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Validation of Konsung Compass 2000 Dry Biochemical Analyzer

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Abstract: Dry biochemical analyzers have been increasingly popular in many tests by primary hospitals, field hospitals and other areas subject to economic and medical underdevelopment as well as poor transportation. With the increasing demand for POCT in primary medical care around the world, upgrading of dry biochemical analyzers has been a hot topic in technical research. Against such context, Konsung Compass2000 dry biochemical analyzer, a POCT system with high precision and accuracy, is developed. Furthermore, the upgraded dry biochemical analyzers can, in a more convenient and accurate way, monitor glucose, lipid and other indices affecting the course of chronic diseases.

Keywords: POCT Dry Biochemical Analyzer; Blood Lipid; Blood Glucose

Introduction

Biochemical testing, a most common method to identify underlying diseases in clinical dignosis, provides basis for doctors to decide on therapeutic regimen in combination with clinical signs. Generally, laboratory biochemical analysis employs automatic or semi-automatic biochemical analyzers; while household testing adopts dedicated devices for self-test. However, neither the laboratory equipment nor the devices for personal use are suitable for the clinical diagnosis of chronic diseases at the primary medical care system; the former, though of good performance, is very costly while the latter is biased by its poor stability and accuracy, which often leads to significant errors. Therefore, it is necessary to develop a biochemical testing system dedicated to primary medical care. To meet this demand by primary medical care system, we consulted a flood of literature of related topics, and finally created the dry biochemical analyzer as presented below..

1. Dry biochemical analyzer

Dry biochemistry has been widely used in clinical applications, from litmus paper that was used in the 16th century for determining the acidity and alkalinity of liquids to dry biochemical testing products used today. However, due to technical barriers, the existing dry biochemical analyzers are still mostly large or desktop devices, such as Reflotron (BM, West Germany) and Seralyzer (Ames, USA). Such large or desktop devices are cumbersome and cost much in maintenance, and additionally, most of them can only test plasma and serum, and their operators need to be strictly trained and can only operate them in laboratories.

There also are one-handed dry biochemical analyzers available, owing to the rapid development of biochemistry, optics, electronics, micro electrode technology and modern microcomputers as well as the increasing improvement of clinical enzymology; moreover, dry chemistry analysis now allows testing on samples from the whole blood, serum, plasma or other body fluids, instead of urine samples which were used; as for dry reagents (dry strips), three-layer strips that can eliminate interfering components, or multi-film strips are available now, replacing the simplest two-layer ones that could only be used for qualitative or semi-quantitative determination.

On this basis, many quantification methods are becoming popular, including reflectometry (dry strip by colorimetric method), differential potential method (dry strip by ion-based method), fluorescence reflectometry (dry strip by immunological method), and digital imaging based on the direct coupling with the CCD; and special or multi-functional semi-automatic or fully automatic dry chemical analyzers that are compatible with dry reagents have been developed and become more popular than single-purpose urine analyzers and blood glucose meters that were used.

1.1 Design principle

With multi-film solid-phase reagent technology, samples are loaded to reagent carriers (solidified in special structures) for analysis and determination. Therefore, dry biochemistry is also called solid phase chemistry. The dry biochemical analyzer features the dry reagent which is the reagent carrier solidified in a special structure.

1.2 Testing principle

Dry biochemical analyzers are mostly similar in the testing principle and technically depend on the test strips. The testing principle is shown in Fig. 1. The sample passes through the blood diffusion layer, to the blood filtration layer, the reagent layer, and then the support layer. Through diffusion and filtration, chemical reactions occur between the two phases at the reaction layer. Finally, the measured results are obtained at the support layer by reflection spectrophotometry.

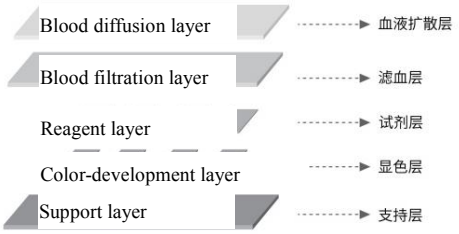

Fig. 1 Strip for Dry Biochemical Analyzer

2. Konsung Compass 2000

2.1 Konsung Compass 2000-1 and attached reagents

Konsung Compass 2000 and its attached reagents are shown in Fig. 2 and Fig. 3. The strips shown in Fig. 3, from left to right, are for blood lipid/glucose, renal function and liver function testing, and blood donor screening. They are able to provide quick POCTs of GLU, TG, HDL, TC, ALT, AST, ALB, UA, UREA, CR and HB in whole blood and serum.

Fig. 2 Konsung Compass 2000

Fig. 3 Strip for Konsung Compass 2000

2.2 Acquisition of measured results

Using photonics reflection, for a solid-phase reaction layer of the dry strip, the thickness is X, and the external light passes through the solid-phase reaction layer and is reflected at the lower interface; in addition to light absorption, there is obvious scattering during transmission and reflection. The light intensity is I0, and the incident light intensity and the emitted light intensity on the deferential-layer thickness dx, which is the distance x from the lower interface, are i and j respectively. Then the differential equation is built and solved, resulting in the reflectivity R (R = j/I0) at the upper surface, which is determined by the scattering coefficient S, the absorption coefficient K per unit thickness of the solid-phase reaction layer and the thickness X of the solid-phase reaction layer. Since K is proportional to the concentration C of the tested substance and, when S and X are constant values, the reflectivity R is only associated with to the concentration C of the tested substance. Thus, the concentration C of the tested substance can be obtained.

2.3 Konsung Compass 2000 vs. conventional devices

2.3.1 Accuracy of Konsung Compass 2000

With the correlation coefficient R^2 as one of the indexes reflecting the system accuracy, the correlation between Konsung Compass 2000 and the results obtained in the laboratory is shown in Table 1. By using the regression equation obtained, the calculated R^2 of glucose, lipid, liver and renal functions are ≥ 95%.

Table 1 Correlation Between Konsung Compass 2000 and Laboratory Results

	Whole blood		**Serum**	
Item	R^2	Conclusion	R^2	Conclusion
GLU	0.99	Qualified	0.97	Qualified
TG	0.99	Qualified	0.98	Qualified
HDL	0.96	Qualified	0.96	Qualified
TC	0.95	Qualified	0.97	Qualified
ALT	0.95	Qualified	0.98	Qualified
AST	0.95	Qualified	0.99	Qualified
ALB	0.99	Qualified	0.99	Qualified
CRE	0.99	Qualified	0.99	Qualified
UA	0.98	Qualified	0.97	Qualified
UREA	0.97	Qualified	0.98	Qualified

2.3.2 Repeatability (precision) (CV%) of Konsung Compass 2000

The quality controls at high and low levels are tested for 10 consecutive times. The CV% of Landau quality control on Konsung Compass 2000 is shown in Table 2, which is ≤ 10% for each index.

Table 2 Results of Landau Quality Control at Two Levels

	R1		R2	
Item	CV%	Conclusion	CV%	Conclusion
GLU	4.3%	Qualified	4.5%	Qualified
TG	5.5%	Qualified	2.3%	Qualified
HDL	3.6%	Qualified	4.6%	Qualified
TC	5.5%	Qualified	6.9%	Qualified
ALT	5.3%	Qualified	8.2%	Qualified
AST	3.4%	Qualified	3.7%	Qualified
ALB	6.9%	Qualified	9.5%	Qualified
CR	5.6%	Qualified	3.5%	Qualified
UA	3.0%	Qualified	3.2%	Qualified
UREA	9.8%	Qualified	4.9%	Qualified

3. Advantages of Konsung Compass 2000

3.1 Advantages in POCT

Konsung Compass 2000 is a POCT device equipped with dry strips, with technical improvements and updates in some aspects based on the advantages of POCT devices. Compared with the previous POCT devices, Konsung Compass 2000works more efficiently, making it possible to shorten theturn around time (TAT), thus reducing costs, and to expand the detection range such that it can provide quick POCTs of GLU, TG, HDL, TC, ALT, AST, ALB, UA, UREA, CR and HB in human whole blood and serum.

3.2 Advantages over common testing equipment in hospitals

By reference to the results obtained by biochemical analyzers commonly used in clinical labs of hospitals in China, the results obtained by Konsung Compass 2000 are validated and found to be excellent in accuracy and stability. The traditional laboratory testing is completed by large liquid-phase biochemical devices that requires centrifugation of venous blood while Konsung Compass 2000 only requires fingertip blood. As a POCT system, Konsung Compass 2000 not only provides early detection, diagnosis and treatment of chronic diseases, but also brings good news to the development of health care in primary medical institutions and inaccessible remote areas.

4. Prospect

In this study, Konsung Compass 2000 is analyzed based on copious literature[11-15]on analyzer performance validation. This analyzer is a reliable POCT system and can be used to determine GLU, TG, HDL, TC, ALT, AST, ALB, UA, UREA, CR and HB in whole blood and serum samples. Featuring simple and flexible operation, quick POCT and low cost, this analyzer can be used in clinical screening anytime and anywhere, and would be applied in various workplaces or to urban and rural health care, especially in inaccessible rural areas. With the development of health care and the increasing needs of patients, the testing efficiency in clinical auxiliary diagnosis must be raised accordingly. Therefore, the research and development of POCT technology and equipment will remain popular for long time.

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