Introduction of Products

Overview of the Automated Clinical Chemistry Analyzer

CHEMIX-800

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INTRODUCTION

Biochemical examination is a globally performed clinical assay and plays an important role in diagnosis. The main parameters are enzymes, glucose and proteins. Current automated clinical chemistry systems have robotic pipetting and cuvette washing systems and can perform a large number of different parameters simultaneously.

Sysmex launched the Automated Clinical Chemistry Analyzer CHEMIX-180 instrument and its reagents for middle and small laboratories in 2003. However, because the number of tests which are performed keeps increasing in the Asia region the demand for quality and accuracy have simultaneously increased. To expand the product portfolio and meet the requirements of the marketplace, we have recently developed the CHEMIX-800 through our partnership with Transasia Bio-medicals Ltd. (***Fig. 1***). ***Fig. 2*** shows the interior with the shield cover of the upper part of the instrument open. The main users of this product are the middle and large scale laboratories.

In this article, we will give an outline of the instrument and explain its basic performance as well as provide some data.

Fig. 1 *Appearance of CHEMIX-800*

Fig. 2 *Upper part of CHEMIX-800*

DEVELOPMENT CONCEPT

This product was developed for biochemical examination performed by middle and large scale laboratories with the main development targets listed below.
1) Enhanced throughput
2) Enhanced measurement accuracy
3) Better reagent on-board stability
4) Efficient system operation

SPECIFICATION

Table 1 shows the specification of CHEMIX-800. ***Table 2*** shows the available parameters and reagents.
The main specification and function are explained as follows.

High throughput

The CHEMIX-800 enables analysis of a maximum of 360 photometric tests/hour. When the optional ISE mod-

Table 1 *Main specification of CHEMIX-800*

Specifications	CHEMIX-800
System type	Discrete, automated, random access, patient prioritized, half volume reagent system
Throughput	360 tests/hour (600 tests/hour with optional ISE module) for a cycle time of 10 seconds.
Sample	• Serum • Urine • Others (CSF, Plasma etc.)
Measurement principle	• Latex Turbidimetric Immunoassay • Turbidimetric Immunoassay • Colorimetry (Rate/End Point) • Ion Selective Electrodes (option)
Applicable analytes	• Photometric assays Enzymes, lipids, proteins, sugar, nitrides, inorganic substances, complements and others • Turbidimetric assays IgG, IgA, IgM, C_3, C_4, RF, CRP, ASO, Transferrin and others.
Light source	Pre-aligned Halogen lamp
Wavelength	12 wavelengths: 340, 405, 450, 480, 505, 546, 570, 600, 660, 700, 750 and 800nm
Reaction time	10 minutes
On board tests	60 test items maximum, 63 test items with ISE
Sample volume	2 - 70 μL
Reaction volume	180 - 550 μL
Reagent table	30 positions for 20 mL bottle and 30 positions for 70 mL bottle
Sample placement	Capacity of 50 samples (inner rim: 25, outer rim: 25)
Barcode identification	Automatic bar code scan performed for sample and reagent
Calibration	• Maximum 40 calibrators can be used. • 10 calibrators maximum per test.
Dimensions	890 (W) x 760 (D) x 1140 (H) mm
Weight	Approx. 150 kg
Power source/consumption	AC110V/220 ± 10%, 50/60Hz ± 1

Table 2 *Available parameters and sysmex reagents*

Analytes	Parameter name	Sysmex reagent name
Enzyme	AST	AST Reagent L
	ALT	ALT Reagent L
	LD	LD Reagent L
	ALP	ALP Reagent L
	GGT	γ-GTP Reagent L
	AMY	AMY Reagent L
	CK	CK Reagent LB
	CK-MB	CK-MB Reagent L
	CHE	CHE Reagent L
Non-protein nitrogen	BUN	BUN Reagent L
	CRE	CRE Reagent LB
	UA	UA Reagent L
Lipid	TG	TG Reagent L
	T-CHO	T-CHO Reagent LA
	HDL-C	HDL-C Reagent KL
	LDL-C	LDL-C Reagent KL
Protein	TP	TP Reagent A
	ALB	ALB Reagent A
Glucose	GLU	GLU Reagent L
Bilirubin	T-BIL	T-BIL Reagent A
	D-BIL	D-BIL Reagent A
Electrolyte	Ca	Ca Reagent A
	IP	IP Reagent A
	Fe	Fe Reagent L
	Mg	Mg Reagent L
	UIBC	UIBC Reagent L
	Na	(ISE Module)
	K	(ISE Module)
	Cl	(ISE Module)
Serum protein	CRP	CRP Reagent B
Immunoglobulin	IgG	IgG Reagent ND
	IgA	IgA Reagent ND
	IgM	IgM Reagent ND
Complement	C_3	C_3 Reagent ND
	C_4	C_4 Reagent ND
Micro protein in urine	m-ALB	mALB Reagent K
	m-TP	m-TP Reagent K

ule for Na/K/CI is installed an additional 240 tests/hour can be analyzed. In total a maximum throughput of 600 tests/hour was achieved.

Optimized for the two-shot reagent

The two-shot reagent system can circumvent the effect of interfering substances such as hemolysis, icterus and lipemia as well as ascorbic acid. The CHEMIX-800 has been optimized to this reagent system by installing 2 reagent probes. Each probe is exclusively used for R1 and R2 reagent, so that reagent contamination can be avoided.

Permanent hard glass cuvette

The CHEMIX-800 uses hard glass cuvettes, and each individual cuvette can be exchanged separately, regular replacement is not required. This leads to cost reduction of cuvette replacement.

Reagent cooling system

The CHEMIX-800 has 50 position reagent trays with buffer cooling. Reagent cooling temperature is kept within the range from 8˚C to 12˚C with refrigeration unit. This system achieved the good on-board stability of reagents.

Efficient system operation

The CHEMIX-800 uses a Windows XP operating system. The CHEMIX-800 operating system was designed to achieve a convenient and high functionality with its user-friendly GUI (Graphical User Interface). It is easy to confirm the workload list, sample processing, reagent volume and the analytical status with screen colors (***Figs. 3 and 4***)

Unnecessesity of plumbing equipment

Because the CHEMIX-800 has tanks for the water supply and drain water systems installed, it does not require special plumbing equipment. Thus it can be easily installed in any location without having to consider any plumbing equipment.

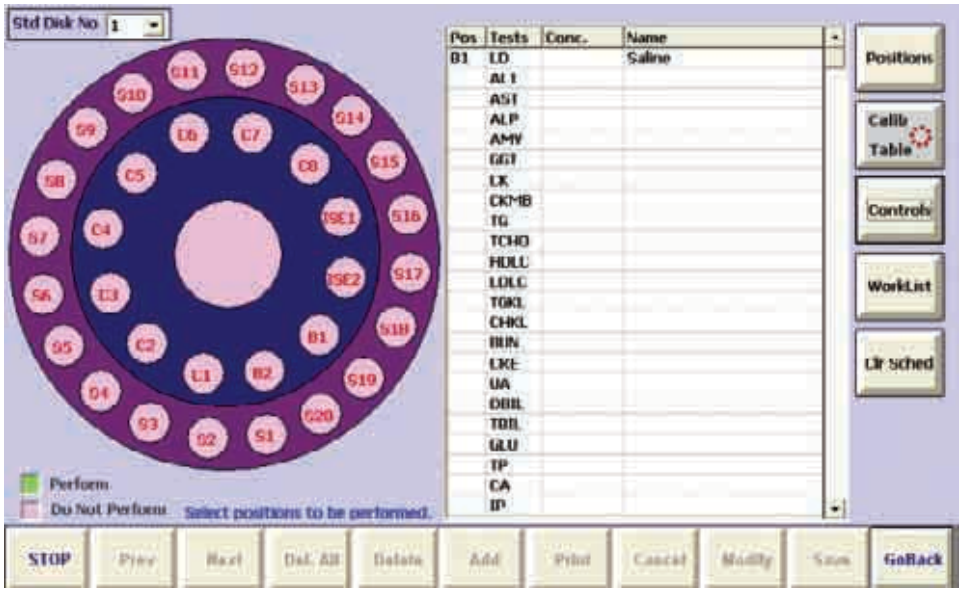

Fig. 3 *Calibrator setting screen*

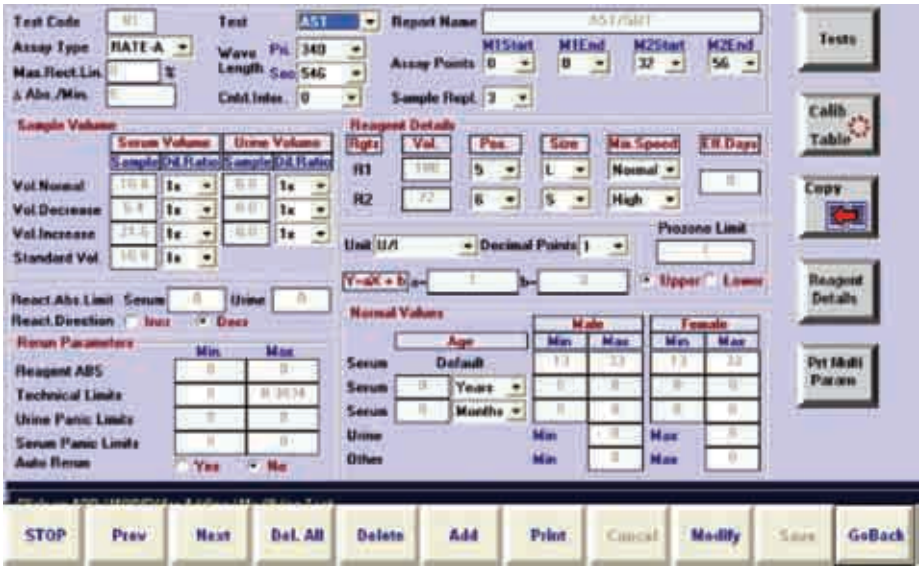

Fig. 4 *Parameter setting screen*

PERFORMANCE OF ANALYZER (ENZYME PARAMETERS)

We evaluated the basic performance of CHEMIX-800 by performing within-run reproducibility, between-run reproducibility, linearity and interference studies. The following 8 enzyme parameters were evaluated with Sysmex reagents.
1. AST (Aspartate aminotransferase), 2. ALT (Alanine aminotransferase), 3. LD (Lactate dehydrogenase),
4. AMY (Amylase), 5. ALP (Alkaline phosphatase), 6. CK (Creatine Kinase), 7. GGT(γ-Glutamyltransferase), 8. CHE (Choline Esterase)

Within-run reproducibility

M-Trol 1 as a normal sample and M-Trol 2 as an abnormal sample were measured 20 times continuously to test within-run reproducibility. The results were excellent and the CVs were less than 3.92% for each parameter (***Table 3***).

Between-run reproducibility

M-Trol 1 as a normal sample and M-Trol 2 as an abnormal sample were measured on 5 consecutive days to test between-run reproducibility. The results were excellent and the CVs were less than 4.73% for each parameter (***Table 4***).

Linearity

M-Trol 2 was used as the low level linearity material for all parameters with the exception CHE. High Level Check E was used as the high level linearity material for all parameters with the exception CHE. For CHE, M-Trol 1 was used as the low level linearity material and High Level Check CHE was used as the high level linearity material.
The linearity of the measurements was tested for each parameter using the materials described and diluted with saline. Good linearity was observed for each parameter. ***Fig. 5*** shows the results of the low level linearity. ***Fig. 6*** shows the results of the high level linearity. ***Table 5*** shows the linearity range for each parameter.

Interference study

Interference from Hemoglobin, Conjugated Bilirubin, Unconjugated Bilirubin, Lipid and Ascorbic Acid was examined for the 8 enzyme parameters. Various concentrations of Hemoglobin, Conjugated Bilirubin, Unconjugated Bilirubin, Lipid and Ascorbic acid were added to M-Trol 2.
Hemoglobin had a strong influence on the AST and LD and had a slight influence on the CK. Other interfering substances did not influence the other parameters. ***Table 6*** shows the results the interference study.
Because the AST and LD are the element contained in the erythrocyte, hemolyzed sample gives a positive error to its measurement value. And released erythrocyte adenylkinase increases the enzymatically measured CK activity[1), 2)]. Haemolysis is an important interference factor, so it must be considered when those parameters are measured.

Table 3 *Within-run reproducibility*

	AST		ALT		LD		AMY	
	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2
Mean	56.9	146.1	23.8	71.2	168.2	700.4	62.9	420.0
Max	59.0	148.0	25.5	73.2	171.6	404.8	64.8	431.8
Min	55.0	144.0	22.3	68.1	163.7	394.0	61.8	407.5
Range	4.0	4.0	3.2	5.1	7.9	10.8	3.0	24.4
SD	1.119	1.334	0.935	1.503	1.891	2.938	0.981	7.942
%CV	1.97	0.91	3.92	2.11	1.12	0.73	1.56	1.89
	ALP		CK		GGT		CHE	
	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2
Mean	237.2	958.5	115.6	540.0	25.2	124.5	111.9	69.4
Max	248.0	997.0	119.3	550.1	26.3	127.4	114.7	71.3
Min	226.0	920.0	112.4	525.0	23.5	121.5	108.2	67.5
Range	22.0	77.0	6.9	25.1	2.8	5.9	6.5	3.8
SD	6.678	23.193	1.727	5.647	0.867	1.668	1.820	1.140
%CV	2.82	2.42	1.49	1.05	3.44	1.34	1.63	1.64

(Units: U/L)

Table 4 *Between-run reproducibility*

	AST		ALT		LD		AMY	
	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2
Mean	56.2	147.4	25.1	74.2	171.7	420.9	64.8	423.1
SD	2.059	1.273	1.187	0.566	2.762	5.406	0.676	9.855
%CV	3.66	0.86	4.73	0.76	1.61	1.28	1.04	2.33
	ALP		CK		GGT		CHE	
	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2	M-Trol 1	M-Trol 2
Mean	234.4	955.2	115.7	561.1	25.8	122.9	116.3	75.5
SD	2.826	9.701	2.518	4.906	0.433	1.688	2.321	1.656
%CV	1.21	1.02	2.18	0.87	1.68	1.37	2.00	2.19

(Units: U/L)

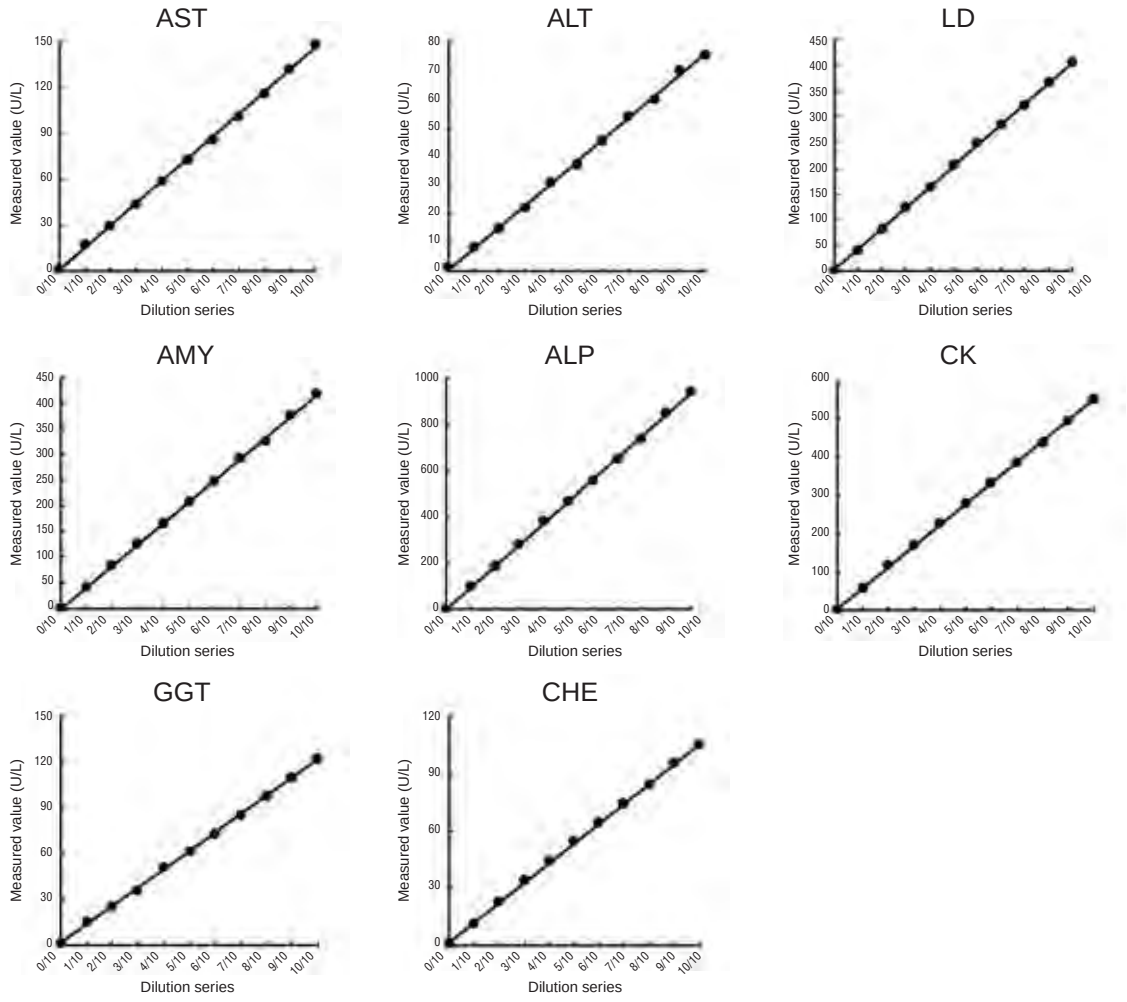

Fig. 5 *Low level linearity*

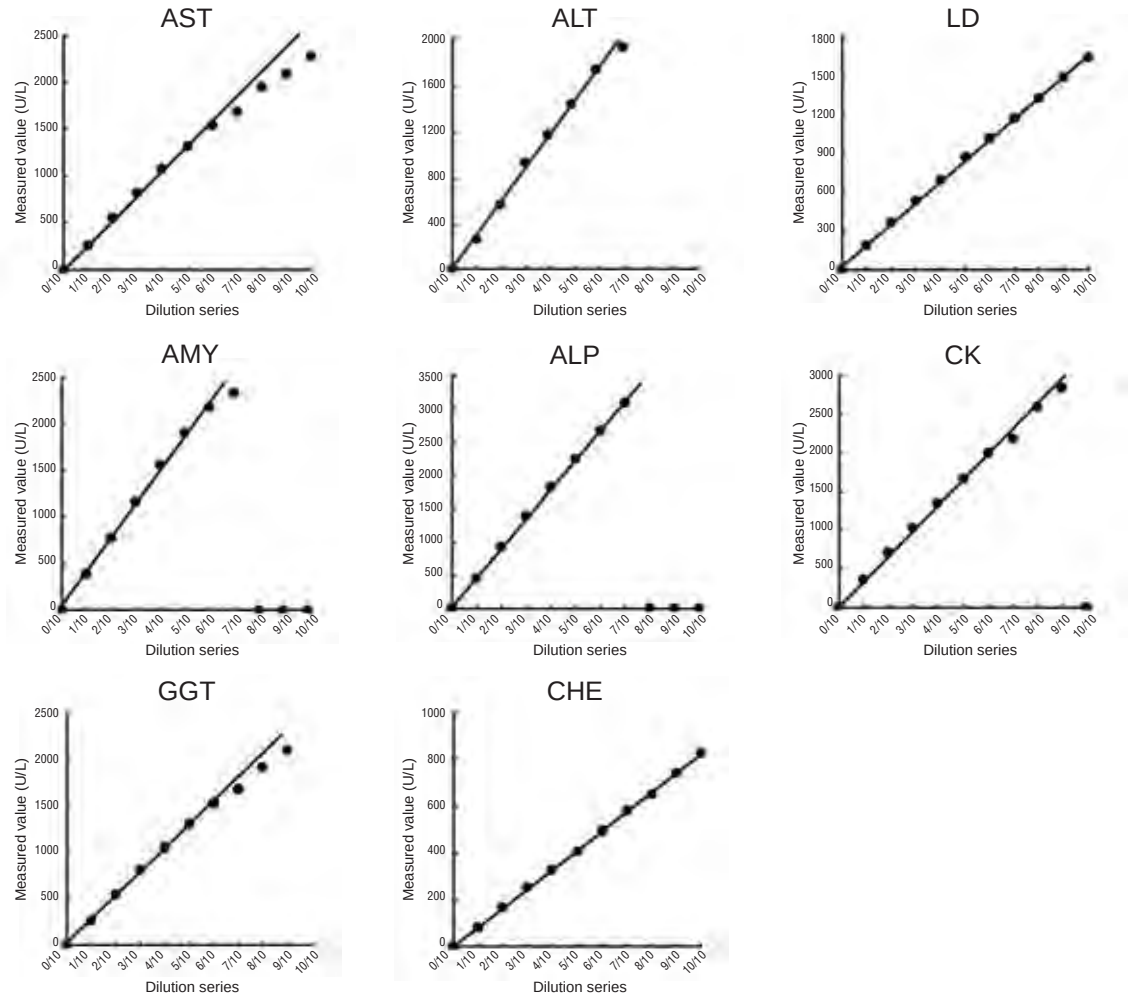

Fig. 6 *High level linearity*

Table 5 *Linearity range*

	Linearity Range			
AST	0	-	1500	(U/L)
ALT	0	-	1700	(U/L)
LD	0	-	1600	(U/L)
AMY	0	-	1500	(U/L)
ALP	0	-	3000	(U/L)
CK	0	-	1900	(U/L)
GGT	0	-	1500	(U/L)
CHE	0	-	800	(U/L)

Table 6 *Results of the interference study*

	Interference substance				
	Hemoglobin	Lipid	Conjugated Bilirubin	Unconjugated Bilirubin	Ascorbic Acid
AST	↑↑	—	—	—	—
ALT	—	—	—	—	—
LD	↑↑	—	—	—	—
AMY	—	—	—	—	—
ALP	—	—	—	—	—
CK	↑	—	—	—	—
GGT	—	—	—	—	—
CHE	—	—	—	—	—

↑↑: strong influence, ↑: slight influence, — : not influence

CONCLUSION

In this article we have assessed the CHEMIX-800 using the basic performance data of enzyme assays. The basic performance data such as reproducibility (within-run and between-run), linearity and the interference study showed good results. Therefore, the CHEMIX-800 is highly suitable for biochemical examination in middle and large scale laboratories. Moreover, this instrument can be interfaced to our laboratory information system (Laboman.net) which has been developed by group businesses in 2004. Laboman.net contributes to improvement of the quality of the results as well as analyzer quality control. It also includes support for the business functions such as revenue management, budget planning, asset management and reagent control within laboratory. It will therefore also become easier to manage patient data. In the future, we will report the performance of other parameters.

References

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