TBA-FX8 Automated Clinical Chemistry Analyzer with Flexibility to Respond to Demands of Large-Scale Clinical Laboratories

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Automated clinical chemistry analyzers are instruments that quantitatively or qualitatively measure the concentration of clinical chemistry assays in biological fluid samples such as serum, urine, and so on. They are widely used in clinical laboratories and examination centers in line with the progress of automation due to the dissemination of computer technology. With the changes in health services and the increasing sophistication of medical technologies in recent years, demand in this field has diversified to include compliance with the ISO (International Organization for Standardization) 15189 standard, which specifies requirements for quality and competence in medical laboratories, in addition to the handling of large volumes of data, shortening of turnaround time (TAT), reduction of the cost per test, and labor saving as universal requirements.

Toshiba Medical Systems Corporation (TMSC) has been developing automated clinical chemistry analyzers with the flexibility to fulfill these diverse requirements. We have now developed the TBA-FX8 automated clinical chemistry analyzer, which has two reagent compartments with large capacity to improve the processing capacity when treating large amounts of specimens and makes it possible to reduce the introduction cost for future expansion through the adoption of a module connection structure.

1. Introduction

The demands placed on hospital laboratories with regard to clinical laboratory tests are expanding due to recent changes in healthcare policies, advances in healthcare technologies, and the aging of society, as well as the increase in the number of examinations performed in developing countries.

As a result, there is now a wide range of diversity in the requirements for biochemical analyzers, and the contents of these requirements continue to evolve. This has led to changes in the priority of universal requirements such as support of multiple-sample processing, shorter TAT, which is a benefit to the patient, lower cost per test sample, and reduced power consumption. In addition, the need to ensure compliance with the international standard ISO 15189, which specifies the quality and performance requirements for clinical laboratory equipment, is leading to changes in the routine operating procedures followed at clinical laboratories.

Automated clinical chemistry analyzers must be flexible to meet a wide variety of requirements in order for laboratories to achieve efficient operation from a technological viewpoint. Moreover, to provide laboratories with new value as well as the latest analyzer technologies, it is becoming increasingly important for analyzer manufacturers to explore and develop new test applications focusing on improvements in analyzer functionality in collaboration with application manufacturers such as a reagent manufacturers, laboratory equipment manufacturers, and so on.

Given this background, Toshiba Medical Systems Corporation (TMSC) has now developed the automated clinical chemistry analyzer TBA-FX8 with outstanding flexibility to meet a wide variety of clinical needs (Figure 1). This report presents an outline of this analyzer and describes its main features.
2. Diversification of laboratory requirements

In order to address the problem of ever-increasing healthcare costs, healthcare reform, including the revision of medical remuneration policies, has been underway in Japan. Hospital laboratories have also been making concerted efforts to thoroughly review the costs related to clinical laboratory testing. One possible solution is to outsource some or all laboratory tests and associated processes to specialized clinical laboratory testing companies.

At the same time, such testing companies have been consolidating and establishing systems to provide appropriate services that meet the requirements of hospitals, such as ensuring a high level of quality control. In addition, since testing companies need to use the same specific analyzers and reagents for each test item in order to maximize the consistency of the test results, they tend to employ a bulk order system for the purchase of analyzers and reagents and to make improvements as required.

On the other hand, when considering hospital management as a whole, it is also essential to take into account the desires of patients, who prefer to visit hospitals that provide healthcare services in the most convenient and efficient manner. One factor in achieving this goal is quicker testing. Specifically, in order to allow patients to receive the full range of healthcare services from testing to diagnosis and treatment on the day of their visit, there is increasing demand for laboratories not only to offer a wide variety of tests within the hospital but also to provide results in only 30 to 60 minutes. In addition, quicker testing has been approved as an additional item in the medical remuneration point system, which is driving advances in in-hospital testing systems.

Given the situation described above, medium-size and large hospitals tend to perform laboratory tests on-site in order to achieve a quicker testing system. On the other hand, smaller hospitals tend to outsource laboratory tests in order to reduce costs. In addition, there is increasing demand for testing companies to return accurate results for large numbers of samples received from hospitals in all parts of the country as quickly as possible.

The above requirements mean that it is essential for automated clinical chemistry analyzers to process large numbers of samples quickly and to provide accurate results for a wide variety of test items.

3. Features of TBA-FX8 to satisfy today’s clinical requirements

We established a partnership with the American company Abbott Laboratories Inc. in 1997. Since that time, we have been providing integrated systems that feature the ability to connect immunoassay systems and clinical chemistry analyzers. Such integrated systems make it possible to perform immunoassay and biochemical analysis, which are the two main types of test procedures, in a seamless manner, which not only helps to improve work efficiency but also opens up new markets.

With regard to the newly developed TBA-FX8, its sample processing speed, a basic performance parameter for an analyzer, has been increased to 2000 tests/hour for a single module. This is top-class performance in the industry. In addition, up to four modules can be connected, resulting in a flexible system that can be configured according to the size of the facility and the number of tests to be performed (Figure 2).

This system provides outstanding flexibility to meet the rapidly diversifying requirements of modern clinical laboratories. For example, as demand on the laboratory increases, the sample processing capacity can be increased with a relatively small investment by simply adding the required number of modules, without the need to replace the entire system. The design also supports the use of universal reagent bottles and employs sample racks that can be used in common with other models, which leads to higher processing speeds, improved processing efficiency, and lower installation costs.

3.1 Reagent carousels and sample racks

The TBA-FX8 is provided with two large-capacity reagent carousels that are compatible with the universal reagent bottles that are currently widely available on the market (Figure 3). Each of the two reagent carousels can accommodate up to 90 reagent bottles, which is the largest number of reagent bottles in our line-up of automated clinical chemistry analyzers.

Since reagents can be selected from among an extensive range of commercially available choices, it is possible to perform a wide variety of tests as soon as the system has been installed. At the same time, compared with models that require dedicated reagent bottles, the price of commercially available universal reagent bottles is significantly lower, helping to reduce operating costs.

With regard to the sample racks, a 5-vial rack design,

(*1) Based on data gathered by TMSC as of February 2015.
which has already gained widespread acceptance at laboratories, is employed (Figure 4).

Moreover, compatibility with many currently installed associated systems such as laboratory automation systems and dispensing systems has been ensured by close collaboration with laboratory system manufacturers.

### 3.2 High-speed sampling

In order to improve TAT, it was important to achieve high-speed operation of 2000 tests/hour while also ensuring high measurement accuracy. Such high-speed operation allows the overall processing time to be reduced by 20%, which has a significant effect on improving sampling accuracy. We have therefore employed a mechanical design in which two sampling arms rotate on the same circle so as to shorten the movement distance for the first sample aspiration process as much as possible. At the same time, a mechanism for detecting the liquid level is provided to achieve quicker operation for the second and subsequent sampling processes. These clever design features have made it possible to ensure sufficient time for reagent dispensing and sample aspiration, and as a result, high-speed sampling is achieved while also ensuring high sampling accuracy.

In addition, the sampling positions of both arms can be set on the same circle, making it easier to connect the analyzer with a laboratory automation system.

### 3.3 Test methods

Automated clinical chemistry analyzers were developed in the second half of the 1950s. Initially, the main test method was the colorimetric method\(^{(2)}\), in which the changes in color resulting from various chemical reactions are measured.

Later, in the 1960s, the ion selective electrode (ISE) method was developed, making it easier to measure electrolytes, such as sodium ion (Na\(^+\)), potassium ion (K\(^+\)), and chloride ion (Cl\(^-\)). Because the ISE is quite compact, it has been installed in automated clinical chemistry analyzers, allowing them to perform electrolyte measurements (ISE assays) as well as photometric assays\(^{(2)}\).

The TBA-FX8 can process ISE assays at high speed when the ISE shown in Figure 5 is installed in each module.

In the 1970s and 1980s, the latex agglutination method was introduced as a new application for automated clinical chemistry analyzers. In this method, specific antibodies are bound to the surface of small latex particles, the latex particles are agglutinated by the antigen-antibody reaction, and the turbidity is measured (Figure 6). Today, this is one of the main applications of automated clinical chemistry analyzers, and it has led to a substantial increase in the range of test items.

### 3.4 Sample handling system

As described above, in collaboration with Abbott Laboratories Inc., we have been offering integrated systems that feature the ability to connect immunoassay systems and clinical chemistry analyzers (Figure 7)\(^{(3)}\). Such integration was made possible by the development of improved washing technology to reduce carry-over,

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\(^{(2)}\) This is a method in which substances are quantitatively analyzed by comparing the color density and tone.
i.e., sample-to-sample contamination, to 0.1 ppm or less as well as the development of a robot-type rack sampler, rather than a conveyor belt-type rack sampler, to support more efficient random access to specific modules.

The TBA-FX8 supports high-speed processing while ensuring excellent washing performance comparable to that of conventional systems. In addition, it is equipped with a newly developed sample handling system that is more reliable than earlier designs (Figure 8).

In this sample handling system, we have employed high-performance and extremely reliable parts similar to those used for industrial robots in order to achieve stable high-speed operation and excellent random access that permits individual racks to be moved directly to the desired modules, even when four measurement modules with a processing speed of 2000 tests/hour are connected.

Unlike the conveyer belt method in which racks are moved sequentially, this method allows the operator to quickly perform high priority tests for individual samples. Even if a measurement unit with a lower processing speed is used in combination, the slower measurement unit does not become a bottleneck. The TBA-FX8 provides the efficient sample handling that will be essential for future integrated systems. It is also remarkably quiet in operation.

In addition to the features described above, the TBA-FX8 is designed to ensure excellent maintainability. Specifically, the photometric lamp, ISE unit, washing unit, and so on are installed in locations which are easily accessible from the front of the analyzer so that maintenance work can be performed quickly and easily.

4. Support of new testing technologies in future

We will continue to work as flexibly as possible in order to meet the changing demands of hospital laboratories and clinical laboratory testing companies. To this end, it is considered necessary to develop even more advanced automatic functions such as a function for automatically changing reagent bottles in real time and an automatic maintenance function that does not require human intervention.

It is also important to take measures to minimize the amount of reagent used, which reduces reagent costs. In the future, it will be necessary to develop new tech-
technologies for obtaining test results from extremely small blood samples, which will help to minimize patient discomfort.

Efficient data management, sample management, reagent management, and so on throughout the laboratory is another important consideration. It is therefore necessary to provide automated clinical chemistry analyzers with a traceability function for handling such information and ensuring full compliance with applicable international standards.

New technologies such as radio-frequency identification (RFID) will be used to manage the flow of samples and reagents in the laboratory, so it will also be important to ensure compatibility with such operational advances and technological innovations.

5. Conclusion

We have developed the TBA-FX8 as a platform product that can satisfy a wide variety of technological requirements. Based on this system and its advanced technologies, we will work hard to identify, investigate, and develop automated clinical chemistry analyzers so that we can offer a wide range of systems based on a clear understanding of market requirements and the voice of the customer. We will also collaborate closely with application manufacturers to contribute to the further improvement of hospital laboratories.

References

