	Description
841780	Industrial Or Laboratory Furnaces And Ovens, Including Incinerators, Nonelectric, Nesoi
841920	Medical, Surgical Or Laboratory Sterilizers
841939	Dryers, Nesoi
842119	Centrifuges, Including Centrifugal Dryers (Other Than Clothes Dryers), Nesoi
851430	Industrial Or Laboratory Electric Furnaces And Ovens, Nesoi
851490	Parts For Industrial Or Laboratory Electric Furnaces And Ovens
901210	Microscopes Other Than Optical Microscopes; Diffraction Apparatus
901290	Parts And Accessories For Microscopes Other Than Optical Microscopes
902720	Chromatographs And Electrophoresis Instruments
902730	Spectrometers, Spectrophotometers And Spectrographs Using Optical Radiations (Ultraviolet, Visible, Infrared)
902750	Instruments And Apparatus For Physical Or Chemical Analysis Using Optical Radiations (Ultraviolet, Visible, Infrared), Nesoi
902780	Instruments And Apparatus For Physical Or Chemical Analysis, Nesoi

Reagents

HS Code	Description
382200	Composite Diagnostic Or Laboratory Reagents, Other Than Pharmaceutical Preparations Heading 3002 Or 3006
382100	Prepared Culture Media For Development Of Microorganisms
300620	Blood-Grouping Reagents

Turkish market for chemical devices and reagents is an imports dominated market. There are almost no major local manufacturers in the devices category whereas there are a few in the reagents market. These facts can be observed in the imports performance of the products covered under the HS Codes noted above throughout the years of 2010-2012. As far as exporting from Turkey is concerned, volume is very low compared to importing but in the coming years, local manufacturing may develop as Turkish Government will start providing incentives to companies investing in medical devices manufacturing in Turkey.

As can be seen in the chart below, U.S. imports to Turkey are stronger in the reagents group and as you will read in the further sections of this report, U.S. companies have the highest market share in reagents compared to companies from other countries.

HS Code	2010		2011		2012		growth % in imports	growth % in exports	U.S. % in Imports			growth % 2010-2012
	Imports USD	Exports USD	Imports USD	Exports USD	Imports USD	Exports USD			2010	2011	2012	
Clinical Laboratory Devices												
841780	27,760,404	5,062,351	57,444,982	6,671,793	46,849,437	5,864,666	69%	16%	142,453	176,805	3,562,039	2401%
841920	13,085,024	4,102,282	16,823,641	5,762,199	11,796,474	8,388,445	-10%	104%	1,028,965	716,077	1,236,032	20%
841939	21,078,237	11,360,213	90,253,181	15,079,746	46,076,933	23,574,137	119%	108%	678,474	6,085,800	399,272	-41%
842119	24,680,415	5,326,491	36,184,608	5,509,006	16,968,780	5,320,449	-31%	0%	1,152,395	1,081,109	514,089	-55%
851430	28,397,678	3,210,955	9,936,071	2,520,871	13,284,980	3,723,499	-53%	16%	5,376,316	310,711	126,097	-98%
851490	12,902,319	25,508,600	14,780,849	36,592,610	8,054,252	45,495,446	-38%	78%	492,745	431,865	1,662,250	237%
901210	4,728,707	14,779	3,679,621	218,457	7,474,229	79,526	58%	438%	189,147	139,324	654,658	246%
901290	2,032,746	72,406	870,481	87,614	902,302	158,691	-56%	119%	1,029,136	168,121	169,648	-84%
902720	19,491,981	372,038	18,230,734	274,269	12,571,991	1,175,296	-36%	216%	4,157,140	4,795,229	2,928,003	-30%
902730	52,178,391	1,552,185	58,506,209	1,590,581	48,336,526	2,019,443	-7%	30%	19,900,500	10,586,952	7,886,671	-60%
902750	37,064,996	519,541	37,684,756	538,124	36,615,243	5,366,252	-1%	933%	18,676,985	13,754,414	11,155,460	-40%
902780	142,449,118	6,466,533	152,274,981	8,858,928	118,297,520	9,333,943	-17%	44%	30,031,993	29,377,795	22,098,855	-26%
Total	385,850,016	63,568,374	496,670,114	83,704,198	367,228,667	110,499,793	-5%	74%	82,856,249	67,624,202	52,393,074	-37%
Reagents												
382200	202,947,684	15,367,741	224,709,703	17,353,524	226,554,697	19,053,215	12%	24%	47,252,883	56,353,833	56,753,951	20%
382100	12,670,882	609,105	14,294,526	583,593	15,541,031	880,443	23%	45%	4,580,128	4,200,674	4,211,440	-8%
300620	8,952,229	273,786	12,677,740	60,519	13,279,593	56,169	48%	-79%	313,597	968,614	1,191,812	280%
Total	224,570,795	16,250,632	251,681,969	17,997,636	255,375,321	19,989,827	14%	23%	52,146,608	61,523,121	62,157,203	19%
Grand total	610,420,811	79,819,006	748,352,083	101,701,834	622,603,988	130,489,620	2%	63%	135,002,857	129,147,323	114,550,277	-15%

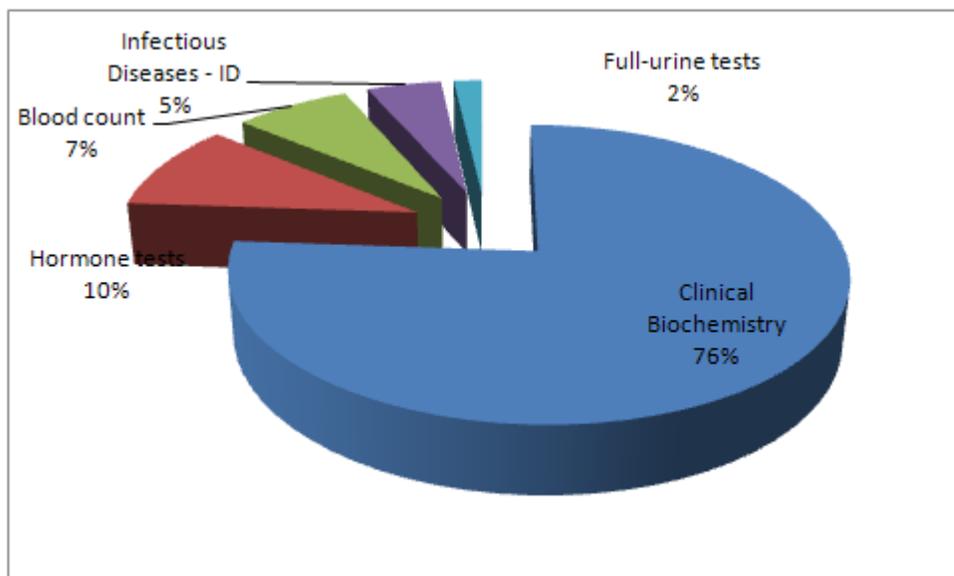
Source: Turkish Institute of Status through Global Trade Atlas

Hospitals use the laboratory testing devices of manufacturers whose reagents they also commit to using. In this 'cost per reportable model', laboratory devices are not sold but are given to hospitals in return for their commitment to buy their reagents. Only if the manufacturer does not have a specific reagent hospital wants to buy and that the manufacturer does not have in its product portfolio, hospitals, then, source these reagents from different manufacturers.

Top 5 tests administered in Turkey are:

1. Clinical biochemistry tests
2. Immunoassay tests
3. Blood count tests
4. Infectious disease tests
5. Full urine tests

Below you can find the percentage of each of these five tests within the total number that they are administered:



Source: Turkish Institute of Status through Global Trade Atlas

Market is quiet saturated in product diversity in these top 5 tests; annual growth rate is around 5% which is expected to be the same in the coming years as well.

Tests that follow these five tests are:

- Coagulation tests
- Microbiology tests
- Molecular tests for measuring viral loads - PCR tests

Higher growth rate is expected for the molecular and genetics tests.

Best Prospects

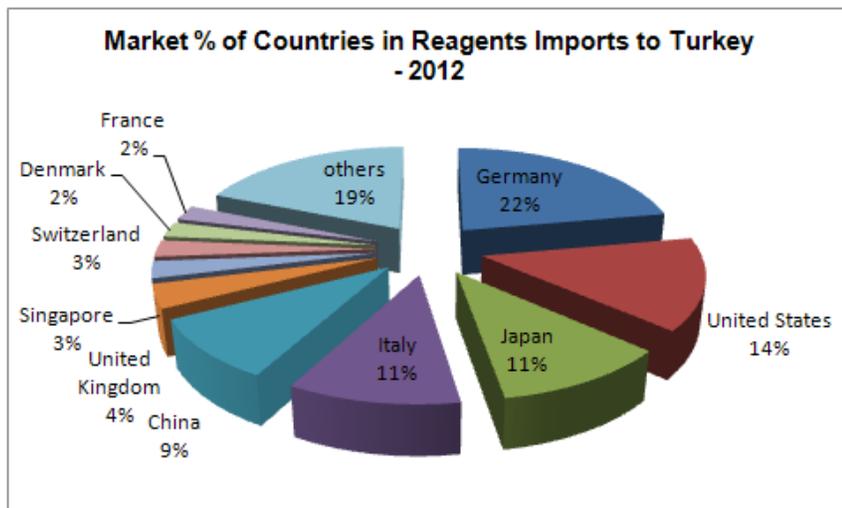
- Molecular tests
- Genetics tests
- Hormone tests
- Chromotography tests
- DNA tests

Key Suppliers

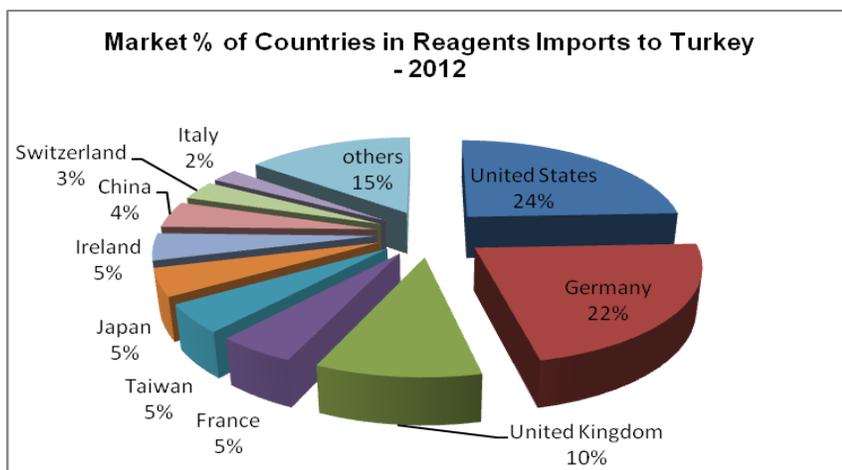
There is a dominance of various international clinical laboratory device and reagents manufacturers in the Turkish market. Most of the companies are represented through their distributors in Turkey. Some other manufacturers like, Abbott Labs, Beckman Coulter, Boston Scientific, Roche, Siemens etc, have their direct offices and sales staff.

Devices market is almost 100% imports dominated. Reagents market is about 90% imports dominated with some local manufacturers producing blood count kits and biochemistry test kits. In the coming years, there may be more local companies both in the device and reagents market as Turkish Government has identified medical devices manufacturing as one of the top industries to incentivize.

U.S. manufacturers of clinical laboratory devices and reagents have strong market shares in the market. However, when sales growth rates of devices and reagents are analyzed year over year, rates of reagents is higher compared to devices. In the country rankings, the same position of U.S. companies can be observed in the group of reagents. Please see the charts for country ranking in both product groups below:



Source: Turkish Institute of Status through Global Trade Atlas



Source: Turkish Institute of Status through Global Trade Atlas

Prospective Buyers

There are 5 customer groups of the clinical laboratory device and reagents in Turkey:

- **Private hospitals:** Each hospital operator chain buys through its own purchasing department. They ask for quotes and decide in line with their criteria for that specific purchase. It is very critical that distributors/manufacturers promote their products with the clinicians in these organizations as well as their purchasing departments.
- **Private clinical laboratories:** Management of these organizations is very similar to that of private hospitals. Their purchasing decision process follows the same route.

- **University hospitals:** Each university hospital that is part of medical schools has its own purchasing department. They open tenders for these purchases. Payment terms of university hospitals are somewhat longer which sometimes become problematic for smaller size distributors.

- **Public hospitals:** Until January 2013, each public hospital had the authority to administer its own tenders and procure per its own needs. However, as of January 2013, a new regulation is in place which groups public hospitals into 90 profit centers. There are about 800 public hospitals which have been grouped under these centers. Each center has been assigned a CEO who will manage the purchasing of all the hospitals in his/her group centrally. They will collect the needs of hospitals for at least the next one year and will administer tenders for the procurement. This restructuring is expected to consolidate the players in the market as volume of purchase in each tender will be higher and not every company will be able to finance this much of volume. This development is also expected to impact prices in the market as with larger volumes to procure, tendering authorities will be expecting lower prices per unit of equipment.

Turkish Ministry of Health has started contracting the construction and operational management of 29 medical campuses to private sector by Public-Private-Partnership model. Each medical campus will have 1,000 to 3,500 beds. Clinical laboratory services will be outsourced to private sector which is not the practice in many of the public hospitals. As much as this project is getting the attention of equipment and reagents manufacturers, international clinical laboratory operators have also started displaying interest in forming consortiums with Turkish companies to compete for these contracts.

- **Doctors In Private Practices:** Medical doctors are very limited in the scope of tests they can administer in their own private practice. Tests that they can do are mainly ones whose sample they can analyze using microscope such as:

- Vaginal and cervical scrub
- Preparates prepared using potassium hydroxide
- Fern test
- Post coital analysis of vaginal or cervical mucus
- Semen analysis
- Urine analysis - only using microscope
- Fecal leukocytes
- Nasal smear analysis for the identification of eosinophil
- ARB
- Thin spread for the diagnosis of malaria

Point of care tests that can be carried out by the patient side are limited to the following tests:

- Blood glucose
- Hemoglobin
- Prothrombin time
- hCG in urine
- Alcohol test
- Blood gas tests

Market Entry

To successfully enter the Turkish market, U.S. Commercial Service recommends U.S. manufacturers and exporters to either have their own office in the country or engage themselves with a distributor that is experienced with the laboratory devices market. A distributor will be invaluable at the time of registering the products in the National Databank and while developing the market for the U.S. company's products. Turkish distributors/imports usually want to work on an exclusive basis with the manufacturers. Main reasons for this preference is the amount of time they spend on the registration process and market building efforts and also the fact that Turkish market, for many medical devices, can be catered with one distributor with reseller channels that across the country. Prominent companies in the industry already have well established reseller channels.

As is noted above, medical devices, locally manufactured or international, have to be registered in the National Databank Bank maintained by the Ministry of Health. All clinical laboratory devices and reagents are also in this category. There is quality related documentation, like CE Mark certificate, that need to be submitted by the manufacturer through its distributor in Turkey. If documentation needed is submitted completely, it takes about 2 months for the product to get registered in the system. If there are missing documents, these need to be submitted fully. Once the products are registered, they can also apply to Social Security Agency for getting in the list of reimbursed products under the Universal Health Insurance Plan, if two sides can agree on the reimbursement price.

The Commercial Service in Turkey has a number of programs and services available to assist the U.S. business community in establishing a presence in this market, e.g., the International Partner Search, the Gold Key Service, and the International Company Profile. Please visit the following website for our further information:

<http://www.export.gov/Turkey>

Market Issues and Obstacles

There are no specific market access issues or trade barriers that would inhibit U.S. clinical laboratory device and reagents manufacturers from exporting to Turkey. Turkey has customs union agreement with the European Union (EU) which provides that products manufactured in the EU are exempt from customs tax when exported to Turkey. As U.S. is not part of this agreement and Turkey does not have free trade agreement with the U.S., U.S. clinical laboratory and reagents are levied taxes.

Marketing of clinical laboratory devices and reagents are subject to the rules established in the Medical Devices Directive which is adapted to the same directive issued by the EU. As a result, devices are required to bear CE-Mark certification for being exported to the EU are subject to the same requirement when being exported to Turkey.

Trade Events

LABMED - 16th International Istanbul Laboratory Technology System and Equipment Fair 2013

April 4-7, 2013

Tuyap Fair and Congress Center

Istanbul/Turkey

For more information: <http://www.labtechistanbul.com/>

LABMED will be organized at either the last week of March or first week of April in 2014.

ISTANBUL HEALTH EXPO

September 26-29, 2013

CNR Convention Center

Istanbul/Turkey

For more information: http://www.cnrhealthexpo.com/en_anasayfa.asp

Resources & Key Contacts

Ministry of Health

Saglik Hizmetleri Genel Mudurlugu (General Directorate of Healthcare Services)

Tibbi Laboratuvar Hizmetleri Daire Baskanligi (Department of Clinical Laboratories Services)

Address: Sağlık Bakanlığı Ulus Ek Binası

Rüzgarlı Caddesi Plevne Sokak No:7 Kat: 3

Ulus, Ankara

Turkey

Phone #: +90 (312) 324 63 89 / 152-154

Website: <http://www.laboratuvar.saglik.gov.tr/tr/anasayfa>

For More Information

The U.S. Commercial Service in Istanbul, Turkey can be contacted via e-mail to Medical Equipment Market Specialist, Ms. Ebru Olcay, at: ebru.olcay@trade.gov; Phone: [90] (212) 335-9223; Fax: [90] (212) 335-9103. Please visit our website at www.export.gov/Turkey

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