Toyobo Co., Ltd., has developed a diagnostic system that can detect Mycobacterium tuberculosis (MTB) and nontuberculous mycobacteria (NTM)* which resembles MTB, through gene analysis.

This system takes approximately 40 minutes to detect these bacteria. Toyobo began marketing this system to university and public hospitals in Japan this fall.

1. Features of the Diagnostic System

This diagnostic system uses Toyobo’s GENECUBE® fully automatic gene analyzing system and dedicated test reagents. The two types of reagents are GENECUBE MTB for the identification of MTB, and GENECUBE MAC, for the identification of Mycobacterium avium complex (MAC). The features of this diagnostic system are as follows.

(1) Analysis is simpler than for previous systems

GENECUBE® carries out gene analyses automatically after the sample to be analyzed (usually sputum) has been processed and the reagent and necessary supplies have been loaded following the system’s directions.

(2) Time for analysis is shortened remarkably

By using a dedicated extraction test reagent and amplified test reagent, the time previously required for analysis has been shorted to about 40 minutes. Thus, the results of gene analysis can be reflected immediately in medical treatment.
(3) Loss of reagent is substantially decreased

Since the reagent and necessary supplies are made available in amounts needed for one test each, waste is eliminated, and the loss of the reagent is reduced markedly. *Nontuberculous mycobacteria (NTM): Nontuberculous mycobacteria cause neither TB nor leprosy, but they do cause pulmonary diseases resembling TB.

2. Background of Development

The best-known methods for MTB examinations are (1) observing biological samples, taken mainly from sputum and fluids used to cleanse the bronchial tubes, and other sources, under a microscope, (2) growing cultures from these samples, and (3) analyzing genes from these samples. MTB and NTM infections are the same acid-fast organism, and they have similar symptoms. However, MTB can spread from one person to another, and effective pharmaceuticals are available for treatment. On the other hand, NTM do not spread from person to person, but effective treatments are limited. Therefore, the methods for coping and treatment are different. Accordingly, it is necessary to determine whether the patient's condition is due to a MTB infection or a NTM infection. Only gene analysis can distinguish between these two. However, such analysis has only been conducted at a limited number of medical facilities for a number of reasons, including (1) the complicated analytical procedures required, (2) the time required (several hours) to determine the results, and (3) the cost.

To address these issues, Toyobo has applied its original technology in the diagnostics field, which it has accumulated through the development of gene research reagents, to develop diagnostic systems for analyzing the genes of MTB and NTM. In the examinations conducted using these systems, tests can be carried out quickly and easily with the same levels of sensitivity and accuracy as with previous methods. However, since these new systems significantly shorten the time needed for analysis, they are expected to contribute to the early identification and treatment of TB and preventing the spread of disease.

3. Future Plans

For the time being, Toyobo will market these systems to relatively large hospitals, including domestic university and public hospitals, and will aim for sales of ¥1 billion, including dedicated reagents, in fiscal 2013. Plans call for expanding the items coming within the scope of analysis step by step, focusing mainly on contagious diseases.
By promoting the more-widespread use of these GENECUBE® systems, Toyobo will contribute to restraining the spread of contagious diseases, to facilitating early treatment, and to developing tailor-made pharmaceuticals.

4. Toyobo's Diagnostic System Products

(1) GENECUBE® fully automatic gene analyzing system (Medical equipment)
Price of main unit: ¥16 million (Recommended retail price, before tax)
Dimensions: Width: 900mm, depth: 550mm, height: 600mm
Weight: About 92 kilograms
(2) GENECUBE MTB (In vitro diagnostic agent)
Test object: MTB
Price: ¥153,600/kit (Recommended retail price, before tax)
Package unit: 96 tests/kit
(3) GENECUBE MAC (In vitro diagnostic agent)
Test object: MAC
Price: ¥153,600/kit (Recommended retail price, before tax)
Package unit: 96 tests/kit

For more information, contact:
Toyobo Public Relations Group
pr_g@toyobo.jp