Semi-auto Chemistry Analyzer

Chem-o-test Vet Operation manual





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Chapter 1 Introduction

1.1 Principle of measurement

The Bio-chemical analyzer is mainly used for the quantitative analysis of the clinical bio-chemical items; it applies the Lamber- Beer law:

 $A=Kbc=Ig(I_0/I)$

Among them:

A: Absorbency

K: Aspirated Index

B: Liquid layer's Thickness

C: Solution's Consistency

I₀: Incident light's Strength

I: Transmit light's Strength

According to the above formulas, under the condition of the certain liquid layer's thickness and incident light's strength, as long as test the strength of transmit light which goes through the liquid, so we can calculate the consistency of the solution.

1.2 Technical Parameters

Condition for operation:

Temperature: 10°C ~35°C. Relative humidity: 20 – 90 %.

Power: 85-264V

Conserved Transportation Condition:

Temperature: 0°C ~40°C. Relative humidity: 10%~90 %.

Technical parameters:

Method: Kinetic. End-point, Linearity, Plus Time, Nonlinearity Plus time, Absorbency,

Sample blank, Multi-standard, Velocity, Calculation, Two-point, Double wavelength etc.

7 wavelengths optic system avoiding outer disturbance, wavelength range: 340-700nm;

Quality control: Quality control for all tests, Statistic and print quality control parameters automatically with QC curves.

Every test can do high, medium, low three groups quality control.

Program: Add or delete test items easily according to the condition. Modify the test parameters.

Display Dynamic curves at real time.

The print content includes comprehensive hospital's name and sample' materials.

Dormant automatically for the lamp to prolong it's lifespan/

Input 8 standard curves at most in testing with Multistandard method.

Test items:≥200

Filter Wavelengths: 340.380.405.505.546.578.620nm, 1 empty position

Wavelength precision:±2nm.

Photometric range: -0.2 - 2.3 Abs.

Flow cell: quartz .measure volume 32ul Lamp: Quartz-halogen lamp, 6V 10W.

Liquid thickness: 10mm.

Screen: 240×128 dots graphic LCD.

Output: Inner thermal printer or external parallel printer

Optional out-printer: Print A4 paper result report.

Thermal paper dimension: Diameter 35mm, width: 78mm(3inches)

Aspirating samples volume: ≥ 500ul, adjustable

Memory: 500 samples or quality controls.

≤30 tests per sample.

Communications connector: RS-232serial.

Dimension: 33cm in Length×35.5cm in Width×12.59cm in Height

Weight: 8KG

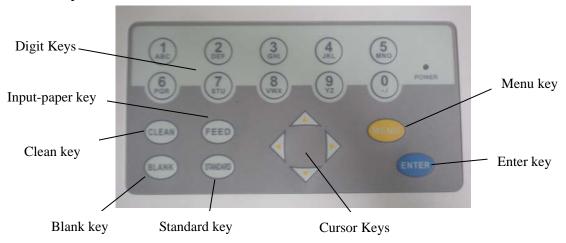
1.3 Structure Introduction

1.3.1 Main components view

This instrument is consisted of microprocessor, main board, power supply system, sample aspirating system, Flow cell, Display screen and printer.



1.3.2 Keyboard view



1.3.3 Back view



1.3.4 Menu view

MEASURE	PRINT	REPORT	
ADI-DUO BIOCHEMICAL ANALYZER Ver 1.80			
PROGRAM	QC REPORT	UTILITY	

Turn on the instrument, it will show the main menu which includes 6 submenus, the operator can select a menu by digit keys 1-6 or by cursor keys (If you use the cursor keys, the color of the menu frame will become dark and the color of the letters will become light, then press the "ENTER" key to enter the menu); you can enter the corresponding menu directly by pressing the digit keys as 1-6. In daily work, the operator mainly operates the first, second and third items, you can measure samples by operating the first item, and print report by operating the second item, and edit, check, print report by operating the third item.

Chapter 2 Installation

2.1 Work Environment

This equipment is a precise instrument, so the environment must meet with certain requirement in order that the instrument can be used normally and get accurate results .such as:

Environment temperature: 10°C~35°C

Relative humidity: 20% ~ 80%

Atmospheric pressure: 86KPa ~ 106Kpa

Voltage: 85-264V

Ground-line: special ground-line of medical instrument, the resistance of connecting the earth must be

less than 0.5Ω .

Additional requirements: the instrument must be put on a platform which has enough room, stable and

level without any vibration; the situation should avoid the equipments such as fans, air conditioners etc.

in order not to effect the accuracy of temperature control; it is prohibited to be installed in the

environment which with high temperature, or sunlight shines directly or has much dust; also it can not

be put with the equipments which has big efficiency, heavy interference such as the centrifuges,

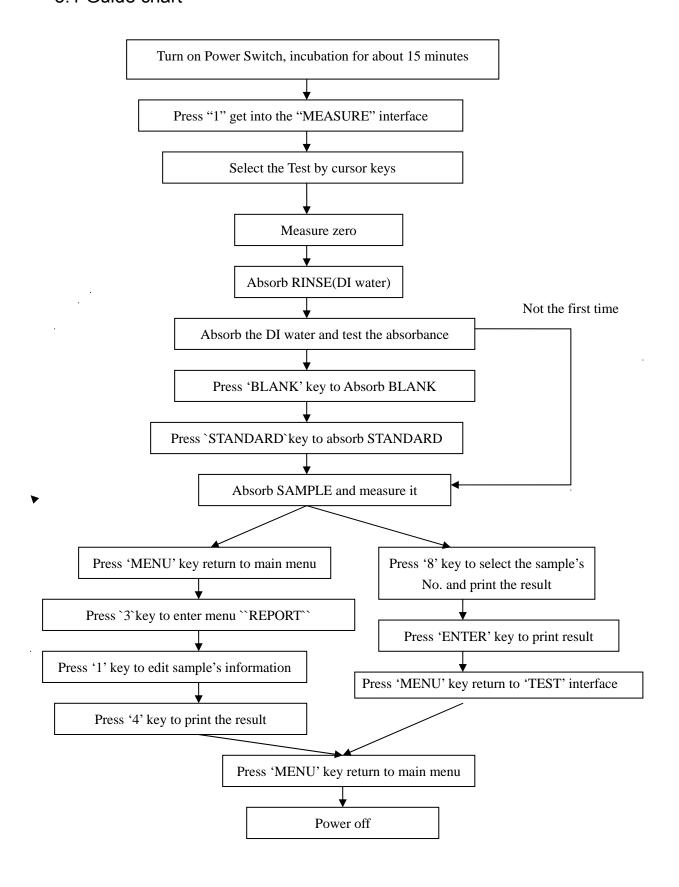
refrigerators, thermostats etc in the same room or use the same elec. Power socket

2.2 Instrument Installation

- 1) Open the instrument's packing box. Check carefully whether the instrument, parts in the box match with the packing list. If there is any shortage or damage, contact with the suppliers in time;
- 2) Take out the instrument carefully after checking, then put it on a stable, smooth work platform;
- 3) Connect the earth-pole to the earth which is on the right side of the back of instrument by special medical earth-line:
- 4) Take out the Power line, connect one side to the Power socket which is in the middle of the back panel, then connect the other side to the three-line plug which has connected earth-line;
- 5) Find a waste bottle, put the waste tube into the waste bottle;
- 6) Use a beaker or other container to get a cup of DI water;
- 7) Turn on the power Switch in the back panel;
- 8) Incubate at least 15 minutes after turn on the instrument's elec. on;
- 9) Follow the English Guide to operate

Chapter 3 Operation

3.1 Guide chart



3.2 General operation

- 3.2.1 Switch the Power on, incubating the instrument for 15 minutes at least;
- 3.2.2 Measure sample: Prepare the sample and reagent according to the reagent manual, enter the first item in main menu after it's reaction time reach the requirement time, Press'1'key to enter 'MEASURE' to measure the samples:
- 3.2.3 Sample's Information: after measuring all Samples, press 'menu' key to return to the main menu, press digit key '3' to enter the third interface: "REPORT", select "1-EDIT SAMPLE", input each patient's info;
- 3.2.4 Report: Press digit key '4' in "REPORT' interface to print or delete results; If you only need to print one sample's results, press the digit key '2' in the main menu, then input the sample's ID to print; 3.2.5 Clean the pipe: clean the tube with RINSE after you finish operation;
- 3.2.6 Power off the instrument: Finish all procedures, then power off the instrument.

3.3 Measurement

Press '1' key to enter into the menu "MEASURE" interface, system check the lamp and temperature to get a stable status automatically .the screen shows below:

LAMP STATUS:ON

INCUBATING

PLEASE WAIT

MENU - RETURN

Then the system enters the next interface:

ALT GOT r—GT ALP TP ALB TbiL DBIL TTT **BUN** CRE UA CO2 NH3 **GLU** TCHO HDLC LDLC TG LDH AMS CL CA Mg Cu PRESS ARROW TO SELECT TEST

Use the cursors to select the test item that you want to measure (the selected item will be high light) Press the 'ENTER' key, Then the system will measure zero automatically:

TEST CODE: 2 ALP

SAMPLE No.: PRINT: ON

TEMP: 36.99 LAMP: ON

MEASURE ZERO

WAVELENGTH: 340nm

And then enter the Aspirate RINSE interface:

1. Aspirate RINSE

In the interface of "Aspirate RINSE", the screen will display as follows:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

ASP RINSE

WAVELENGTH: 620nm

FACTOR: 1746.0

The word "ASP RINSE" is flashing to note you to put on the RINSE liquor.

Put the RINSE (DI water), press 'ENTER' key, the instrument starts to aspirate RINSE;

Press 'CLEAN' key to aspirate RINSE again if needed, it can clean for many times;

Press "\" key to ignore Aspirate RINSE and enter next step if it without cleaning;

Press 'MENU' key back to the main menu.

2. Aspirate and measure DI water

The system will automatically enter the "Aspirate DI water" interface to measure absorbency if TEST is set with END-point method, the screen will display:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

ASP DI WATER

WAVELENGTH: 620nm

Put DI water, and press 'ENTER' key, system starts to aspirate DI water and measure absorbency, the screen will display:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

MEASURING

WAVELENGTH: 620nm

FACTOR: 185.0

Shows after measuring

It will prompt you to aspirate DI water after filter-wheel rotated in order to adjust absorbency

3. Aspirate and measure BLANK

When you measure the TEST for the first time, you need to measure BLANK and STANDARD first, the system will enter into 'ASP BLANK' interface automatically after finishing cleaning or measuring

absorbency, "Aspirate BLANK" will twinkle continually on the screen, it will display as follows:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

ASP BLANK

WAVELENGTH: 620

FACTOR: 185.0

Put on the BLANK, then press "ENTER" key, system starts to aspirate the BLANK; the screen will display "MEASURE BLANK" 5 seconds, then it will measure the absorbency and original value of BLANK, the result will be shown in the chart.

4. Aspirate STANDARD

When the system enter into "ASPIRATE STANDARD" interface, the screen will display as follows:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

ASP STANDARD

WAVELENGTH: 620

Shows after measuring

Standard

STANDARD: 70.0

You can operate as follows when "ASP STANDARD" twinkle continually: Press "ENTER" key to aspirate STANDARD; the test coefficients of standard will be shown as the above chart after finishing measurement:

Press "BLANK" key to measure BLANK again;

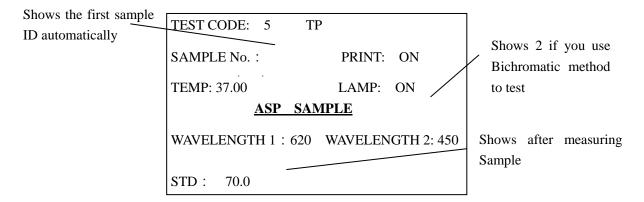
Press "CLEAN" key to clean again;

Press "STANDARD" key to measure STANDARD again;

Press "MENU" key back to main menu.

5. Measure SAMPLE

If system had measured BLANK and STANDARD, it will enter into 'Measure Sample' interface after cleaning and measuring absorbency just as the above chart. If it is the first time to measure TEST, you should measure BLANK and STANDARD before measuring the samples.



Press the "ENTER" key to aspirate SAMPLE to measure when "ASP SAMPLE" twinkle continually. The result will be shown in the above chart, SAMPLE No. will increase automatically and system is ready to next sample.

You can operate as follows in this interface (When "ASP SAMPLE" twinkle continually)

Press 'Standard', 'Blank', 'Clean' keys to do the same operation as above.

Press the digit key '6' to enter into TEST select interface to select other TEST:

Press the digit key '7' to alter the sample No., just shows as follows:

SAMPLE No. : 0

NEW SAMPLE No. : _

Press the digit key '8', the screen will show as follows:

TEST CODE: 5 TP

SAMPLE No.: PRINT: ON

TEMP: 37.00 LAMP: ON

INPUT SAMPLE No.: _

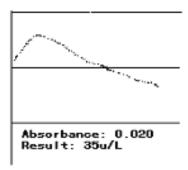
WAVELEBGTH: 620nm

Input sample No. and press "ENTER" key, the system will print the sample's report instantly, press "MENU" key back to 'TEST' interface;

Press the digit key '9' to set the TEST's coefficients;

Press the 'MENU' key back to main menu.

If the TEST is set with Kinetics method, the screen will show the reaction curves when you measure the standard and samples, such as follows:



During measuring press "ENTER" key, the screen will show the recent curve to observe it better till "MENU" key is pressed. Or the screen will be back to "ASP SAMPLE" interface to be ready to measure next sample.

3.4 Example

3.4.1 Measure ALT/GPT with Kinetic method

1) Set the parameters in the menu "PROGRAME" according to the reagent manual as follows:

TEST CODE:1, TEST NAME : ALT/GPT

FACTOR: 1746, UNIT: u / L, METHOD: K-Kinetic

TEMP: 37°C, DECIMALS: 0, WAVELENGTH: 340nm,

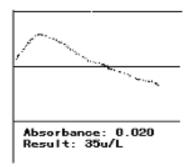
REAGENT BLANK: N, SAMPLE BLANK: N HIGH: 36.0,

LOW: 8.0, LINEARITY RANGE: < 500, DELAY TIME: 30S, INTERVAL TIME: 40S ASP VOL: 500uL, SAMPLE POINTS: 2,

2) Press the digit key'1' in "TEST" interface. select the ALT, the screen will show "ASP RINSE", put the

RINSE, then press "ENTER" key to aspirate RINSE.

- 3) The screen will show "ASP SAMPLE", please assure the sample No. press the digit key '7' to modify the sample No. and press "ENTER" key. Put the sample and press 'ENTER' key to aspirate and measure SAMPLE.
- 4) System will show the curve in the reaction process after aspirating SAMPLE:



If you want to check the curve carefully, press 'ENTER' key before the reaction is completed, the screen will show the reaction curve, press 'MENU' key to return. Or the screen will enter the next interface of "ASP SAMPLE" to be ready to next measurement.

5) If you want to measure other TEST, press the digit key '6', then select the corresponding TEST, system will select the TEST to measure automatically.

3.4.2 Measure total protein(TP) with End-point method

1. Set the TEST's parameters in the "PROGRAME" menu according to the reagent manual as follows:

TEST CODE: 5. TEST NAME: TP.

FACTOR: 0. UNIT: g / L. METHOD:E-END POINT TEMP: 37°C. DECIMALS:0. WAVELENGTH: 546nm.

REAGENT BLANK: Y. SAMPLE BLANK: N HIGH: 82.0. LOW: 62.0. LINEARITY RANGE: < 100. DELAY TIME: 4S.

INTERVAL TIME: 2S ASP Vol: 800uL STANDARD: 1, STD 1: 70.0

- 2.In measure interface . Select the "TP". The screen will show "ASP RINSE", then put on the RINSE and press the "ENTER" key to start the clean operation.
- 3.The screen will show "ASP DI water" after cleaning, put the DI water and press 'ENTER' key to measure the absorbency, the screen will show "ASP BLANK" after measuring, put the Blank liquor and press the "ENTER" key to measure.
- 4.The screen will show "ASP STANDARD" (Press the "STANDARD" key to turn to the "ASP STANDARD" interface if the screen show "ASP SAMPLE"), put standard and press "ENTER" key to aspirate and measure it and calculate the factor.
- 5.The screen will show "ASP SAMPLE" after measuring standard, press the digit key'7'to modify the sample No, then put the corresponding sample and press 'ENTER' key to measure it.

3.4.3 Measure ALT/GPT by multi-standard end-point method

1) Set the parameters in the menu "PROGRAME" according to the reagent manual as follows:

TEST CODE: 1. TEST NAME: ALT/GPT.

FACTOR: 0. UNIT: u/L. METHOD: Mult STD. TEMP: 37°C. DECIMALS: 0. WAVELENGTH: 505nm. REAGENT BLANK: Y. SAMPLE BLANK: N. HIGHT: 40.0. LOW: 5.0. LINEARITY RANGE: < 100. DELAY TIME: 5S. INTERVAL TIME: 10S. ASP Vol: 800uL. DATA POINT: 2. STD 2: 50. STANDARD No.: 5. STD 1: 0. STD 3: 109. STD 4: 209. STD 5: 406.

- 2) In the measure interface, select "ALT". The screen will show "ASP RINSE", put the RINSE and press 'ENTER' key to start the clean operation. Put the DI water to test absorbency after finishing operation.
- 3)The screen will show "ASP BLANK" after measuring DI water, put the BLANK and press the "ENTER" key to assure the operation.
- 4) Now the screen shows "ASP STANDARD" (Press the 'STANDARD' key to turn to "ASP STANDARD" interface if it shows "ASP SAMPLE"), put the standard 1-5 successively, then press 'ENTER' key to measure the standard liquor to calculate the parameters.
- 5) The screen shows "ASP SAMPLE" again after measuring the standard, press the digit key '7' to modify the sample's No., put the corresponding sample and press 'ENTER' key to measure the sample

Attention: The TEST (end-point) do not have to measure the standard after the first time, also you can measure the standard to assure the parameters again. It is better to measure the blank before measuring the TEST everyday to get accurate results.

3.5 Report

Press the digit key '3' in the main menu to enter into the "REPORT" menu as follows; you can do the EDIT, MODIFY, PRINT, DELETE etc. operations of sample's result in this menu.

REPORT

- 1 EDIT SAMPLE
- 2 DEL RESULT
- 3 ADD RESULT
- 4 PRINT/DELETE

MENU - RETURN

3.5.1 Edit sample

You can input each sample's name, gender, age and blood type according to this function. First, the screen will display:

EDIT SAMPLE

SAMPLES SUM: 15

SAMPLE No.: _

MENU - RETURN

You can input the sample number directly or use the '↓' key to search for the sample's No., then press "ENTER" key, system will show as follows if the No. you input is not existed in memory:

EDIT SAMPLE

SAMPLES SUM: 18 SAMPLE No: 1234

THE SAMPLE IS NOT EXIST!

ENTER – CREATE MENU - RETURN

The system will establish the sample's record in memory if the answer is 'Y' or press 'ENTER' key, then turn to the next step, system will be back to the former interface if the answer is 'N'. System will enter into next step after discovering patient in memory or creating new sample, The chart is as follows:

SAMPLES SUM: 15

SAMPLE No: 1 NAME: ABC

GENDER: MALE/FEMALE

AGE: 20

BLOOD GROUP: A

NAME: You can input 8 letters at most here .Use the cursor key ↑to switch between uppercase And lower-case. Press 'ENTER' key to confirm.

GENDER: Select correct option of MALE / FEMALE / INFANT/NONE by cursor key \leftarrow or \rightarrow .

AGE: Input number 0 ~ 199 there,

BLOOD GROUP: Select: A / B / AB / O by cursor key \leftarrow or \rightarrow .

If the No. you input is existed in memory, the system will show the information which has been saved in memory, you can modify at freedom and press 'Menu' key to return.

3.5.2 Del result

You can delete the incorrect result in MODIFY RESULT according to this function.

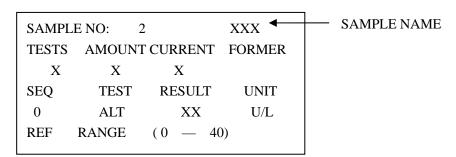
You can input the existed sample's No., then press 'Enter' key to enter the modify interface directly, or press '\' key to enter into search interface to find the sample.

The search interface is as below:

DEL RESULT
SAMPLES SUM: 6
SAMPLE No: 1234
1 RESULT EXISTED

MENU - RETURN

The second row shows the existed samples sum No., the third row shows the searched sample's No., the third row shows the total results of this sample:



You can see the sample's all results with ' \uparrow ' ' \downarrow ' keys, see the last or the next sample's results with ' \rightarrow ' or ' \leftarrow ' keys, please press 'ENTER' key to delete it when the screen shows the result if the result is not needed. Whenever press 'MENU' key it can return to the last interface.

3.5.3 Add result

Some tests may not be done in this analyzer but the results can be reported together.

In the 'REPORT' menu, press '3' key to select 'Add result', input sample No. or press '\' key to search the sample No., then press 'ENTER' key.

It will show 'CREAT NEW ITEM?' if you input one sample No. which is not existed, Press 'Y' or 'ENTER' key to create the sample No., press 'N' and 'MENU' key to quit. Press 'ENTER' key to enter into 'ADD OTHER RESULTS' interface:

ADD RESULT

SAMPLE No: 1234
TEST CODE: 3 GOT
RESULT: 4.5mmol/L

MENU-RETURN

Shows differently with the different methods

First, the cursor will stop at the back of the 'TEST CODE' in second row, input the TEST No. then press 'ENTER' key it will show the TEST name in the third row and show the result in the fourth row, the cursor will stop at the back of the result, it will show the radix point if there is decimal (the definition of decimal is introduced in 'PROGRAME'->definition of test item).

Please input the results get from other instrument, if the selected TEST is 'SUBTRACTION' or 'DIVISION', you should not input the value there, system will look up the needed data in the sample's results automatically and calculate the result; press 'MENU' key to return to the last interface.

3.5.4 Print/Delete Report

Select 'Print/Delete Report' in the 'REPORT' interface, it will show the interface as below:

PRINT/DELETE

1 - PRINT APPOINTED SAPLE

2 - PRINT ALL SAMPLES

3 - DELETE APPOINTED SAMPLE

1. Print the appointed sample

You can select this function if you only want to print the certain samples, you can input the sample No. to print directly; or press '\partial' key to startup the searching function either, then press 'ENTER' key to print the sample's report, press 'MENU' key to return.

- 2. Print all samples
- a. The system offers this function of printing all samples' reports easily.

When you startup this function, the system will show:

PRINT/DELETE

START DATE (MMDD): _ —

Now you can input the start date of samples, press 'ENTER' key, it will show:

PRINT/DELETE

START DATE(MMDD): 06 —10

END DATE(MMDD): _ —

When you input the end date, the system starts to look up all storage file in memory, it starts to print for each sample if it find the result fit for the condition until finishing printing; if you want to stop printing in midway, you must turn off the system.

When the system suggests you input the start date, press 'ENTER' key directly to print all results in memory, then it will show:

PRINT ALL SAMPLES $\underline{\mathbf{Y}}$?

Print all results in internal memory instantly with pressing 'Y'

Return to 'START DATE:' state with pressing 'N'. Return by pressing 'MENU' key.

3. Delete the appointed sample

You can delete the file and all storage result of the appointed sample in memory by selecting this function. First the system suggests to input the sample No. You can input with digit keys or use searching function, then press 'ENTER' key to delete. If the system find the existed number in memory, press 'ENTER' key, it will delete the sample directly without suggesting, so be careful when you input the No. or use searching function.

4. Delete all samples' file

This part is the same to "Print all samples' report", the first one is to delete, this is to print, it can not recover after deleting, so be careful.

Chapter 4 PROGRAM

This chapter mainly introduces how to setup TEST parameters when you use reagent for the first time. It suggests that TEST parameters must be checked again according to the reagent manual when you use new reagent to get the right result.

Select 'PROGRAME' in main menu to enter into this function interface which including 8 functions:

PROGRAM
1 —TEST SETUP
2 —ADD TEST NAME
3 —DELETE TEST NAME

4.1 Test Setup

It's main function consists in setup parameters of TEST in order it can measure samples according to the correct instruction.

Independent TEST definition

Press '1—TEST SETUP', the system shows:

ALT	ALP	GOT	r—GT	TP
ALB	TbiL	DBIL	TTT	BUN
CRE	UA	CO2	NH3	GLU
TCHO	HDLC	LDLC	TG	LDH
AMS	CL	CA	Mg	Cu
PRESS ARROW TO SELECT TEST				
PRESS	'1' FO	R NEW	TEST	

(1). Use the cursor keys, the test name will become high light, Then press the "ENTER" key to enter the next interface

TEST CODE: 2
TEST NAME: <u>A</u>LP
FACTOR: _1746.0
UNIT: u mol/L

METHOD: TWO-POINT

TEMP: 37°C

(2).now the cursor is at the back of the 'TEST NAME' .you can change the test name by cursor key '←''→',here you can index the name that you added in the "add test name" interface When you have got it, press 'ENTER' key or '↓' to the next step

- (3). you can modify or input the test FACTOR from zero to 59999. if you input the number from 1bit to 5 bits, please press 'ENTER' key or '↓' key directly to enter the next step.
- (4). Select unit with '←'or '→' keys, press '↓' or 'ENTER' key to enter into next step, there are 12 units to select: None.u/L.u/mL.umol/L.mmol/L.g/L.mg/Dl.g/ml.g/Dl.X10(12)/L.ABS
- (5). Select analyze method with '→' or '←' keys at the back of 'METHOD'. There are 10 methods to select: TWO-POINT, BICHROMATIC, FACTOR, SUBTRATION, DIVISION, POLAR, ASPIRATEENCY, END POINT, KINETICS, MULTI STD.
- (6). This instrument has Temperature Control system, you can select "37°C", "30°C" or "ROOM-TEMP" state with '←' or'→' keys;

Press '\' or 'ENTER' key to enter into the next screen:

DECIMAL:0

FILTER: 340nm

REAGENT BLANK: Y SAMPLE BLANK: N REFERENCE HIGH: 92 REFERENCE LOW: 24

- (7). Input the needed decimals at the back of 'DECIMAL', input digit '0','1'or '2', input '0' if there is no decimal;
- (8). Select the correct wavelength for the test at the back of 'FILTER' by '→'or '←' key; When 'DAUL-WAVELENGTH' is selected, it will show 'FILTER2:', There are 7 wavelengths to select: 340nm, 380nm, 405nm, 505mm, 546nm, 578nm, 620nm;
- (9). Setup 'REAGENT BLANK' and 'SAMPLE BLANK' according to the reagent manual; press 'ENTER' key or '\',' key to enter into the next step
- (10). You can setup the TEST reference value, Then press 'ENTER' or '↓' key to enter into next step.

2 ALP

LINEARITY RANGE: < 200

DELAY TIME: 55

INTERVAL TIME: 10S

DATA NO: 2

ASP VOL: 250uL STANDARD: 100

PRESS '←''→'TO SELECT

- (11). Find the reagent's linearity time in the reagent manual, select "<" or ">" with cursor key '→'or '←', press 'ENTER' key to enter into the next step, input the value ,such as "200".
- (12). Find the delay time and measure time in reagent manual, input the times in the 2 positions. Standard number is 0 for kinemics, standard is 1 for general reagent, you must set the standard number for multi-standard reagent; press 'ENTER' or '↓' key to turn to next step after setting the standard.

STANDARD 1: 130.0

(13). You can set the TEST standard or standard curve in this interface. Press 'ENTER' key or '↓' key to turn to next step after setting the standard. The system will prompt 'Save changes?' Press 'Y' or 'ENTER' key to save, or press 'N' key; The system will return to this section's beginning state after input all parameters, now you can input or modify the next TEST.

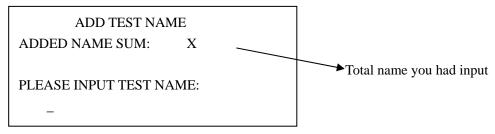
Attention: a. If the test method you selected is : S-SUBTRACTION, press '↓' or 'ENTER' key, it will show:

Input all test codes under A.B.C.D.E.F, the corresponding codes for A.D must be existed, the decimal of all tests must be equal, or it can not get correct result.

b. If the test method you selected is: D- DIVISION, press 'ENTER' or '\' it will show:

Input both test codes under A.B, the corresponding codes for A.B must be existed, the decimal of all tests must be equal, or it can not get correct result.

4. 2Add Test Name



Input test name directly .and press 'ENTER' key to write it into the memory space(Then you can use the ' PRESS '1' TO ADD NEW TEST ' function in 'TEST SETUP' submenu to add test code for the test name you just input) **Note**: You can use the cursor key ↑to switch between upper-case And lower-case.

4.3 Delete name

You can delete the needless test name, If there is test in sample result, please delete it firstly, or it will show error suggestion. It will show:

Press '→' or '←' key to choose the test name, press 'ENTER' key to delete, press 'MENU' key to quit.

4.4 Delete TEST

You can delete the needless test, it will show as below after entering this interface:

ALT	ALP	GOT	r—GT	TP
ALB	TbiL	DBIL	TTT	BUN
CRE	UA	CO2	NH3	GLU
ТСНО	HDLC	LDLC	TG	LDH
AMS	CL	CA	Mg	Cu
PRESS	ARROV	V TO SE	LECT TE	ST
PRESS	'ENTER	R'TO DI	ELETE	

Then press "ENTER" key to delete. And press "MENU" key to return

4.5 Example of program

(1). Endpoint

For example: edit the test parameter of TP according to TP manual "TP End point Method Reagent Manual" (See in Appendix).

- 1. Enter into "PROGRAM" interface in main menu.
- 2. Press '1' key to enter into "TEST SETUP" interface, input digit 1 in TEST CODE(You can look up the solidified item amount and name of the instrument in test form, the test No. is 1). Press 'ENTER' key.
- 3. Select "TP" with cursor keys '←' or '→' in "NAME", press 'ENTER' key to enter into next step.
- 4. Input 0 in "FACTOR", when system measures BLANK and STANDARD, the value will be calculated automatically.
- 5. From "NORMAL VALUE: 60-80g/L" in manual, you will know the reagent unit is g/L. press 'ENTER' key or '↓' to turn to next step.
- 6. In the manual's "TEST METHOD", you will see "TEST BY ENDPOINT", it means the measure method of the reagent is "ENDPOINT", select the method with '←' or '→' keys, then enter into next step.
- 7. Please set the temperature to "37°C" in the position which doesn't point out the temperature range in "TEST METHOD".
- 8. Set the decimal according to the normal decimal value, for example: In the reagent "REFERENCE VALUE: 60-80g/L", no decimal, you can set the decimal to 0.
- 9. There is "FILTER: 620nm" in manual, select 620nm with cursor keys '→' or '←' in "FILTER".
- 10. It requires "REAGENT BLANK IS 0" in manual, set reagent blank to 'Y', set sample blank to 'N'.
- 11. This manual requires "REFERENCE VALUE: 60-80g/L", there isn't special requirement for people, so you can setting "HIGH LIMIT" to 80.0 and "LOW LIMIT" to 60.0.
- 12. There is "LINEARITY≤200g/L" in "TECHNICAL INDEX", select "<" with cursor keys '←' or '→' in setting "LIEARITY RANGE", press 'ENTER' key then input "200.0".
- 13. Generally, you can setting "DELAY TIME" to 5 in ENDPOINT method, "INTERVAL TIME" is 10, "ASP vol" IS 800, "DATA No." is 2
- 14. General reagent is single-standard if there is no special explain, input "1" in "STANDARD", and input 70.0 behind "STANDARD 1:"
- 15. Press 'Y' to assure the operation, the system will save the setting automatically.

(2). Kinetic

For example: GTP/ALT velocity reagent manual, input parameters in turn as follow:

TEST CODE: 1 NAME: ALT

FACTOR: 1746.0 UNIT: u/L METHOD: KINEMIC TEMP CONTROL: 37°C DECIMAL: 0 FILTER: 340nm REAGENT BLANK: N SAMPLE BLANK: N HIGH REF.: 36 LOW REF.: 8 LINEARITY RANGE: <500 DELAY TIME: 30S

INTERVAL TIME: 40S DATA No: 2 Asp vol: 250

STD.: 0

The circles in reagent manual shows how to confirm the parameters. REAGENT BLANK, SAMPLE BLANK, SAMPLE TIME, SAMPLE POSITION, STD. have not explained in reagent manual, please explain the setting according to the manual.

ALT KINETIC REAGENT MANUAL

1. PRINCIPLE: L-ALALINE +a-KETOGLUTARIC ACID ALT PYRUVIC ACID+ GLUTAMIC ACID, PYRUVIC ACID + NADHLDH → L- LACTIC ACID + NAD+

When the wavelength is 340nm, measure NADH absorbency decrease value every minute, calculate ALT activity value.

- 2. REAGENT CONTENT, SIZE AND SPECIFICATION:
 - a) Single vial: 2 kit descriptions: 10ml X 10, 18ml X 10.
 - b) Two vials: It is consisted of RI and RIL with different kit descriptions, 10ml X 5, 18ml X 5.
- 3. Storage and Effective Date: 2-8°C, effective date is 12 months.
- 4. Reagent Mixing

Single vial: It can be used after dissolving with DI water according to the specification, Reconstituted reagent is stable for 3 days at 2-8°C.

Two vials: Pour the RII and cushion to the RI bottle, dissolve them then use, effective date is 3 days.

5. TEST METHOD

FOR EXAMPLE:

PARA	ŴAVĘ	METHO	T/ÉM\	ØELAY	T/EST\	REACTI	REAGENT	SAMPL	FAC
MET	LENG	🖟 🛝	<i>p</i> \	/TIME\	TIME \	ON	VOL.	Е	/TOR\
ER	/TH \		¢c \	\	\	DIRECTI	UI.	VOL.	/ \
SIZE	nm					ON		UI.	
ISP-I II	340	Kin	37/30	30	40	-	500	50	-176
	\]\	\	1	Λ				8
Beckma	β 40 /	Kin /	\$7/30	30	40	-	500	50	-241
n700									2

Attention: Icterus patient's best ratio of serum to reagent is 1:20, factor is -3376.

Calculate Formula: u/l= A/min X (10³ X Vr) / (6.22 X Vs)

□A/min: Change value of absorbency every minute Vr: Total Vol. for reaction liquor

Vs: Sample Vol.

6. Normal value: 37°C: 0-40 u/L

- 7. Reagent characters and technical specifications:
- 1) Characters: This reagent is packed with screw-mouth plastic bottle, it has long effective date. The double-bottle reagent is made to cushion with high purified DI water, it solves the unpurified DI water of user and pollution of microorganism. The cushion is installed in R II bottles with certain quantity according to the specification.
- 2) Technical specifications:

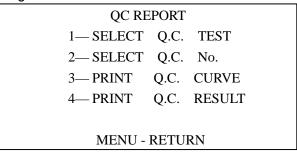
3) The ratio of this reagent to Beckman reagent is γ: 0.994, in one group CV: 2.8% Between two groups 3.9% Linearity ≤600u/L

Special note: Please write down and save the tested item parameters to avoid the system's internal memory to be disturbed by environment.

Chapter 5 Q. C. REPORT

The aim of Q.C. is to control the precision degree of the measurement; supervise the change of stability; improve the conformity of sample test result about one group or between two groups in common test work; it will assure the reliability of the test result for every sample.

You need to measure Q.C. material in "TEST", then print Q.C. curve and result in "Q.C. REPORT". "Q.C. REPORT" menu including:



5.1 Preparation

1.1 Select Q.C. material:

The Q.C. material dry powder produced by professional supplier;

1.2 Prepare Q.C. material:

Dilute the Q.C. dry powder according to the manual, lay it aside for 20 minutes, use it after it becomes stable.

5.2 Measure Q.C. material

- 2.1 Press '2' key to enter "TEST" submenu in main menu, select the TEST No. of the Q.C. (For example: if the TEST is ALT, input '1'), press 'ENTER' key to assure. It will suggest "ASP SAMPLE" after aspirating the RINSE, then press '7' key to set the sample No., such as 59000(It's better to set it as 59XXX to avoid to confuse it with normal samples; please remember the No. because it will be used in the follow procedures), then measure the prepared Q.C. material according to the method of measuring sample.
- 2.2 Enter "REPORT" submenu after measuring, press '1' key to enter "EDIT SAMPLE INFORMATION", select the Q.C. sample No., such as 59000, Input the TEST name (For example: ALT) in "NAME" to check and print. Press 'menu' to quit, it is the whole test procedure of Q.C..
- 2.3 Later, you only need to operate the first step to measure the TEST's Q.C. result, Be care that the TEST No. and sample No. should be the same to the setting of the first time test completely. Enter "Q.C. REPORT" submenu to print the curve and result when there are more than 5 test results of the sample.

5.3 Print the curve and result of Q.C.

- 3.1 Enter "Q.C. REPORT", select TEST No. of the Q.C. in the operation '1—SELECT Q.C. TEST' and setting the target value. You can evaluate or consult other materials.
- 3.2 Select the corresponding sample No. such as 59000 in the operation '2- SELECT Q.C. No.'
- 3.3 Carry out the Operation '3'.'4'to print the Q.C. curve and result (Including MEAN and SD) after carrying out operation '1'.'2'.
- 3.4 When you measure and print the Q.C. curve and result later, you should define the target value.

Attention: 1.The steps for all TESTS are the same except the test name. Select the sample No. and the same TEST for each measurement, you can not test other TEST for this sample No., or it will not print the correct Q.C. curve and result.

- 2. If there is not target value for the Q.C. material, you can measure it for 10 times continually to assure all TEST target values, then calculate the MEAN and SD as the target value and deviation. The target value should be ascertained when you change new reagent.
- 3. Because the normal value range for different areas and different people are different, also the instruments are different, other range only can be reference. Please create the normal range fit to local people!

Chapter 6 UTILITY

This menu mainly consists in "UTILITY" submenu. Press '6' key to enter it in main menu:

UTILITY

1-TEMP ADJ 5-ABSORBANCE
2-ASP PARA 6-DATABASE
3-ADC 7- COM SETUP
4- PTR SETUP 8-CLOCK SETUP

MENU - RETURN

6.1 Temp adj.

TEMP ADJ

SET TEMPERATURE: 37.00 CELL TEMPERATURE: 37.02

FAN STATUS: OFF

CURSOR - SET TEMP

0-CONTROL/UNCONTROL TEMP

1-TURN ON/OFF FAN

You can change temperature with ' \rightarrow ' or ' \leftarrow 'keys with 1°C unit, or with ' \downarrow ' or ' \uparrow ' keys with 0.1°C unit, test temperature to observe the movement of Flow cell.

6.2 ASP Para

ASP PARA

1 - CLEAN VOL

2 - SET ASP

3 - CELL SET

MENU - RETURN

You can set the clean VOL and the ASP parameter here ,the CLEAN VOL menu is used to set the volume of rinse water when cleaning the tube. And the SET ASP menu is designed to adjust the real asp volume when system aspirate the sample or the std. water

Enter digit key '1', you get:

CLEAN VOL

CLEAN VOL: <u>1</u>500 uL

MENU - RETURN

Enter dight key '2', system shows:

SET ASP

SETTING VOL: 1000 uL
REAL VOL: 850 uL
FACTOR: 0.85

FEED – ASP MENU - RETURN

Enter dight key '3', system shows:

CELL SET

 $\sqrt{1 - \text{FLOW}}$ CELL

2 - CUVETTE

MENU - RETURN

Which used to choose between FLOW CELL and CUVETTE

6.3 ADC:

It shows the internal AD transfer parameters of the instrument, service man use it in repairing.

6.4 Printer setup

PTR SETUP

1— PRINT DAILY RESULT

√ 2— INSTANT PRINT

√ 3— PRINT CURVE

4— FORWARD PRINT

Press key '1' to set the "PRINT DAILY RESULT" item, and there will show a '√' symbol

When item 1 is select, the printer will only print the document the create in the current day

When item 2 is select, system will print the result automatic when measuring.

When item 3 is select, system will print out the reaction curve

Item 4 is designed to choose the font format when printing

When item 5 is select, the printer will switch to the LQ300K+ dot printer

6.5 Measure Absorbency

It will show:

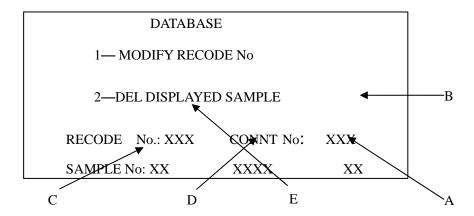
ABSORBANCE
MEASURE ABSORBANCE **A**SP DI WATER

MENU - RETURN

Operate according to the screen's suggestion, the aim is to assure the variety of absorbency between different periods, then rectify. Each wavelength will show 'OK!' in ABSORBENCY testing. Or it will suggest 'FAIL' and need to be adjusted.

6.6 Data base

The internal memory will be affected because of some reason, then it will save wrong data and it will affect report if without correction, this function is as follows:



A: The amount of samples saved in the system, range: 1—255;

B: The actual amount of samples detected by the instrument.;

C: Current position of samples' file: range 0—249

D: Sample No., range:1-9999

E: Saved test No. of the sample, range: 0—30

(1) In normal condition, A should be equal to B, now '1' key is useless. In actual application, because there are too many disturbance factors especially the moment of turning on and turning off, it is instability in the twinkle of power on and power off, now it is very easy disturbed to make mistake. It will suggest wrong information after detecting the mistake, now you need adjust the samples' file with handwork modification, or it will show wrong result.

Method: Press '1' key, the cursor will appear in A, modify the value in A equal to the one in B then press 'ENTER' key to correct the mistake.

(2) If you delete the sample's information in sample's file, search the sample with '↓' or '↑', the sample No. will be shown in D, press '2' key to delete the patient.

Attention: This operation can not be recovered, so be careful. If you delete the appointed result of the sample, operate in "REPORT".

(3) Press 'MENU' key back to last menu.

6.7 Com setup

Enter "Serial com." interface, it will show:

COM SETUP

SERIAL: ON PARITY:DISABLE BAUD RATIO: 19200

MENU - RETURN

Set the Serial com., select the parameters with ' \rightarrow ' or ' \leftarrow ' key.

□ Select "ON" or "OFF" for 'Serial com.', set the parameters of 'Serial com.' as the one in the interface, set the 'Serial com.' with the same method for every time to power on, all 'Serial com.' state must be set to asynchronous communication.

☐ There are ODD, EVEN, NONE to select for PARITY.

☐ There are 5 BAUD RATIOS to select: 19200, 9600, 4800, 2400, 1200;

Input the BAUD RATIO, press 'ENTER' or '\' key to select parameters of PARITY.

6.8 CLOCK SETUP

Enter "CLOCK SETUP" menu, it will show:

CLOCK SETUP TIME FORMAT: 24 Hr DATE: 2007 — 02 — 27 TIME: 14:23:56 XX '←' '→' CHANGE HR FORMAT MENU - RETURN

a>. Time Format: HOUR-MINUTE-SECOND XX XX: AM: MORNING

PM: AFTERNOON

If it is 24 HOURS SYSTEM, XX is blank.

b>. Date Format: YEAR-MONTH-DATE

c>. Press 'MENU' key if you don't modify the time and date, don't press 'ENTER' key, or it will effect the time's correctness.

6.9 Utility

When the system is disturbed by other reasons, this function can help you to reset the system to back to factory setup. Input XXXXXX in 'MAINTAIN' to startup the function, it will ask you:

PRESS '1' TO RESET SYSTEM PRESS '2' TO RESET SAMPLES MENU - RETURN

Press '1' key to reset the system, then press 'Y' twice; press '2' key to clean the samples file, then press 'Y' twice; press 'MENU' key to back, all samples' information and results will be lost after reset in internal memory, so be careful.

Chapter 7 Maintenance

7.1 Maintenance

Maintenance and Utilities of ADI-DUO BIOCHEMISTRY ANALYZER is as follows:

1. Keyboard usage

Keyboard is a 'TOUCH' key, there is no sound when pressing each key, only sound for pressing then loose it, so the operator shouldn't press keys heavily.

2. Maintenance for every day

Clean the cell and tube with DI water repeatedly after measuring sample every day to get rid of residual reagent and serum, protein especially remain thing in the cliff of Flow cell. The tube should be full of DI water at last.

3. Maintenance for every week

Clean the tube twice with DI water after measuring sample, then aspirate the CLEAN once (Main Component: NaClO, diluted it to 5%), let the CLEAN stay in the tube for 10 minutes, cleaning the tube with DI water for 3 times. At last it should be full of DI water.

4. Cleaning instrument's appearance

Wipe the instrument appearance with wet cloth (Turn the electricity power off).

Attention: Clean the instrument with clean water , neutral purge reagent or non-causticity scour, but it can't be cleaned with organic reagent or hot water, or it will be distorted or damaged.

7.2 Trouble and Handle

Description	cause	method
	a) The pump doesn't work	a) Tight the screw of the pump
Fail aspirating	b) Loose pipe	b) Cut down a part of the pipe's tie
	c) Aspirating time is zero	c) Install the ASP TIME again
	d) The pipe is damaged	d) Change the pipe(Appendix)
	a) The power doesn't supply	a) Turn on the power
No Display	b) The electricity doesn't work	b) Check the power socket
	c) Signal display line is loose	c) Check the display cable
		Adjust the contrast adjustor
Dark Display	The contrast of the display is changed with the environment.	Contrast adjustor
	a) No paper.	a) change the new paper
No Printing	b) Print paper is blocked.	b) install the paper again
	c) Thermal print paper is in reverse	c)install the paper again
Fail Absorbency	a) Do not aspirate DI water b)There are bubble in the colorimetric cell. c) Flow cell is dirty d) The lamp is aging	Test it with DI water a): Clear the bubble in colorimetric cell b): Clean the colorimetric cell with CLEAN c): Change the lamp
Instable results	 a) No absorbency when power on b) Invalidate reagent c) Inadequate ASP quantity d) No STD. e)Improper wavelength f) Aspirate air into reagent to get high result 	a) Absorbency again b) Change validity reagent c) Adjust the ASP quantity≤600uL d) Test the BLANK and STANDARD again e) Test another wavelength f) Operate carefully and standard

Appendix 1: Input Method

The system uses "input method" in 'PATIENT NAME', 'DOCTOR NAME', 'REPORT HEAD', 'ADD TEST ITEM', the consent method is ENGLISH, press 'MENU' to enter 'INPUT METHOD' interface, it will show:

The correspondent relation of cursor keys to ENGLISH characters are as follows:

Press '1' key one time and you will get A.	1	Α
Press '1' key twice quickly and you will get B.	1—1	В
Press '1' key three times quickly and you will get C.	1—1—1	С
Press '1' key four times quickly and you will get C.	1—1—1—1	1
Press '2' key one time and you will get D.	2	D
Press '2' key twice quickly and you will get E.	2—2	Ε
Press 2 key three times quickly and you will get F.	2—2—2	F
Press 2 key four times quickly and you will get F.	2—2—2—2	- 2

Use the cursor key †to switch between uppercase and lower-case

Appendix 2: Communication protocol

Hardware condition: Connect 2 communication instruments' RS-232C ports together with RS-232C cable, or connect the instrument to PC's COM port.

Serial communication parameters:

BAUD ratio: 19200, 9600, 4800, 2400, 1200;

WORK MODE: 0(SYNCHRONISM), 1, 2, 3, 4(ASYNCHRONISM)

PARITY: ODD, EVEN, NONE;

WORK STATE: SEND, RECEIVE, DUPLEX OPERATION.

Concentration values are sent in frame with the following format:

Blank raw data:

Bite	Туре	Code
1	Frame head	FA
1	Version	01
1	Instrument Type	01
2	Instruments No.	01
1	Frame Length	0-7F
1	Frame No.	0-7F
3	Patient ID	0-7F
1	Item NO.	80H-80FH
1	Measure state	D0
1	Result type	D3
3	Data	0-7F each
1	Decimal	E0-E4
1	Check sum	D7=0
1	Frame end	FBH

Standard raw or sample raw data:

Bite	Туре	Code
1	Frame head	FA
1	Version	01
1	Instrument Type	01
2	Instruments No.	01
1	Frame Length	0-7F
1	Frame No.	0-7F
3	Patient ID	0-7F
1	Test NO.	80H-80FH
1	Measure state	D1-D2
1	Result type	D4
3	Data	0-7F each
1	Decimal	E0-E4
1	Unit	COH-CFH
1	Check sum	D7=0
1	Frame end	FBH

The result:

Bite	Туре	Code
1	Frame head	FA
1	Version	01
1	Instrument Type	01
2	Instruments No.	01
1	Frame Length	0-7F
1	Frame No.	0-7F
3	Patient ID	0-7F
1	Test NO.	80H-80FH
1	Measure state	D2
1	Result type	D5
3	Data	0-7F each
1	Decimal	E0-E4
1	Unit	COH-CFH
1	Check sum	D7=0
1	Frame end	FBH

Test code: (80-0xBF, 64 codes at most)

NUM	TEST CODE	CODE	NUM	TEST CODE	CODE
1	1	81H	8	8	88H
2	2	82H	9	9	89H
3	3	83H	10	10	8AH
4	4	84H	11	11	8BH
5	5	85H			
6	6	86H			
7	7	87H			

Unit code:

NUM	NAME	CODE	NUM	NAME	CODE
0		C0H	8	g / d L	C8H
1	u / L	C1H	9	g / m L	С9Н
2	u / mL	C2H	10	Leu/uL	CAH
3	u mol/L	СЗН	11	X1012 / L	СВН
4	m mol/L	C4H	12		CCH
5	g / L	C5H	13		CDH
6	mg/L	C6H	14		
7	mg/dL	C7H	15		

Measure State			Result Type		
NUM	NAME	CODE	NUM	NAME	CODE
1	BLANK	D0H	1	originality	D3H
2	STANDARD	D1H	2	Absorbency	D4H
3	SAMPLE	D2H	3	Consistence	D5H

Attention:

- a)Use originality to test BLANK, no unit;
- b)Use absorbency to test, no unit, data is 3*N bites for N standards;
- c) Use no unit absorbency and unit consistence to test;
- d) Absorbency value: turn the decimal to left for 3 bites;
- e) Consistence: turn the data to left for (D decimal—0xE0)bites;.
- f) The CRC check begins with the start bite of FA and end with front one bite of the check sum;
- g) Item's result data bite and patient No. are $((D_0\&7F) << 14) + ((D_1\&7F) << 7) + (D_2\&7F)$;
- h) The frame length is which begins with the item type bit and end with the front one bit of the check sum.
- i) The first frame's No. is 1, and it will add 1 when send one frame till 0x7f, then begins with 1 again.
- j) The instrument sends data to the serial when the screen shows the result report. For example, it will send data automatically when get the result in "TEST SAMPLE" and "RESULT REVIEW"

Appendix 3: Tests List

Code	Abbreviation	Code	Abbreviation
1	ALT	26	Zn
2	ALP	27	Р
3	GOT	28	K
4	γ-GT	29	Na
5	TP	30	CO ₂ -CP
6	ALB	31	Fe
7	TBIL	32	HGB
8	DBIL	33	RBC
9	TTT	34	GRP
10	BUN	35	A/G
11	CRE	36	UDBIL
12	UA	37	IGG
13	CO ₂	38	C3
14	NH ₃	39	IGM
15	GLU	40	CHE
16	TCHO	41	CK
17	HDLC	42	BU
18	LDLC	43	U-PRO
19	TG	44	U-Hb
20	LDH	45	U-GLU
21	AMS	46	U-URO
22	CL	47	U-BIL
23	Ca	48	U-KET
24	Mg	49	U-NIT
25	Cu	50	U-PH