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Toyobo Markets Respiratory Syncytial Virus (RSV) Diagnostic System that Detects RSV Infections in Less than Half the Time of Previous Systems

Toyobo Co., Ltd. (Toyobo), will launch the marketing on January 27 of its "POCube RSV" diagnostic reagent for use in its "POCube[®]" compact chemiluminescent autoanalyzer, which can measure a wide range of clinical examination items with a high degree of sensitivity.

Thus far, POCube[®] has been able to diagnose three items. Now, this RSV reagent allows users diagnose four items.

1. Development Background

RSV infections spread about the same season as influenza, and the symptoms are similar, including high fever and coughing. About 70% of infants become infected with the RSV within one year from birth, sometimes with severe consequences in Japan. In addition, immunodeficiency patients, older persons, and others with weak immune systems may also experience serious consequences after infection. There are also some reports that the number of deaths per year among infants one year old or less exceeds deaths from influenza.

Compared with other viral respiratory infections, RSV infections tend more often to lead to severe consequences, and determining whether patients are infected with the RSV is extremely important. However, diagnostic methods used thus far have (a) required about 15 minutes to detect the virus and (b) have been relatively insensitive and able to make diagnoses in only about 70% of the cases. Toyobo has focused on the market need for improved diagnosis and has now developed an RSV diagnostic system that can detect infections faster and is more sensitive than previous systems.

2. Features of the Diagnostic System

This diagnostic system consists of Toyobo's compact chemiluminescent autoanalyzer POCube[®] and the POCube RSV reagent cartridges designed for this system. Droplets of the specimens are poured in the reagent cartridges, and then the cartridges are loaded into the analyzer to determine the viral infection. The features of this diagnostic system include the following:

(a) Speed – Test results are available right away

Results can be obtained in approximately six minutes with this system. Meanwhile, previous diagnostic methods require around 15 minutes to perform a diagnosis.

(b) High sensitivity – Excellent sensitivity makes early-stage diagnosis easier

This system offers between 10 to 40 times the diagnostic sensitivity of previous systems. Therefore, it is possible to detect the virus at an earlier stage when relatively few are present. This is expected to be useful in deciding on diagnosis and treatment approaches.

(c) Clear results display – Test results can be viewed at a glance

With previous diagnostic methods, the time was measured and results were judged visually. With Toyobo's system, after the specimen is dropped into a specially designed reagent cartridge, it is loaded onto the system, which automatically determines the presence or absence of the virus and then shows the results.

(d) Simplified diagnostic procedure

This system simplifies diagnostic procedures. Users must just load the cartridge onto the autoanalyzer and then push a button. Thus far, it has been possible to use the POCube[®] for measurement of (i) CRP (C-reactive proteins), (ii) influenza viruses, and (iii) PSA (prostate specific antigens, an early marker for prostate cancer). When users purchase the reagents for these three items, it is also possible to conduct diagnoses for a fourth item, RSV infections.

3. Future Directions

Toyobo is aiming for a 30%-or-higher share of the RSV diagnosis market.

Toyobo plans to increase the scope of diagnoses, focusing especially on children's diseases, to include streptococcus pyogenes, adenovirus, rotavirus, allergies, and other diseases in the near future.

4. Overview of Toyobo's Diagnostic Systems Products

(a) Compact chemiluminescent autoanalyzer POCube[®]
Price: ¥1.2 million (MSRP*, excluding tax)
Measurement principle:

Chemiluminescent immunoassay (filter solid phase) External dimensions:

280mm (width) x 310mm (depth) x 275mm (height) Weight: Approximately 12kg



(b) RS virus reagent cartridges POCube RSV
Price: ¥12,000 (MSRP*, excluding tax)
Number of tests: 10 per kit (box)
Detection time: Approximately 6 minutes

*MSRP: Manufacturer's suggested retail price

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