Tear Total IgE Detection Kit

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1 Abstract

This product is an in vitro diagnostic kit and is used for auxiliary diagnosis of allergic conjunctival diseases. This product has been launched in medical institutions after its approval by MHLW in September 2008. The unique value of this product is that it is able to take the tear fluid directly from the patient's eye. The doctor can collect the specimen and test immediately, in person, at the medical practice. Therefore the development of this product to new markets is expected to be categorized as POCT (Point of care testing).

This product form is strip shape, which is suitable for testing small amounts of tear fluid. In certain cases, it had been reported in the medical field that tear fluid collection from a patient took too long due to the patient's inability to produce the necessary tear volume to conduct the test. We have developed a product, which improves the collection time of the tear fluid.

2 Features

- Improved sample absorbency by decreasing the void ratio of sample collection fabric, hydrophilic treatment of fabric and optimizing placement size
- Reduction of the sampling time and sample volume

3 Background of Development

Although the method of easily measuring a small quantity of IgE was not available before, we succeeded in commercializing this method by using high-efficiency antibodies and by an immunochromatographic technique used for influenza diagnostic products and pregnancy tests. This product form is strip shape. **Figure 1** shows the principle of reacting IgE in tear fluid on the strip.

The required tear fluid volume for measuring with this product is about 10 μL. Samples are collected by applying the sample collection area, which is made of non-woven fabric, on the lower conjunctival fornix of the eye. When the collected tear fluid moves from the sample collection area to the test area made of nitrocellulose membrane via capillary action, the test area impregnated with reagent is immediately moistened with the tear fluid, whereupon reaction begins. The time taken for the test area to get wet was problematic at the medical practice. We examined the possible improvements in the tear fluid absorbency of the sample collection fabric, and the optimization of the connection between the collection areas and the test areas, and improved the product to shorten the time required to collect tear fluid.

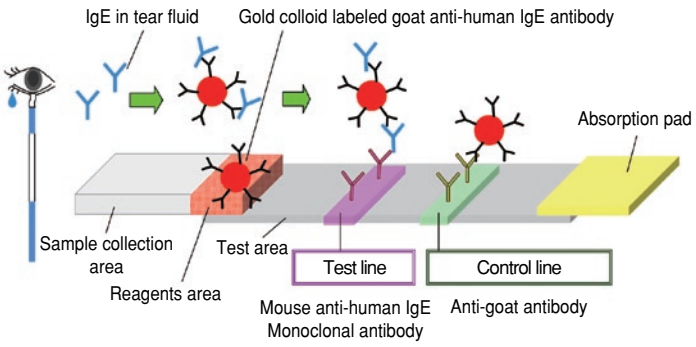
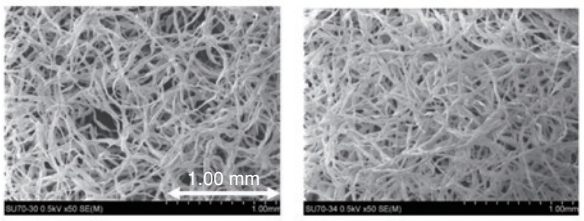


Figure 1 Principle of the assay

4 Details of Technology

(1) Design

The sample collection area is made of cellulose non-woven fabric, and contains voids between entangled fibers. As it was supposed that a smooth movement of the fluid to the test area would be interrupted if the fluid were trapped in these voids, the void ratio was reduced by compressing the non-woven fabric. **Figure 2** shows SEM images of conventional fabric in (a) and compressed fabric in (b). The product was improved by the hydrophilic treatment of fabric and by optimizing placement size (**Figure 3**).



(a) Conventional non-woven fabric (b) Compressed non-woven fabric

Figure 2 Non-woven fabric SEM image

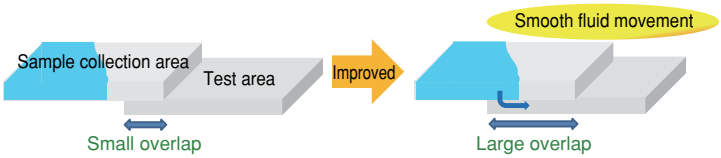


Figure 3 Optimization of placement

(2) Evaluation

1) Sample absorption time

With 10μL of control sample, the time taken for the test area to get wet was measured. The result is shown in **Figure 4**. Whereas the conventional product took about 30 seconds to start getting the test area wet from the start of absorbing the sample, the improved product took 10 to 15 seconds, it is nearly half the time of the conventional product. The time of the improved product for getting the entire test area wet is also shorter than the time of the conventional product by about 30 seconds.

2) Sample volume

The sample volume were divided into ten categories, and 10 strips were tested for each volume. The number of measurable strips and absorption time were also measured. **Figure 5** shows the results. Using 5 to 7.5 μL that were less volume than the volume to be required by the conventional product, improved product strips were measurable. When the sample volume is small, the absorption time usually increases, however, with the improved product, a smaller volume was absorbed in shorter time than the time of the conventional product.

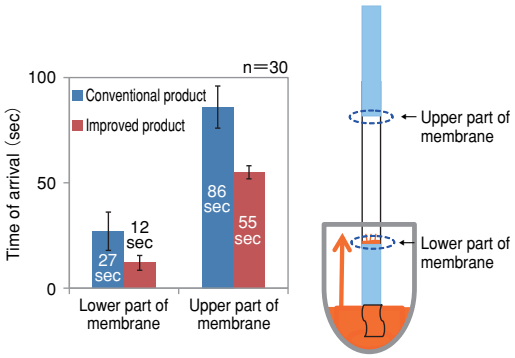


Figure 4 Sample absorption time

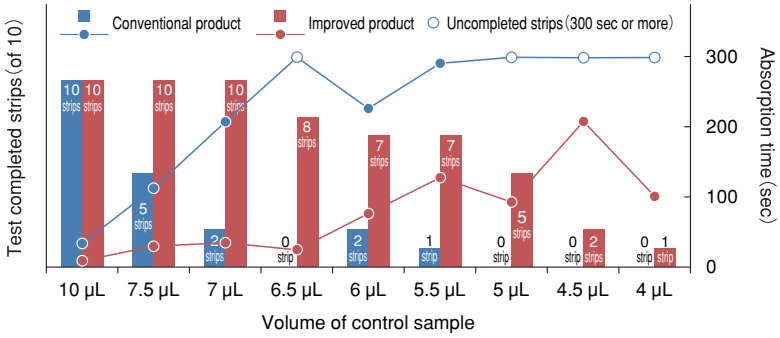


Figure 5 Study of sample volume

Regarding the basic reagent performance including sensitivity, precision and within-run reproducibility, the improved product has basic performance that is equivalent to conventional products and meets the required quality standard.

5 Future Prospects

- Development of test reagents for small amounts of body fluids except tear fluid (e.g. saliva, nasal discharge)
- Development of specific IgE test reagents

[References]

1) Hitachi Chemical Technical Report, No. 52 (2009-1)

[Patent]

Japan Patent No. 5218235