OPERATION MANUAL

FLUORESCENCE IMMUNOASSAY ANALYZER

QUANTITATIVE

HTY-100

MR International Healthcare Technology Co.,Ltd.

Table of Content

1 Summary

1.1 Description

Thank you for choosing Fluorescence Immunoassay Quantitative Analyzer of MR International Healthcare Technology Co.,Ltd. It was researched, designed, developed, produced and sold by MR And it is an immunofluorescence detecting system that is easy to operate, small, portable and can be used for rapid test of the concentrations of various analytes blood and urine. The system is only for in vitro diagnostic use.

This operation manual contains operation guidance and graphic operation process of the Fluorescence Immunoassay Quantitative Analyzer, convenient for your use. Please read this operation manual carefully before using the analyzer.

Fluoroimmunoassay (FIA) is a kind of trace analysis method developed in recent years. It also is one of the most sensitive trace analysis technologies for now. Certain substances molecules can absorb energy and emit fluorescence, do qualitative or quantitative analysis on substances depending on the fluorescence spectra and fluorescence intensity, this method is called fluorescence analysis.

FIA has advantages of high sensitivity, strong selectivity, small sample volume and simple methods, and usually its lower limit is 2-4 magnitude higher than spectrophotometry, it is widely used for biochemical analysis.

1.2 Product Performance

a) Sensitivity

The minimum detectable amount for CRP is 0.5mg/L.

b) Linear range

For the range of CRP 0.5 mg/L～200mg/L, the correlation coefficient r ≥ 0.98.

c) Accuracy

In the range of CRP 0.5mg/L～5mg/L(include 5): Error does not exceed ±15％.

In the range of CRP 5mg/L～200mg/L: Error does not exceed ±10％.

d) Repeatability: CV≤5％

e) Stability: CV≤5％

1.3 Structure and Principles

1.3.1 Main Structure

The analyzer is composed of optical inspection (light source, filter, sample room, photocell, signal amplification and conversion), SCM analysis and control, display and print.

1.3.2 Working Principle

When the test card that has been added sample is inserted in the Fluorescence Immunoassay Quantitative Analyzer, LED light source irradiate test area and control area of the test card, excite attached fluorescent substance, emitted light is collected and converted into an electrical signal, the strength of the electrical signal is strictly related with the number of fluorescent molecules. Detector automatically scans and calculates the content of the analyte in the test sample.

1.4 Scope of Application

Fluorescence Immunoassay Quantitative Analyzer applies to test CRP indicator with

immunofluorescence method.
The test system is only for in vitro diagnosis, is widely applicable for the central laboratory of medical institutions, outpatient and emergency laboratory, clinical departments and other medical services station(eg. Community medical station), medical center etc, and also applies to scientific research and laboratory testing.

1.5 Ensure the Effectiveness of the Diagnosis

Due to that the analyzer is affected by optical components, electronic components and structural components and different batches of reagents. The performance of the analyzer will change. These changes will affect the accuracy of the test results. Therefore, when change reagents, continuous use more than one month or shorter time, should do calibration test on the analyzer.
Method: Purchase qualified quality control of corresponding reagents via formal channels, inspect control quality as per reagent instruction. If the test results excess the requirements of quality control, meanwhile, the accuracy and repeatability of the instrument excess its performance indicators, should inform the manufacturer to let the manufacturer do further inspection or calibration.
When using the analyzer, the user has to operate as per the reagent instruction and analyzer instruction. Cannot simplify the process.
The test results need to combine with other clinical and laboratory data. When the test results do not match with the clinical assessment, further examination is needed.
Please do not use expired reagents or reagents those are about to expire.
Diagnosis results should be made combined with clinical symptoms. For these results in the critical region should re-test or re-test the in one day.

2 System Components

After opening the package, please configure every components as below table, meanwhile, check if the analyzer components have any deficiency or damage.

2.1 Standard Configuration of the Analyzer

No.	Name	Quantity	Unit
1	Analyzer	1	Set
2	Power Adapter	1	Set
3	Printing Paper	1	Roll
4	Operation Manual	1	Piece
5	Certificate	1	Piece
6	Calibration Card	1	Bag

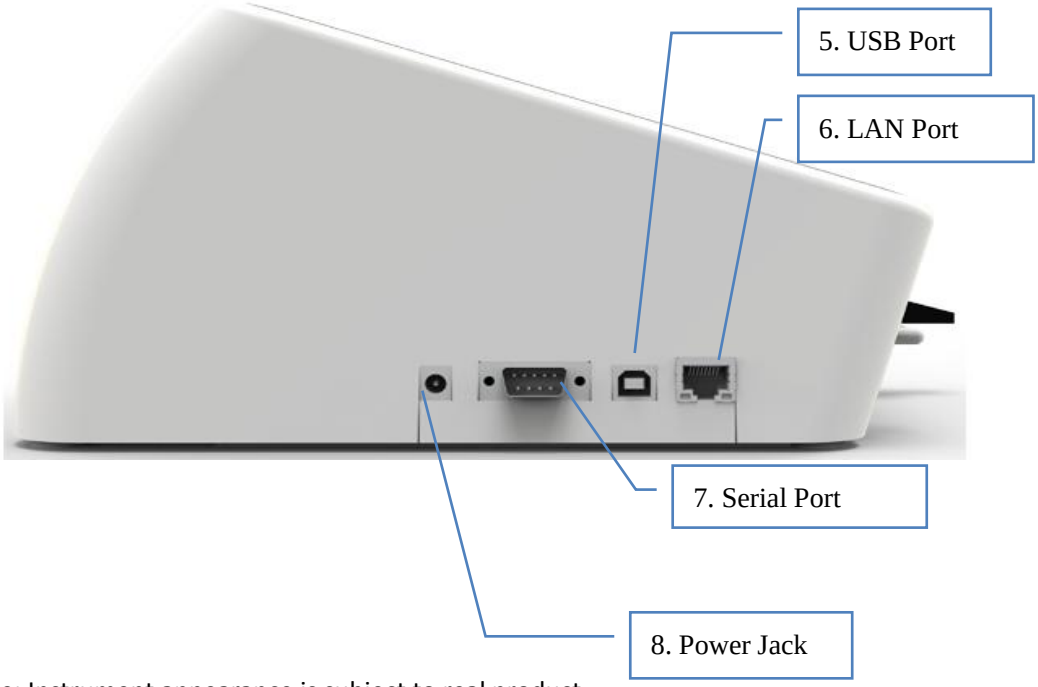
If any components deficiency or damage is found, please contact MR International Healthcare Technology Co.,Ltd. timely and local sales representative.
The detailed contact information, please refer to Chapter 11.

2.2 External Construction

2.2.1 Top view

2.2.2 Main view

2.2.3 Left view



Note: Instrument appearance is subject to real product.

2.3 Power Cable and Connection Cable

3 Basic Parameters of the Analyzer and Conditions of Use

3.1 Basic Parameters of the Analyzer

Light source	5mW　LED
Excitation Spectra	Central wavelength λ_0＝635nm
Emission Spectra	Central wavelength λ_1＝665nm
Sample Type	Whole Blood, Serum/Plasma, urine
Soft System	Inside real-time operating system
Interface	RS232，USB、LAN port
Storing Number	Up to 40,000 copies of the reports can be saved
Printer	Built-in thermal printer, external serial printer(Optional)
Paper Specifications	57*30
Power Adapter	Input AC 220V, Output DC 12V 5A
Size	230mm*175mm*305mm
Weight	About 2.4kg

3.2 Conditions of Use

Ambient temperature	15℃～30℃
Relative humidity	40%～85%
Atmospheric pressure	86kPa～106kPa
Power Source	AC220V±22V 50Hz±1Hz 36VAC
Placement	dry, clean, flat table
Avoid direct sunlight, mechanical vibration and strong electromagnetic interference.	

4 Analyzer Installation

4.1 Power Requirements

Fluorescence Immunoassay Quantitative Analyzer can only use the power adapter provided together with the analyzer. Please do not use any other power adapters. If the power adapter need to be replaced, please contact with local sales representative or MR International Healthcare Technology Co.,Ltd.

4.2 Instrument Installation

Operate the analyzer under the conditions of temperature 15℃～30℃, relative humidity 40%～85%.(See Chapter 3 " Conditions of Use").

1) Place the analyzer on a fixed and flat operation platform. The platform should be flame retardant materials and can bear no less than 10kg, the distance between the back, the right and the front of the analyzer to the edge of the platform should no less than 10cm. The distance between the left of the instrument to the edge of the platform should no less than 20cm to turn on/off the analyzer conveniently. The other items should not be stacked on the platform to operate the instrument conveniently.

2) Connect the power adapter connector to the power interface which is on the left of the analyzer.

3) Connect the power interfaces of the power adapter and the analyzer.

4) Press the power switch to turn on the analyzer.

5) The analyzer enters into the system self-inspection. Below is the interface of the self-inspection.

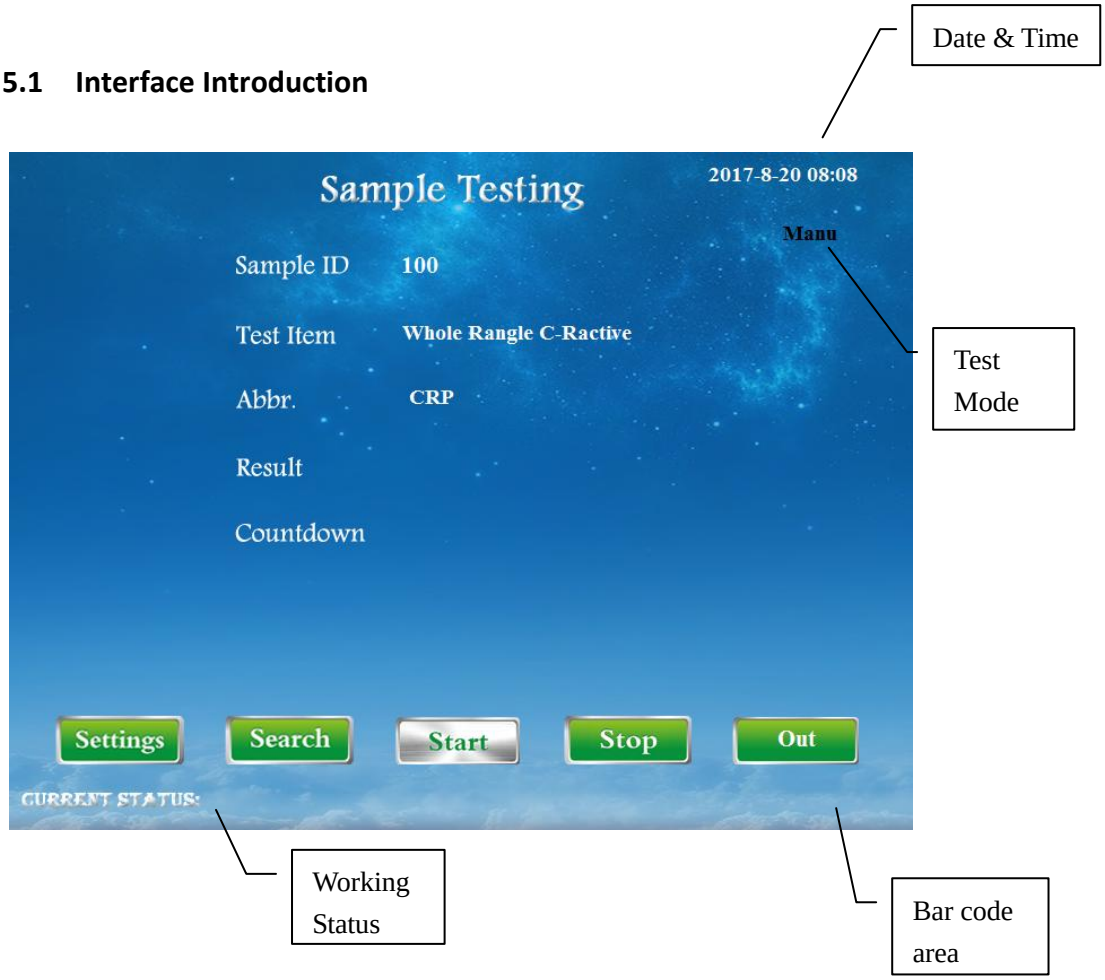
The number on the upper left corner is the version number of the running software.

6) After completion of the self-inspection, entering the main interface.

Note: The installing procedure should be guided by HIGHTOP's engineers.

5 Analyzer Operation Introduction

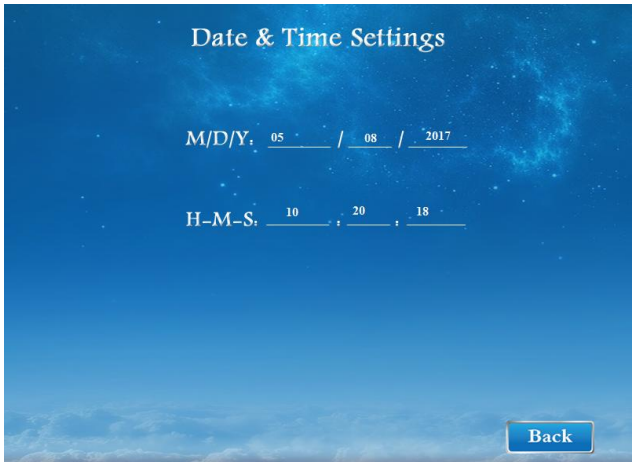
5.1 Interface Introduction



5.1.1 Instruction for Use

5.1.1.1 Setting of Date and Time

Display current time on the upper right corner. it can be modified on "Settings" Menu. If computer connected, time of analyzer will synchronize with PC.



5.1.1.2 Mode of Testing

The mode of testing is named with abbreviation.

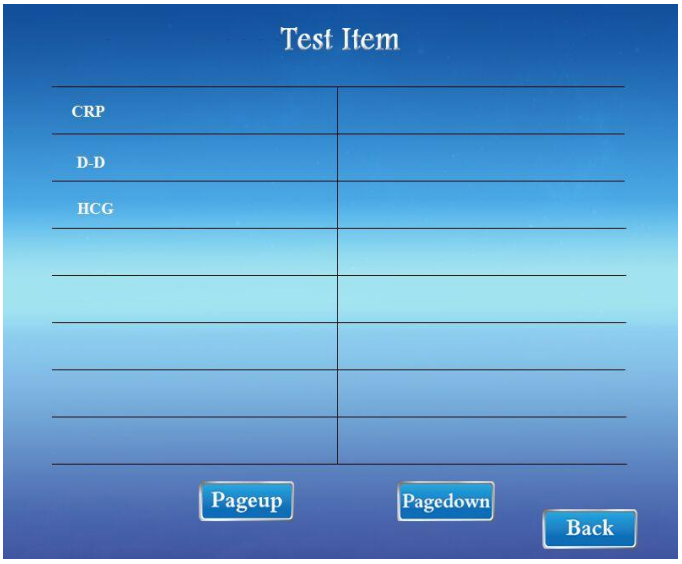
a. Auto: Automatic mode.
b. Manu: Manual mode.
c. Follow: Following mode.
d. Series: Succession mode.

5.1.1.3 Testing Report

If it can finish testing normally, the result will be displayed in the results report area. If the printer is set on, the results will be printed by the printer automatically. (Printing please see the Printer Setting)

5.1.1.4 Choose Test Item

Click the "Test Item" or "Abbr." on the interface of "Sample Testing", the Test Item interface will show up, see image below. All items that tested before will be shown on this page. Please click on the Item Name if user want to see more detailed information of it. When insert the ID chip, the information inside ID chip will be copied and saved in the analyzer automatically.



5.1.1.5 Sample ID Setting

The daily Samples ID number of the analyzer is starting from 1 to the maximum number 9999, please use within this range. Click ""Sample ID" on the interface of "Sample Testing" to enter ID numbers interface. See image below.

Enter ID number by clicking numbers and then press "OK" to complete and back to "Sample Testing" page. If the page do not back to "Sample Testing", it means the number entered is over the range of 9999, please choose new number within the range.

5.1.1.6 Current Status

The Current Status on the bottom left corner, it displays the status of the analyzer's current

operation, such as "Insert IC or select item", "Measurement", etc.

5.1.1.7 Choose Barcode

The Barcode display area is shown on the bottom right corner. The analyzer will automatically save the information of the ID Chip once it is inserted. If want to measure the same test item but different bar code, then click on the Barcode display area to enter the Barcode choosing interface. See image below.

Click on the corresponding Barcode to select. If click on the blank area or "Back" bottom, it is still using the original ID chip.

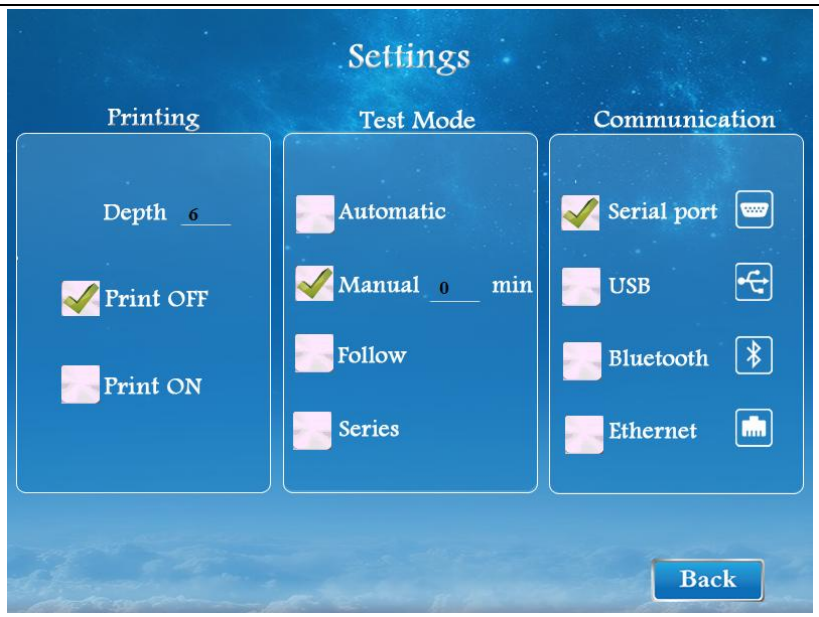
5.2 Function specification

5.2.1 Measurement

Choose the test model first before testing (refer to the settings of "Test Mode"). Click "Start" to enter testing procedures. If the system has the countdown mode (refer to the settings of Countdown that behind Manual Mode, the countdown is both for Automatic Mode and Manual Mode only), then it will start with countdown(Please note the Test Mode chosen). When the countdown is over, analyzer begins to measure. Firstly, the analyzer will detect bar code, compare its value with IC card if it is same or not. If they are same, then recall the value of IC card to measure the reaction area and analyze the peak value of reaction area to calculate the results of concentration and then the results will be displayed on the report area of the main interface. If the printer is in the ON status(refer to settings of "Printing"), at the moment, the analyzer will print the results automatically.

5.2.2 System Settings

When enter system settings, the interface show below.



5.2.2.1 Printing Setting

5.2.2.1.1 Printing Depth

This setting is only for the built-in thermal printer, the depth arranges from 1 to 12. Click on number area to enter numbers' interface to set up.

5.2.2.1.2 Printing On & Off

The built-in thermal printer is turned on by default. The size of printer paper is 57 x 30mm.

Note: Description of printing report

Printer off:

a. It will not print the results automatically after testing finished.

b. The error report and search report can be printed.

Printer on:

a. Report of normal measurement(analyzer running well).

b. Debug report(under the debug mode of the analyzer).

c. Error message report under Series Mode testing.

5.2.2.2 Test Mode

There are four kinds of test mode on the middle of "Settings" interface. The abbreviation of test mode is shown on the upper right corner. (Auto: Automatic mode, Manu: Manual mode, Follow: Follow mode, Series: Series mode)

5.2.2.2.1 Automatic Mode

Under the Automatic mode, the analyzer is checking if there is test card inserted or not all the time, when there is test card inserted (no need to press any buttons), the testing will start automatically if the countdown is "0". If the countdown is set up, system will start counting until finish then test. Countdown range from 0 to 30 minutes. The countdown setting is behind the "Manual Mode".

5.2.2.2.2 Manual Mode

Under the Manual Mode, test is operating by buttons on the touch screen, insert the test card, press "Card In" then press "Start" to starting the measurement. The testing will start automatically if the countdown is "0". If the countdown is set up, system will start counting until finish then test. Countdown range from 0 to 30 minutes. The countdown setting is behind the "Manual Mode".

5.2.2.2.3 Follow Mode

Under the Follow Mode, the system is same as under Manual Mode, only the countdown is set

up by IC card automatically. After adding samples on test card, immediately press the button "Start" to start the countdown for this test.

5.2.2.2.4 Series Mode

The above three mode are all for single testing. Under the Series Mode, operator can continuously add samples into several test cards. After each adding samples in one test card, click on the button "Start" at the same time to make this sample ID into the sort queue. Sample adding time interval between two test cards should be more than 15 seconds. When click "Start", numbers of sample that already added will be shown on the Current Status area. In the last 5 seconds of the countdown, the analyzer will alarm with sounds of "Tick...", at this time the correspondent test card should be put on the card holder to measure.

If missed this measurement time, the analyzer will discard this Sample ID and start the next Sample ID measurement. The analyzer will also discard the Sample ID which bar code cannot be identified or value incorrect, that will cause the results cannot be printed properly. The analyzer will output the error report to the printer(even the printer is in off status, it will print the error message) in order to facilitate the user to review the wrong sample and re-test the wrong sample after all samples testing finish.

The countdown has been set by the ID Chip initially.

5.2.2.2.5 Suspend Measurement

If want to suspend the measurement due to some problems such as adding wrong samples during the measuring, click the button "Stop" to suspend during period of countdown. If under Series Mode, the analyzer will cancel the following Sample ID, and if adding new samples, the ID will start from the one suspended.

5.2.2.3 Port Setting

5.2.2.3.1 Serial Port

The parameters for serial communication are 115200, N, 8, 1. When selecting this communication, connect the RS232 serial cable (DB9) and select the serial communication on the computer.

5.2.2.3.2 USB

Please note when using this method. This is USB changed to serial port, it will be displayed "USB Serial Port(COM3)" on the computer. See image below.

COM 3 is set by computer automatically, your serial port may be in other data. The parameters for communication still are 115200, N, 8, 1. If selecting this method, please connect the USB cable and install CH340 driver on the computer.

5.2.2.3.3 Bluetooth (Wireless module)

Using the Bluetooth (wireless module) transmission, need to install driver on the computer(same driver and install method as 5.2.2.3). After the driver installation, communication settings can still be chosen as serial port or Bluetooth serial port, the name will be displayed as "USB-SERIAL CH340 (COM1)". See image below.

5.2.2.3.4 Ethernet

In the Settings interface, click the Ethernet option, will pop up the following interface. The Local IP is the IP of the analyzer, the Server IP is the IP of the computer which connects to the analyzer. Please contact the network management to help setting.

Note: Using Ethernet, the data transmission may delay due to the router or network problem.

As the Serial port and USB are the same port in the analyzer, so the serial cable and USB cable cannot be inserted into the analyzer at the same time, otherwise the serial cable will be shielded by USB cable and cannot communicate.

5.2.3 Search Report

The test results are stored in the RAM of the analyzer by default, it can store 40,000 reports at maximum, the most previous report will be covered if beyond this number. The report is stored in memory as a sector in the form of date, and a report can hold up to one year in memory. If want to search reports, please click button "Search" to enter.

Note:

For one day, the Sample ID only keep results of the latest test, it means if the Sample ID is used repeatedly the old one will be covered.

5.2.3.1 Setting of Sample ID for Search

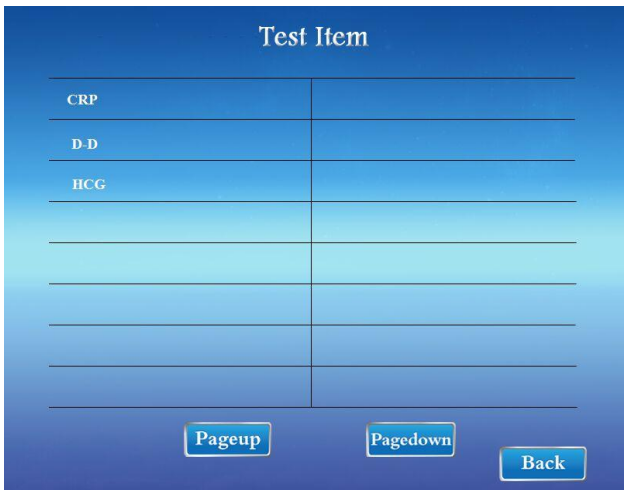
Click the ID area to enter the start and end number. The default of start number is 1, the default of end number is the last tested number.

Note: If there is no result after search, please check whether the start and end number are set reasonable.

5.2.3.2 Setting of Test Item for Search

The default of test item of search is the item of current IC. Click on the abbreviation area to check others, then the following interface will pop up.

Click on the item that want to check. If want to check all items on the day, please click on the blank area, then all the results will show up.



5.2.3.3 Setting of Date for Search

Click on the year/month/day area to set the date want to check. If it cannot be set, please check

the date whether valid.

5.2.3.4 Search

Click button "Search" to start searching according to the conditions that set. The results will be tabbed display If the query results more than 7. If no any reports founded, please check whether start and end number are right or the date is correct.

5.2.3.5 Print

Choose and click on the report which want to print, the chosen report will be highlighted, then click "Print" to print the report.

5.2.4 Card In & Card Out

Click on the button "Card In", the card holder will run into the analyzer if it is outside, then the button "Card In" will turn to "Card Out" after the holder inside analyzer completely. The default of card holder is inside the analyzer in order to easily packing. If want to start the test, firstly click the button "Card Out" to move the card holder out.

6 Operation procedures

Preheat 3 to 5 minutes after turn on the analyzer

6.1 Single-step Measurement

Note: If using independent stopwatch instead of analyzer countdown, please set the Countdown in "0".

1) Press the power switch to turn on the analyzer, waiting for completing self-inspection.

2) Choose the testing mode (AUTOMATIC, MANUAL, FOLLOW).

3) Set the countdown for mode of AUTOMATIC and MANUAL if using analyzer countdown. No need to set countdown for FOLLOW mode, it is set by ID Chip.

4) Remove the test card and ID chip from package and insert ID chip into chip port of the analyzer. Make sure the test of ID chip is same as test card (Same item name and batch), and the test card is in the validity period.

5) Click button "Card Out" to move the test holder out if it is inside the analyzer.

6) Make sure the Sample ID of the analyzer is same as the real sample ID of the test(if not the same, please reset the Sample ID of analyzer), otherwise the result will not correspond.

7) Using marker to mark the specimen ID on the handle end of the test card, and then adding sample into test card according to Instruction for Use of the test item. Click button "Start" immediately after adding samples to start the countdown(if the countdown is not zero). If under Automatic mode, the countdown will start once insert test card into card holder.

8) Put the test card with samples on card holder and push inside till the end.

Note: Push the test card into card holder till the end, do not force too much, otherwise it will cause mechanical failure.

9) When countdown complete, the analyzer will scan and measure automatically and displays the results, then automatically print report if printer is on.

10) Click button "Card Out" to remove the test card, repeat step 6 - 9 to perform next test.

11) If the test is finished, remove the test card and click "Card In", then turn off the power switch. If want to change the test item, please repeat step 3 -10.

6.2 Series Measurement

1) Press the power switch to turn on the analyzer, waiting for completing self-inspection.
2) Choose the testing mode(SERIES).
3) The countdown is set by ID Chip already.
4) Remove the test card and ID chip from package and insert ID chip into chip port of the analyzer. Make sure the test of ID chip is same as test card (Same item name and batch), and the test card is in the validity period.
5) Click button "Card Out" to move the test holder out if it is inside the analyzer.
6) Make sure the Sample ID of the analyzer is same as the real sample ID of the test(if not the same, please reset the Sample ID of analyzer), otherwise the result will not correspond.
7) Using marker to mark the specimen ID on the handle end of the test card, and then adding sample into test card according to Instruction for Use of the test item. Click button "Start" immediately after adding samples to start the countdown(if the countdown is not zero).
8) If no countdown, the analyzer will start to last five seconds counting directly. If there has countdown, the analyzer will display the counting time.
9) Put the test card with samples on card holder and push inside till the end when the analyzer sounds for last five seconds counting.
10) Click button "Card Out" to remove the test card and then insert another ready test card, wait to perform next test.
11) Repeat step 10 until finish, remove the test card, click "Card In" and then turn off the power switch.

 *Precautions:*

1) Using Ethernet, the data transmission may delay due to the router or network problem.
2) Select the right mode.
3) Note the countdown is different for different mode. The Automatic Mode and Manual Mode is set by manual, the Follow Mode and Series Mode is set by IC card.
4) If problems happen in Series Mode, such as bar code cannot be identified or value incorrect, etc. The analyzer will output the error report to the printer(even the printer is in off status, it will print the error message). Re-checking the whole test samples and find the wrong report, then decide whether re-testing or not.
5) Make sure the Sample ID of the analyzer is same as the real sample ID of the test, otherwise the result will not correspond.
6) Do not change the mode during the analyzer measuring.
7) Click "Card In" before analyzer turn off.

7 Maintenance and Repair

7.1 External Cleaning

Clean the outside surface with a damp cloth and 75% of medical alcohol. Do not use strong bleach(>0.5% solution),because oxidants and solvent may damage the shell and touch screen of the analyzer.

7.2 Decontamination, Disinfection

After being used in a clinical environment, if the analyzer does need to be fixed or replaced, decontaminate before repackage and transportation. Then disinfect the analyzer (Can use 20

ml/L of NaClO solution(Containing 5% effective chlorine)). Finally, wipe thoroughly the outer surface of the analyzer with soft cloth. Do not spray the analyzer with disinfectants or clean any internal parts and the inner surface.

7.3 Maintenance

Generally, the analyzer no need special maintenances besides replacing printing paper or regularly cleaning. Wipe the surface of the analyzer with soft cloth to make sure it can work normally.

Besides daily cleaning, should pay attention to regular maintenance and calibration of the analyzer. When insert a test card to the analyzer, any spill liquid should be wiped. For such dirt that is difficult to clean, wipe wit skim cotton dipped in a little alcohol.

7.4 Repair

When the analyzer breaks down and cannot work normally, cut off power source immediately and wait for maintenance staff. Place 'Stop Using' label on the analyzer. Maintenance staff should disinfect the whole analyzer firstly, then do the next operating.

7.5 Waste Treatment

The test card used for testing by the analyzer may contain biological contamination, do incineration handling on the waste test card. The waste card cannot be reused and be regarded as household garbage. Handle the waste card according to requirements of medical waste.

7.6 Battery

The battery inside the analyzer is used only for the clock. This battery is rechargeable. If the analyzer is not turned on for a long time, the analyzer will reminder low battery when turn on(May also be directly printed to remind.). The analyzer time will be initialized to the initial time, just need to modify the time and turn on for a period of time to complete charging.

7.7 Replace Printing Paper

Under the conditions that the analyzer is used for the first time or it lacks printing paper, the analyzer needs to replace new printing paper. Please get ready of a roll of thermal printing paper(Specifications for the 57 × 60mm) to install.

7.8 Quality Control

7.8.1 Scaling

Quantitative analysis needs scaling on reagent and analyzer, this work has been completed by reagent manufacturers, and the calibration curve have been written into the IC card which packed together with reagents. The users only need to insert the IC card(ID Chip) into the analyzer when measuring.

7.8.2 System Calibration

With the change of time, the analyzer may produce offset of results, in order to reduce such offset, the calibration has to be made on analyzer regularly.

Method: Take out of the calibration ID chip and calibration test card from the zip-lock pouch, insert the ID chip into the chip port at the front left of the analyzer, "Calibration Card" will be displayed as item name on the LCD screen. Select Manual mode and set the countdown as "0". Insert the test card into card holder, click button "Start" to begin the test. If the test results are

within the calibration range, the printer will print out the results and remind that the calibration passed. If the test results are beyond the calibration range, it will display on the screen. Try it for three times, if all results are beyond the calibration range, please inform the manufacturer timely, the manufacturer will ask to return it back to factory for calibration. After calibration being finished, the calibration ID chip, calibration test card and desiccant should be put back into the zip-lock pouch and seal for storage.

Note: After the continuous or frequent measurements or under the light, the fluorescence value of the calibration card will drop sharply. The validity period of the calibration card is one year, please ask the manufacturer to have new one when beyond the validity period.

7.9 Touch Screen Calibration

In the normal working condition, if click on the non-touch area of touch screen more than 20 times within 4 seconds, it will enter the touch screen calibration mode, procedure as follow:

1) Click on the non-touch area of touch screen more than 20 times within 4 seconds.

2) The buzzer beeps for 1 second, then stop clicking.

3) Enter the calibration mode, click on the designated location of the torch screen to calibrate according to the cross-line prompts.

4) The calibration finishes and return back to the interface that before entering the calibration.

The touch screen will automatically check whether the calibration is valid or not. When the calibration is disabled(such as by enter calibration mode due to misoperation, etc.), the DGUS screen will not be calibrated by incorrectly setting. If try to calibrate the touch screen several times but all failed, it seems the touch screen has been physical damaged, such as screen rupture.

The analyzer does not include the components that the operator can use to repair. Regular maintenance and calibration must be performed by an authorized service technician to avoid electric shock.

Calibration ID Chip and calibration test card should be kept sealed and avoid light.

8 Safety Attentions

8.1 Attentions of Using the Test Card

1) When the test card is pushed into card holder, the one end with an arrow should be towards the interior of the analyzer.

2) Push the test card into card holder till the end, do not force too much, otherwise it will cause mechanical failure.

3) The used test card should be destroyed according to local biohazardous materials handling regulations.

8.2 Attentions of Using the Analyzer

1) Without manufacturer's allowing, do not place any other things into the card holder.

2) Do not make the analyzer fallen from a height place and do not crash.
3) Don’t place the analyzer in a mechanical vibration environment.
4) Without the authorization of manufacturer or its representatives, please do not unload the analyzer.
5) Do not place any heavy objects on the analyzer, this will result in performance degradation or mechanical damage.
6) The analyzer can only use its dedicated power adapter.
7) Please use the analyzer in the conditions of Chapter 4.
8) Test results are used as reference of pre-screening. Test results should be interpreted by professional medical personnel.
9) The analyzer should be operated by professional operator. Quality control should perform on every batch or regularly, if the performance have deviation, the analyzer should be calibrated by the manufacturer.
10) If the analyzer has any unusual circumstances during working, e.g, There are smoke inside the analyzer or abnormal sounds made by moving components etc, in such conditions, the operator should switch off the power immediately and unplug the power cord.
11) In order to test if the analyzer has potential safety hazard, users can request the manufacturer to do the dielectric strength, leakage current and ground test. But repeatedly such tests will reduce the life of the analyzer. After anti-shock testing, the protection for risk will be reduced.
12) Do not use the analyzer in the humid environment. Humid environment will not only do harm to internal components but will reduce the safety protection level of the analyzer .The analyzer must not be placed nearby water spray, splashing and basin. The analyzer can not be spread by any liquids from any direction by sprinkling, splashing, spraying.
13) Operating the analyzer should according to the Instruction for Use, such as installation, measurement, maintenance, storage, transportation etc. The incorrect operation will not only affect the test results, but be more likely to cause damage to the analyzer's safety. For such damages, MR will not take responsibility.
14) The analyzer does not contain any components for repairing. If any queries, please contact the manufacturer or the local representatives.
15) The analyzer maintenance and debugging should be performed by professional staff from MR (Or the authorized after-sales agencies), do not allow layperson to do these work related with maintenance and repair. For such accessories which need to change or repair, should be supplied by the manufacturer or authorized after-sale agencies.MR does not take any legal responsibility for such damage caused by maintenance or repairing by other ways.
16) The user should keep all accessories and packaging of the analyzer, in case to avoid damage if return the analyzer back to manufacturer for repairing. If users do not use the original packaging or other more efficient transport protection, the resulting property damage shall be borne by the users themselves.

8.3 Marks

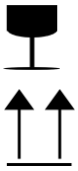
1) Marks on the analyzer:

: Biohazard

: During the working process, must not touch any moving parts of the analyzer.

DC12: Host DC 12 V input

2) Marks on the outer packaging:



Fragile

Upward

Rain-proof

Sun block

8.4 Safety Operation

Operators should be familiar with “Laboratory Biosafety Manual” or hospital related biosecurity regulations. Generally, the operator needs to touch specimens or reagents directly, the operators must wear gowns, surgical masks and medical rubber gloves when operating. Never operate with bare hands directly. The samples been used should dispose, can not be retained.

The power should be cut off before maintenance, move or repair, and then do disinfection disposal for analyzer or components(With 20 mL/L Naclo solution (Contains 5% available chlorine)). Disinfection personnel must wear gowns, surgical masks, medical rubber gloves and eye protection.

All the disinfection operating should be recorded.

When using the analyzer, need to conform to the requirements described in the chapter 3 and attentions described in chapter 8. Otherwise, the built-in security features of the analyzer might cause electrical, mechanical or biological hazards.

9 Troubleshooting

Symptoms	Probable Causes	Recommended Remedial/Corrective Measures
Noting happens; Analyzer does not show any sign of functioning.	Power failure.	Check if the wall outlet is alive.
	Poor connection between the power adapter and the power cable.	Remove the power cable (connecting the SMPS to the analyzer) and reconnect firmly.
	Main switch is "Off".	Turn the main switch "On".
Turn on, only the screen displays.	Printer cable error.	Call HIGHTOP’s Technical Services.
	Card holder cable error.	

"Test Run" over but no result returned .	Excessive computational load or computational abnormality.	Wait till the computation is finished. Turn the power 'Off' and turn it "On" again.
"Test Card Holder" does not protrude out as and when required.	Mechanical failure (Buzzing noise) .	Call HIGHTOP's Technical Services.
	Incorrect connect to computer due to choosing Bluetooth or Ethernet or dropped, analyzer is in a waiting status.	Set the connection mode to serial(COM).
"Printer" does not print.	No printing paper(it will run out when red paper appears).	Install new printing paper.
	Setting of "Printing" turns off.	Turn on the printer in "Print ON" - "Settings".
	Data from analyzer passed to the printer is blocked.	Remove the power cable, wait for 2 minutes.
Without Barcode or Without Test Card.	No bar code or printing is not clear or the printing position is not centered enough or the front blank area over 5mm that cannot be properly scanned.	1 Under "Singe Step Mode", re-insert the test card or using a new test card. 2 Under "Series Mode", analyzer will print the wrong Sample ID, and then re-test the sample after all testing complete.
Barcode Match failed.		
Insert ID Chip.	"Lot Number" of the "Test Card" does not match with that of the "ID Chip".	Check whether "Test Card" and the "ID Chip" are matching with each other.
	No "ID Chip" inserted in the "ID Chip Port".	Insert a proper "ID Chip" in the 'ID Chip Port'.
Barcode and Test Card cannot be tested.	Light source of test card has been decayed to the analyzer unacceptable.	Call HIGHTOP's Technical Services.
Cannot print the summarized report.	For the same sample, the Sample ID should be revised to the same in different test item.	Set the same Sample ID in different test item for same sample.
No result returned when "Search".	Report does not store in the analyzer.	Choose "Analyzer Storage" for report by computer.
Printing Tips: Measure or calculate overtime, re-test it after confirm.	Results calculating overtime.	1 Under "Singe Step Mode", re-test this sample, Sample ID keeps the same. 2 Under "Series Mode", re-test the sample after all testing complete.
Printing Tips: No reaction line or it is too weak.	Adding too less amount of sample or test card invalid .	
Thermal printer cannot print clearly.	Printing depth is too low.	Set the "depth" - "Printing" - "Settings".

	Effects of printing paper is poor.	Change to better printing paper.
Screen display appears garbled or white screen or the analyzer automatically restarts frequently.	Caused by electromagnetic interference.	Restart the analyzer .

10 Storage and Transport

10.1 Storage

In order to store the used analyzer for a long time, it should be disinfected. The packaged analyzer should be stored at 0℃～40℃, relative humidity no more than 85%, no corrosive gas and ventilated room, can not be stored together with poisonous, harmful or corrosive substances.

10.2 Transportation

In order to transport the used analyzer, disinfecting firstly and then pack it with original packaging or the materials same to original packaging. In the transportation process, can not be transported together with poisonous, harmful or corrosive substances. If you entrust a third party to transport, transportation requirements and responsibilities should be added in the contract.

11 Information of Product and Manufacturer

MR International Healthcare Technology Co.,Ltd. declares that warranty is available only in the condition that uses fully comply with the using guidance published by the manufacturer, MR is not responsible for other indirect or consequential damages.

Product Name: Fluorescence Immunoassay Quantitative Analyzer
Model: HTY-100
ADD: Unit 83 on 3rd Floor,Yau Lee Center No.45,Hoi Yuen Road,Kwun Tong Kowloon,HK
Tel: +86-431-81317781 / +86-431-81317079
E-mail:sales@mr-healthcare.com
Website:http://www.mr-healthcare.com

Disinfection Record

Date	Item	Disinfection Content(Component)	Operator	Inspector

Products Transportation, Carry Record

Transport date	Origin	Destination	Transport way	Carry company	Carrier	Arrival Status	Acceptor	Acceptance conclusion

Notice: Arrival status: intact, damaged, seriously damaged.

Acceptance conclusion: Put into use, return of goods, scrapped, pending.