ALLTEST^{TM} LF Reader

User Manual

HANGZHOU ALLTEST BIOTECH CO., LTD

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1. Intended Use

AllTest^{TM} LF Reader is designed to provide digital test results of test units based on Lateral Flow Immunoassay. The reader is based on optical imaging technology. The results can be qualitative, semi-quantitative or quantitative based on the specific test units used. This reader should be used solely for the purpose of reading test results obtained with Lateral Flow-based Rapid Tests manufactured by AllTest as per Package insert provided with specific test kits used.

2. Application

AllTest^{TM} LF Reader is intended for the use of reading rapid tests manufactured by Hangzhou AllTest Biotech Co., Ltd. It is not designed to work with rapid tests manufactured by other manufacturers. The results obtained by using this equipment with test units manufactured by other manufacturers cannot be reliable.

Note: AllTest^{TM} LF reader can only read and provide test results for tests that have been developed for use on such equipment. AllTest has a range of products that may not be compatible with this equipment. Please refer to specific package insert, before using such tests with this reader.

3. Product and Model Type

3.1.   **Product name:** AllTest^{TM} LF Reader
3.2.   **Model type:** Rev.001

4. Composition and Principle

4.1. Composition

AllTest^{TM} LF Reader is composed of Image Capture and Processing Systems, Main Board, Digital Storage, Digital Information Processing & Management System. It also includes five cartridges, one single cassette/dipstick cartridge, three panel cartridges, one multi-drug cassette cartridge, as well as one calibration cassette.

4.2. Principle

AllTest^{TM} LF Reader works on the principle of Optical Imaging. When exposed to controlled lighting, the image capturing and processing system installed in the reader capture the optical signals emitted by test lines. These optical signals are then transformed into electronic signals. Based on these electronic signals combined with a complex algorithm, the final result is then presented.
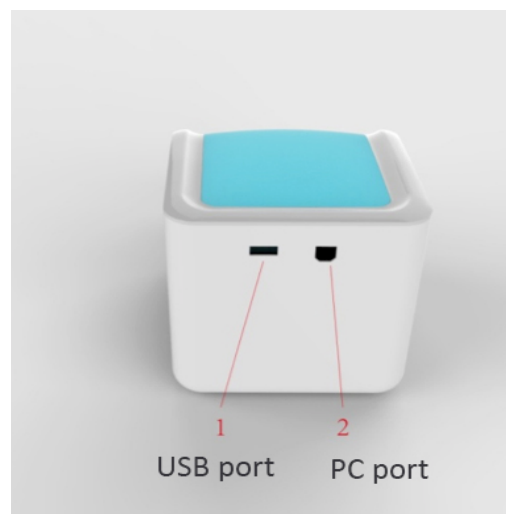
5. External View

5.1. AllTest^{TM} LF Reader front view (Fig.1)
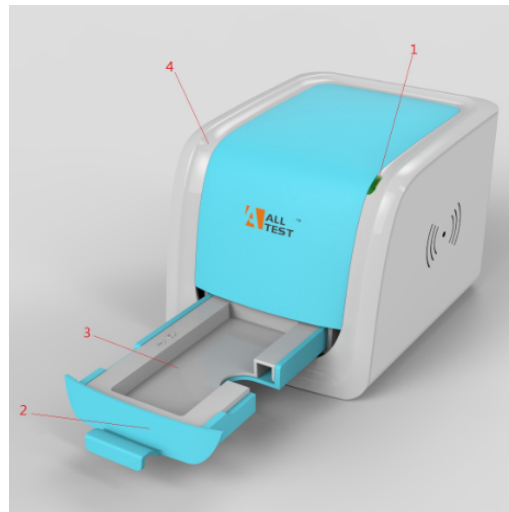
Fig.1 AllTest^{TM} LF Reader (Front view)

1.Indicator Lamp   2.Cartridge Tray   3.Cartridge   4. Plastic housing

5.2. AllTest^{TM} LF Reader rear view (Fig.2)

Fig.2 AllTest^{TM} LF Reader (Rear view)

1.USB port   2.PC port

5.3. Equipment type

- **Equipment type:** Laboratory Equipment

- **Device class:** Portable Device

- **Power Source:** DC 5V

5.4. Technical specifications

The reader is used to read and export results of rapid lateral flow tests for immunological assays.

- Methodology   : Optical Imaging
- Test formats   : Cassette, Dipstick and Panel

- Measurement : Qualitative, semi-quantitative, quantitative
- Read Time : 10 seconds
- Test Time : Ref: Package insert
- Specimen : Ref: Package insert
- Power Source : DC 5V
- Internal Memory : 8GB
- Dimensions : 155 mm× 119 mm× 111 mm
- Weight : 440g
- OS : Windows-based proprietary program
- Storage Conditions : -10-60℃
- Operating Conditions : 15-30℃
- Interface Connections : USB2.0

6. Installation

6.1. Checklist upon opening the box

6.1.1.　Check before opening the box:

Before opening the box, check the packaging is in good condition and box was not damaged during transportation.

6.1.2.　Check after opening the box:

① Open the box carefully, check the contents according to Appendix I (Page 20) to ensure it is complete.

② Examine the reader, connecting cable and cartridges to see whether they are in good condition. If you find any defects, please contact the manufacturer or your local agent.

Note: Please keep the reader's original box and packing materials for any future shipping/reference purpose.

6.2. Environmental requirement

- Surrounding temperature: 15~30℃;
- Relative Humidity：≤80%RH；
- *Avoid strong magnetic field, vibration, shock, corrosive gas, direct sunlight, high humidity，and high temperature in work area, where the reader is placed for operation.*

6.3. Placement

6.3.1.　Put the reader on the working platform around 20 cm away from the computer.

6.3.2.　Insert the connecting cable to the USB port on the back of the reader's interface. Connect the other end of Connector's cable to the computer's USB port through which the reader would be operated.

7. Directions for Use

Please read the instructions carefully before use, and be familiar with the proper operation method. This system works only with Windows-based computers. Connecting this system with computers operating on other systems such as Apple or Linux are not compatible with this equipment.

WARNING: Inappropriate use, not in accordance with the user manual may result in safety hazards apart from providing inaccurate results.

7.1 Start the program

7.1.1 Switch on the computer. Open "My computer". A list of all drives would pop up on the screen including removable drives. In this window, you can see "**LF READER** [LF READER (E:) 7.43 GB 可用 , 共 7.48 GB] ".

Left-click twice on the icon "**LF READER** ", upon left clicking twice on the icon " **LF reader** [LF reader]

", you can see "Login Window **(Ref: Fig.3)**". Type in User name and Password. Default User name and password is "admin". You can change this later. Left-click **Login** to start the operation.
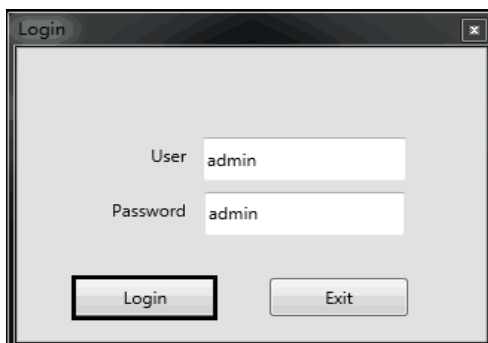
Fig.3 Screen view of Login window

7.1.2 Switch language

Click **Settings➜ Language** to change the language **(Ref: Fig.4)**. Default language is English. It can be customized to another language.
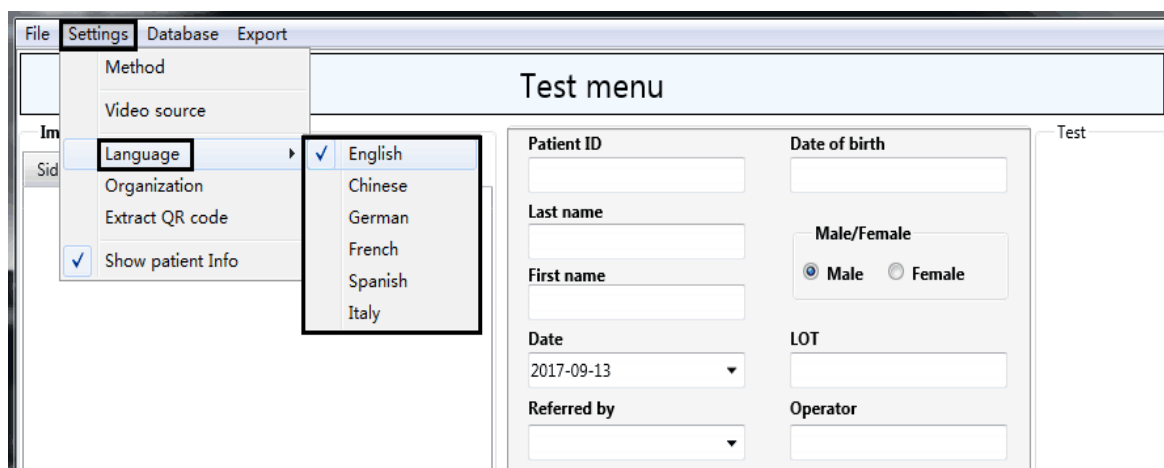
Fig.4 Screen view of Language selection

7.1.3 User management

Click **File➜Users (Ref: Fig.5)**. A Window will pop up, prompting you to enter Name and Password.
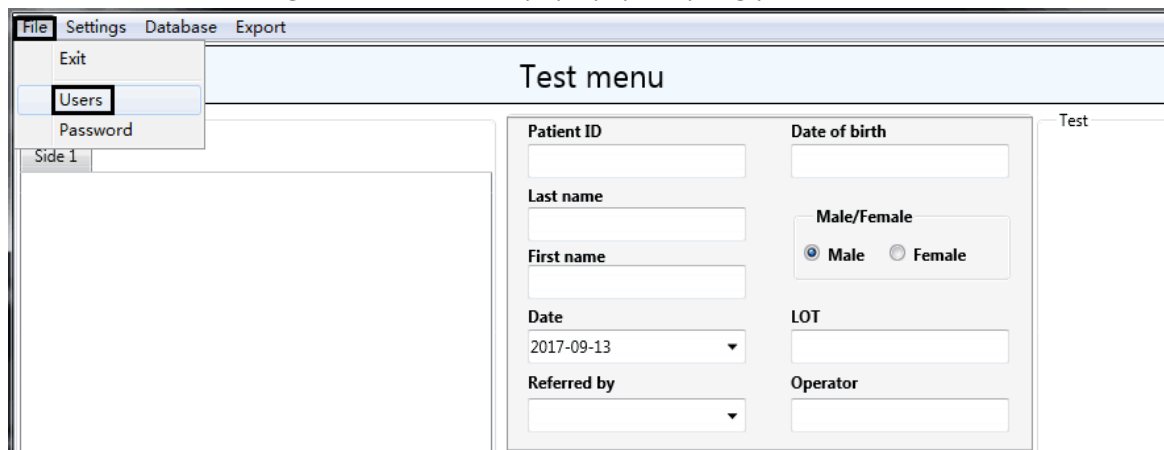
Fig.5 Screen view of file-users

A: To create user and password, **click"+"➔ type in user and password➔ click " √ "** to authorize the user. The new user is authorized from next login with new user ID and password **(Ref: Fig.6)**.

B: To delete user name, select target user and click "-". The selected user would be de-authorized in the next login attempt **(Ref: Fig.7)**.
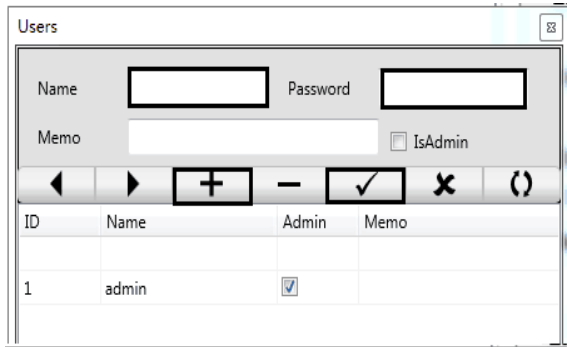
Fig.6 Screen view to create user
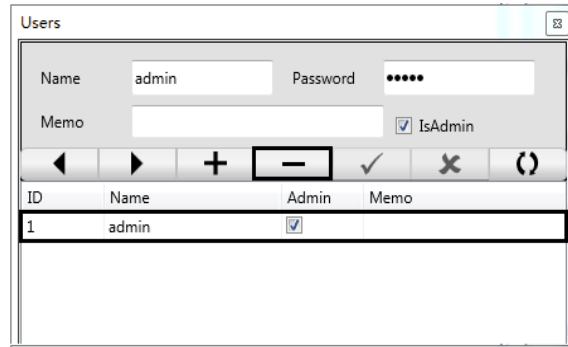
**Fig.7 Screen view to de-authorize user**

7.1.4 System calibration

Step1: Click **Test Menu** in the reading window **(Ref: Fig.8)**.

Step2: Select **System calibration (Ref: Fig.9)**.

Step3: Place the Cartridge with calibration cassette on the Cartridge tray and move the tray into the reader's Reading Area.

Step4: Click **Test Analyte** to obtain the test image. The main reading window of the software will appear with the image of the tests and results **(Ref: Fig.10)**.
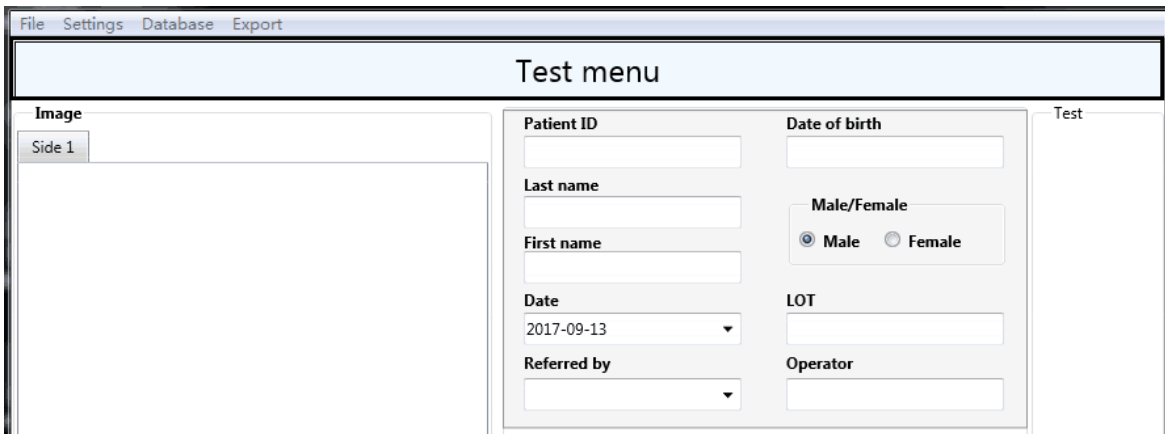
Fig.8 Screen view of test menu
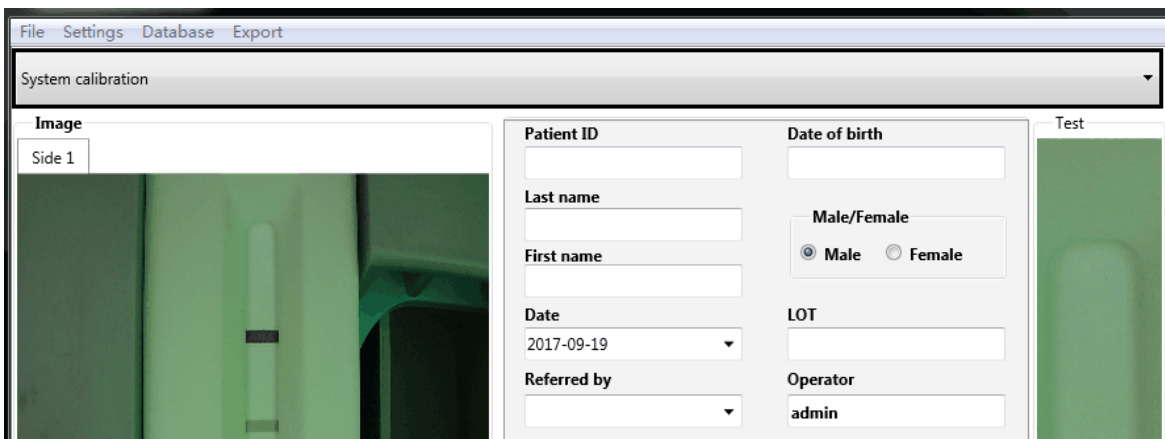
Fig.9 Screen view of system calibration column

5
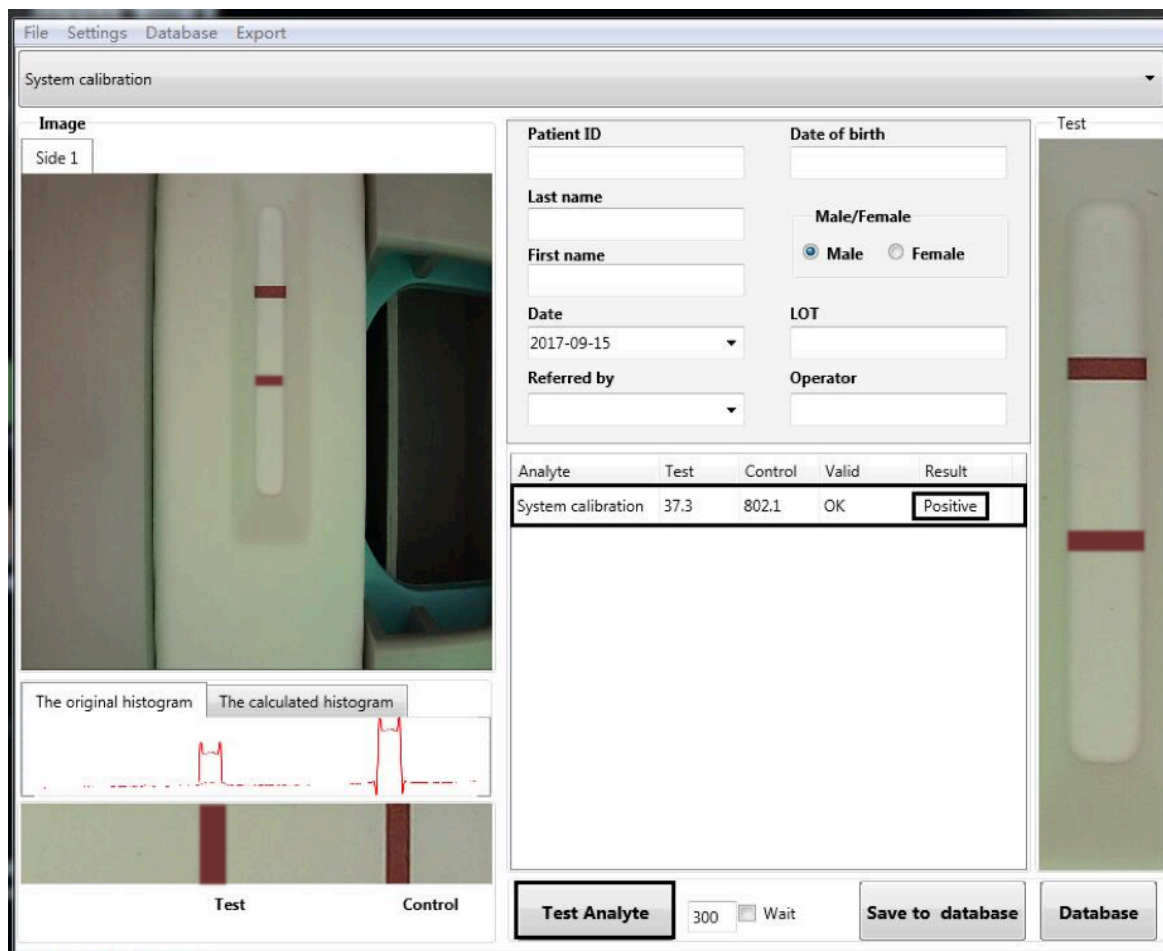
Fig.10 Screen view of test calibration cassette

7.1.4.1 Interpretation of result

Positive result means system running is normal, you can perform a test.

7.2 Performing a test

7.2.1 Test programming

Method 1: Extract QR code from QR Code Card provided in the AllTest Rapid test kit.

Step 1: Place QR code Card in the cartridge tray **(Ref: Fig.11)**

Step 2: Click **Settings➔Extract QR code (Ref: Fig.12)**.

Step 3: Click **Extract QR➔Yes➔Save** to install the test program associated with the specific test kit **(Ref: Fig.13)**.

Note: Use only QR code Cards provided inside the test kits for which the tests are being programmed to ensure correct test program.

Fig.11 Place QR code Card in the cartridge tray and then insert the tray into the Reading Area
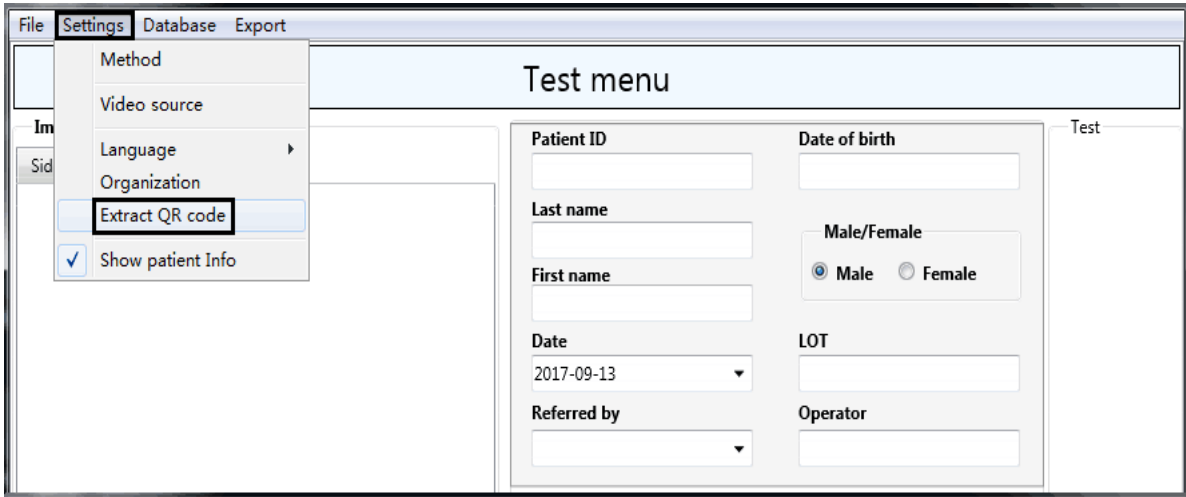
Fig.12 Screen view of Settings-Extract QR code
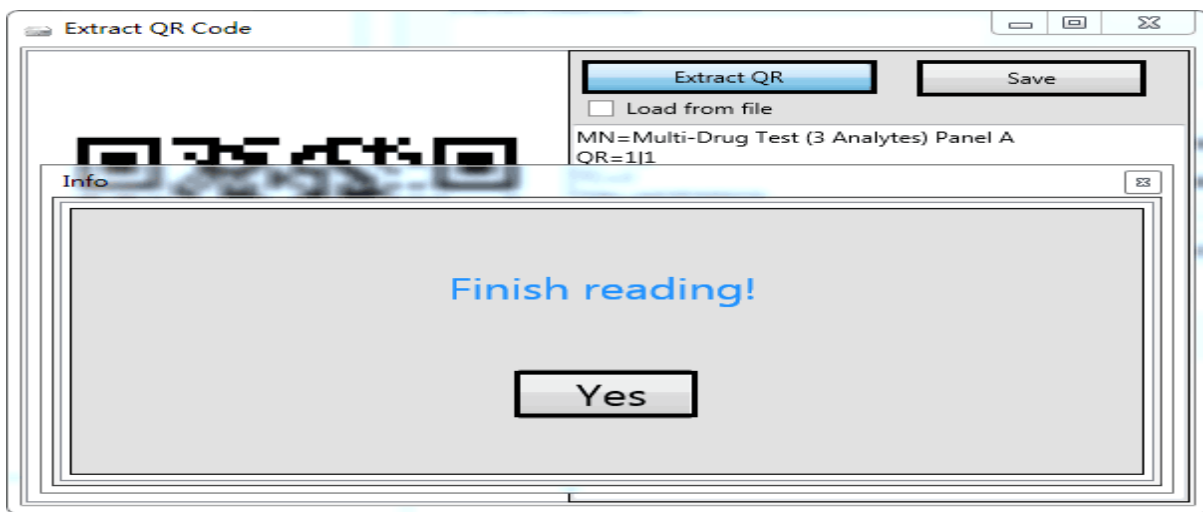
Fig.13 Screen view of Extracting QR code from QR Code Card

Method 2: Extract QR code from electronic file specific to the Kit.

Step 1: Click **Settings➔ Extract QR code (Ref: Fig.12)**.

Step 2: Click **Load from File➔Extract QR➔Yes➔Save** to install test programs associated with the specific test kit **(Ref: Fig.14)**.
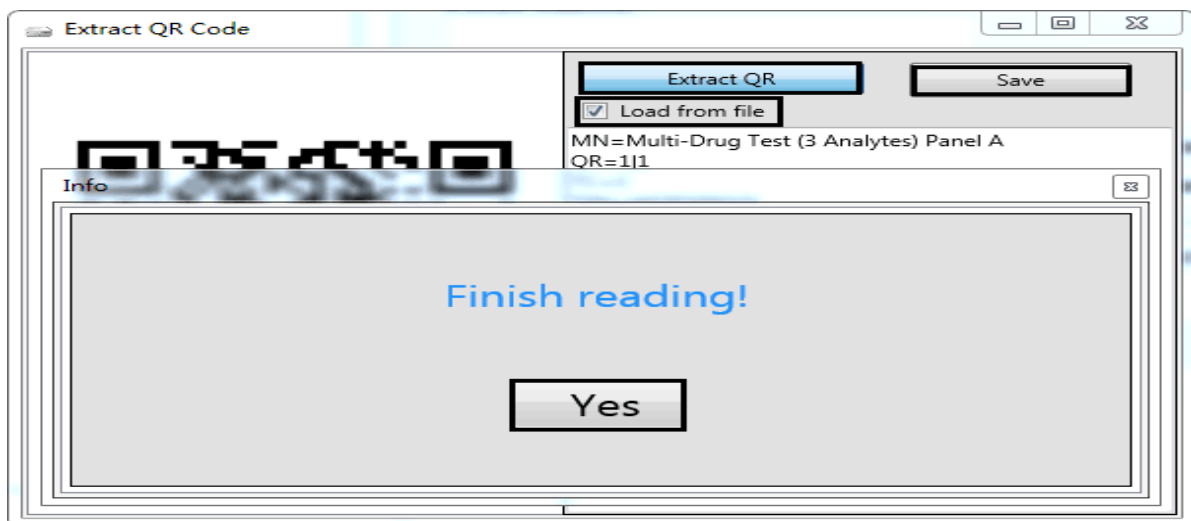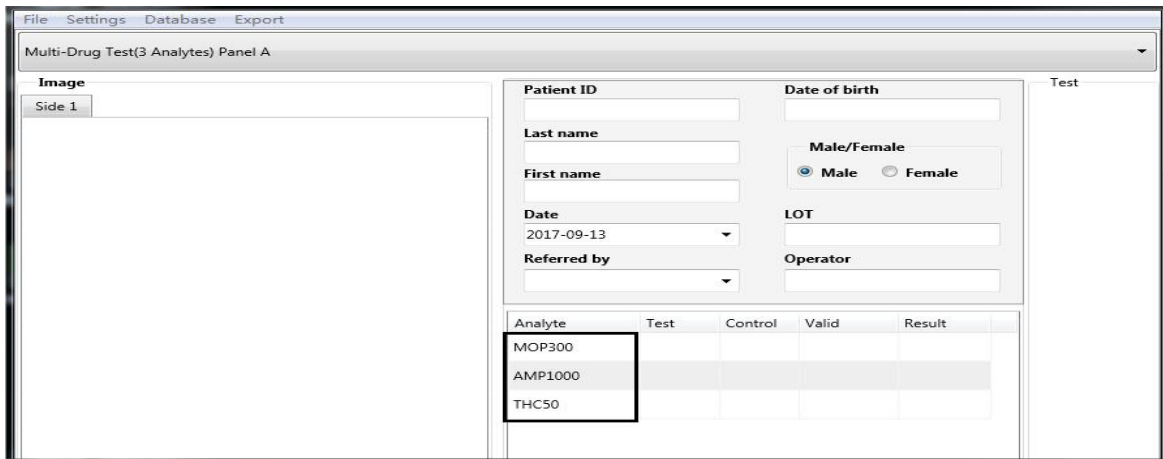

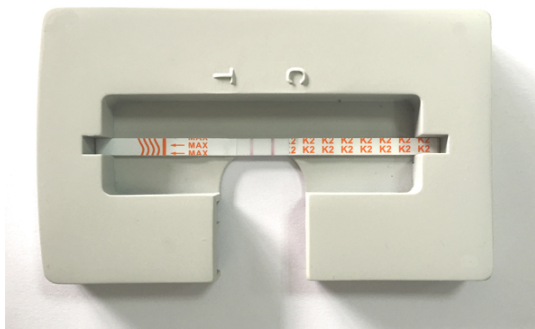**Fig.14 Screen view of Extracting QR code from electronic file**

Fig.15 Screen view after extracting QR code

7.1.5 Insert test unit to the cartridge

7.1.5.1 Dipstick

Place the dipstick in the cartridge with the test side facing upwards and sample application area towards the user as it is shown in the **Fig.16**

**Fig.16 The placement of test strip in the cartridge**

7.1.5.2 Cassette

Place the Cassette in the cartridge with the test side facing upwards and sample application area towards the user as it is shown in the **Fig.17 and Fig.18**

Fig.17 The placement of test cassette in the cartridge
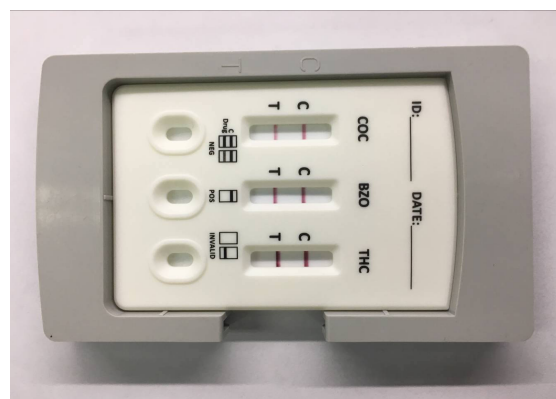
Fig.18 The placement of multi-analytes test cassette in the cartridge

7.1.5.3 Panel

Place the Test Panel in the cartridge with the test side facing upwards and sample application area towards the user as it is shown in the **Fig.19, Fig.20 and Fig.21**.
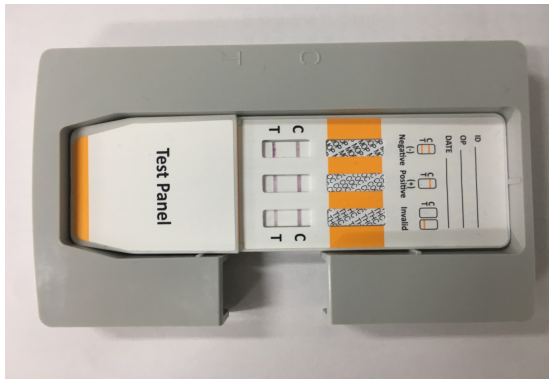
Fig.19 The placement of three in one test panel in cartridge

Fig.20 The placement of four in one test panel in cartridge

Fig.21 The placement of twelve in one test panel in cartridge

7.4 Fill in relevant information

Fill in patient information in the corresponding fields in the patient information window **(Ref: Fig.22)**.
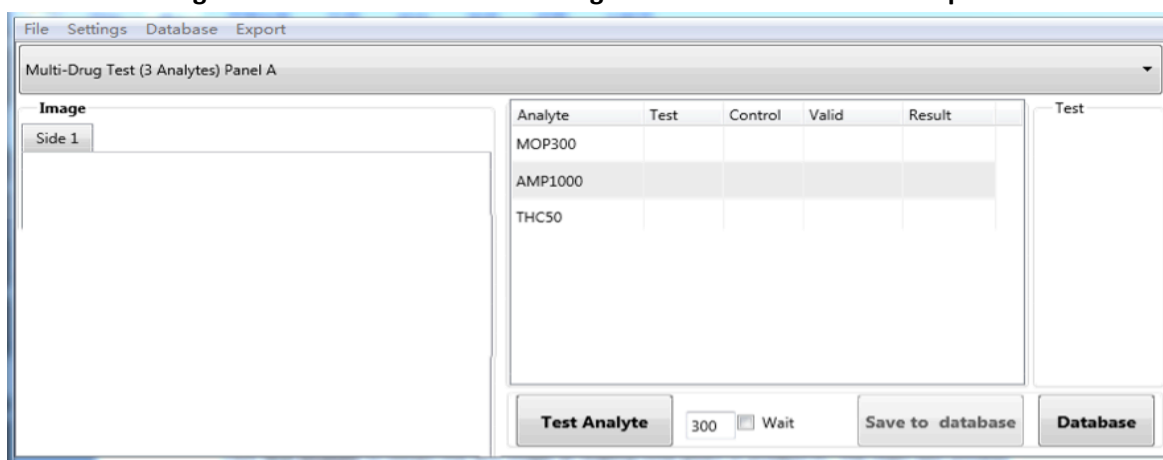

Fig.22 Screen view of Main reading window with Patient information

If you wish to exclude patient information from view and commands, click **Settings➔Show patient info (Ref: Fig.23 and Fig.24)** and de-select this option.
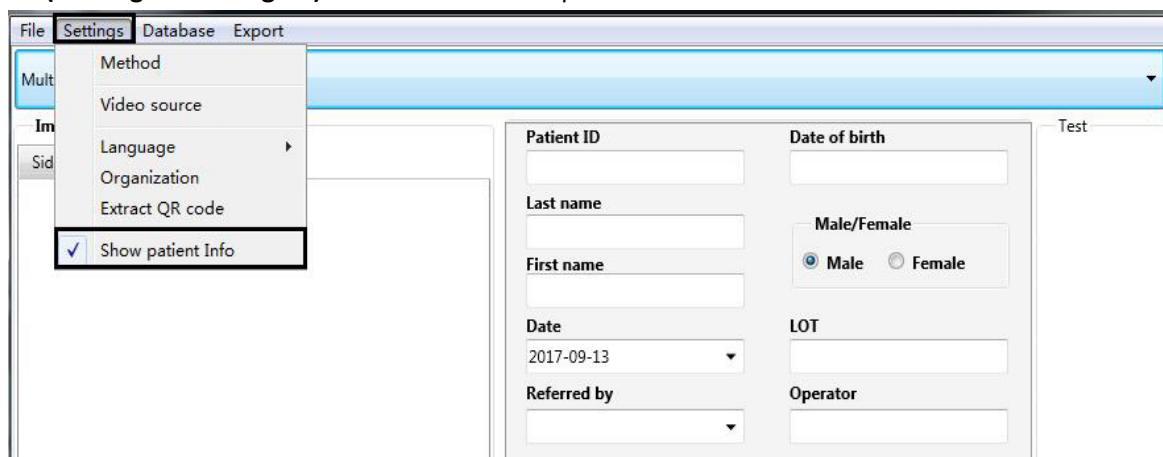
Fig.23 Screen view of Main Reading Window with Patient Info option

Fig.24 Screen view of Main Reading window without patient information

7.5 Test analyte

Click **Test Analyte** to obtain the test image at reading time given in product package insert. The main reading window of the software will appear with the image of the tests and results **(Ref: Fig.25)**.
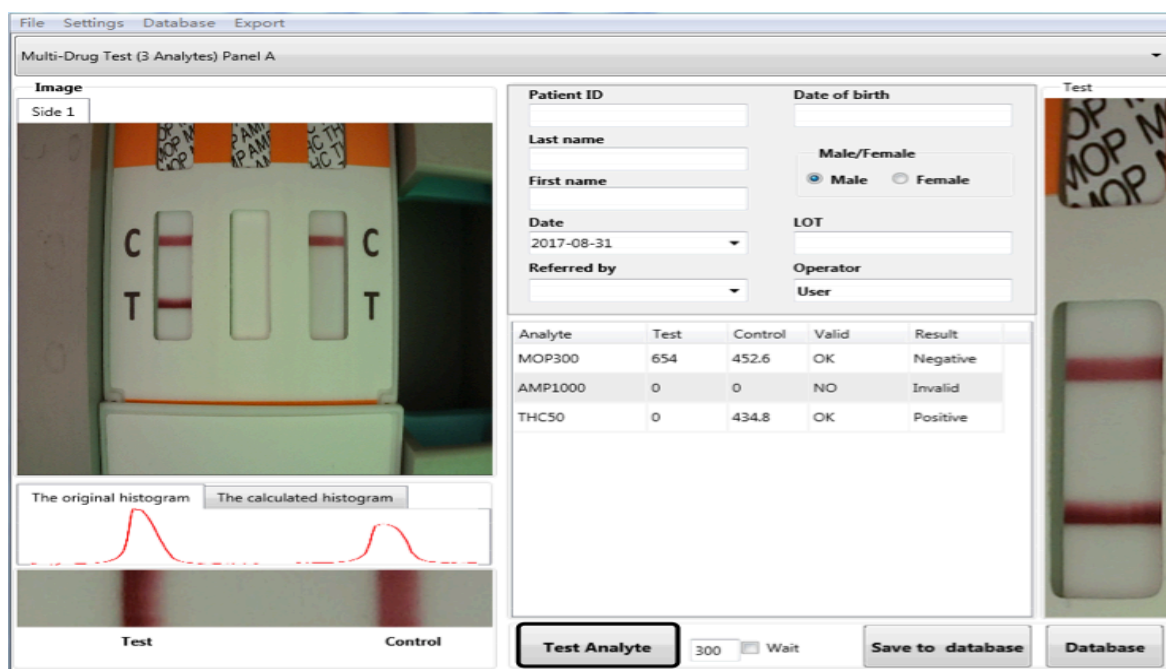
Fig.25 Screen view of test image and results

Note: If you are performing tests with **multi-drug test panel having test strips on both sides**, there will be a dialog window popping up as below **(Ref: Fig.26).** After reading test results on one side, you need to open the cartridge and flip the test panel, then close the cartridge and click **Yes** on the pop-up window. The reader will measure the test results on the other side.
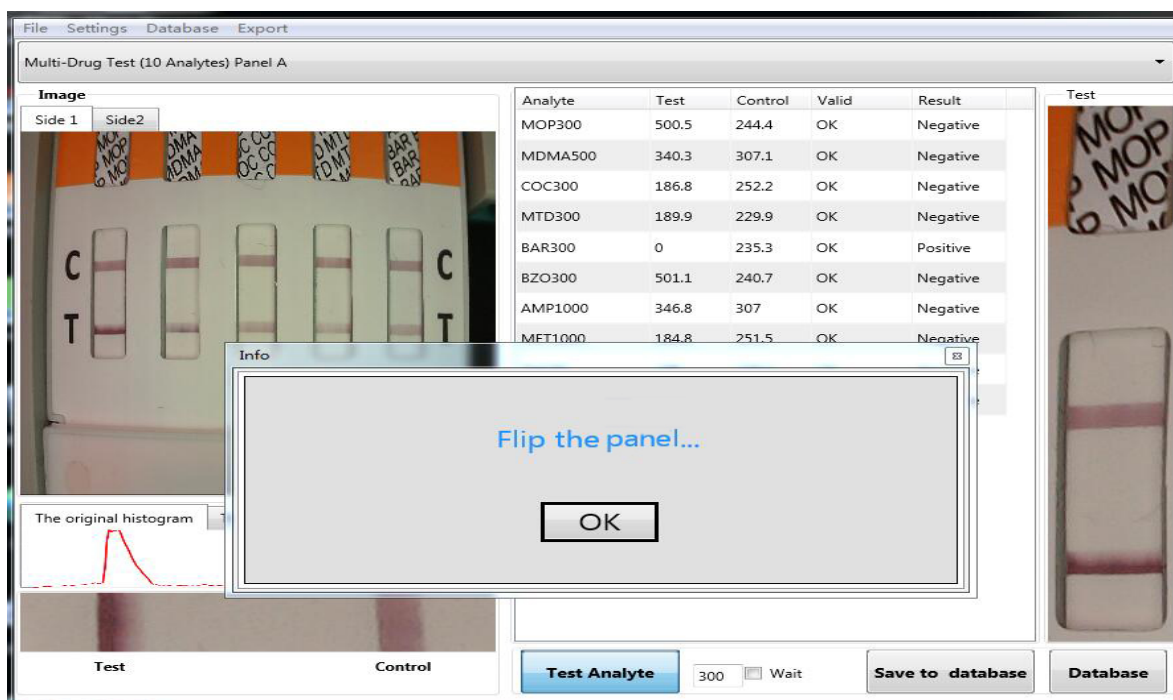
Fig.26 Screen view of test image with strips on both sides of test panel

7.5.1 Interpretation of results

Results will be obtained in the reading window. Some examples are given below with some analytes. However, they are just for reference. The results obtained would be as per analyte test. Examples are to be used for reference only on how the results would appear **(Ref: Fig.27, Fig.28, Fig.29, Fig.30).**

Fig.27 Example: Multi-drug test results MOP300 Negative/AMP1000 Invalid/THC50 Positive result
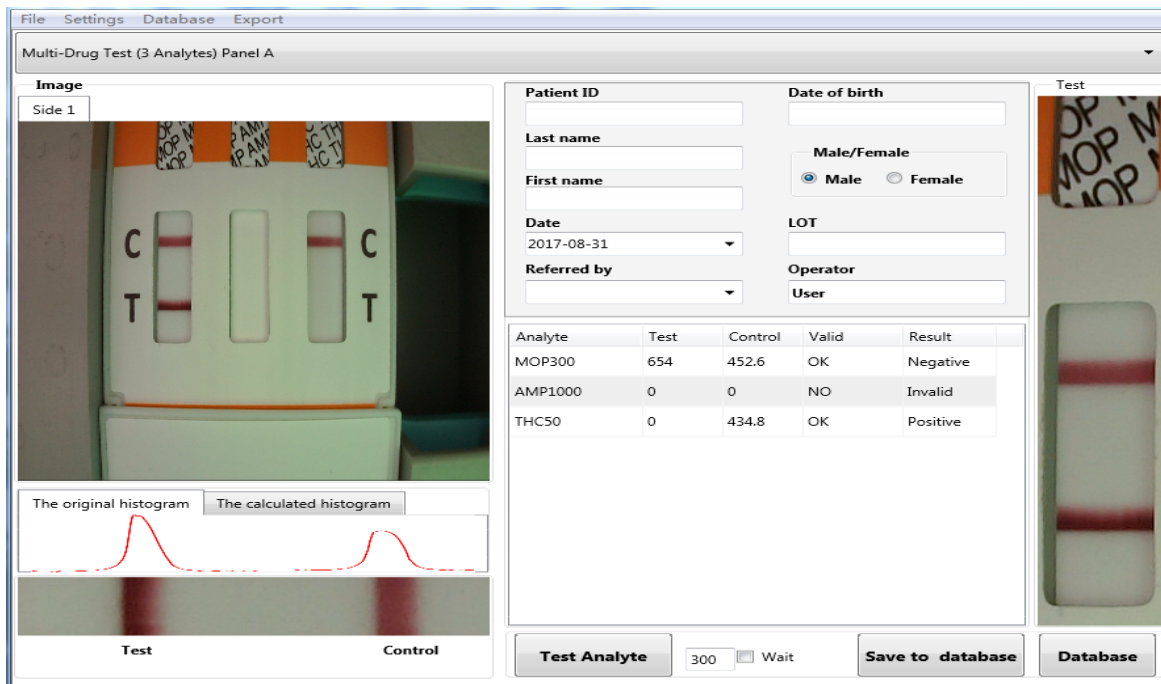
Fig.28 Example: Cardiac Troponin I (cTnI) Positive Result

Analyte	Test	Control	Valid	Result
Troponin I	19.563ng/ml	572.9	OK	Positive

Fig.29 Example: Cardiac Troponin I (cTnI) Negative Result

Analyte	Test	Control	Valid	Result
Troponin I	0ng/ml	567.5	OK	Negative

Fig.30 Example: Cardiac Troponin I (cTnI) Invalid Result

| Analyte	Test	Control	Valid	Result
Troponin I	77.16ng/ml	0	OK	Invalid

7.5.3 Save the test results

For saving the test results in the database, click **Save to database (Ref: Fig.31)**.
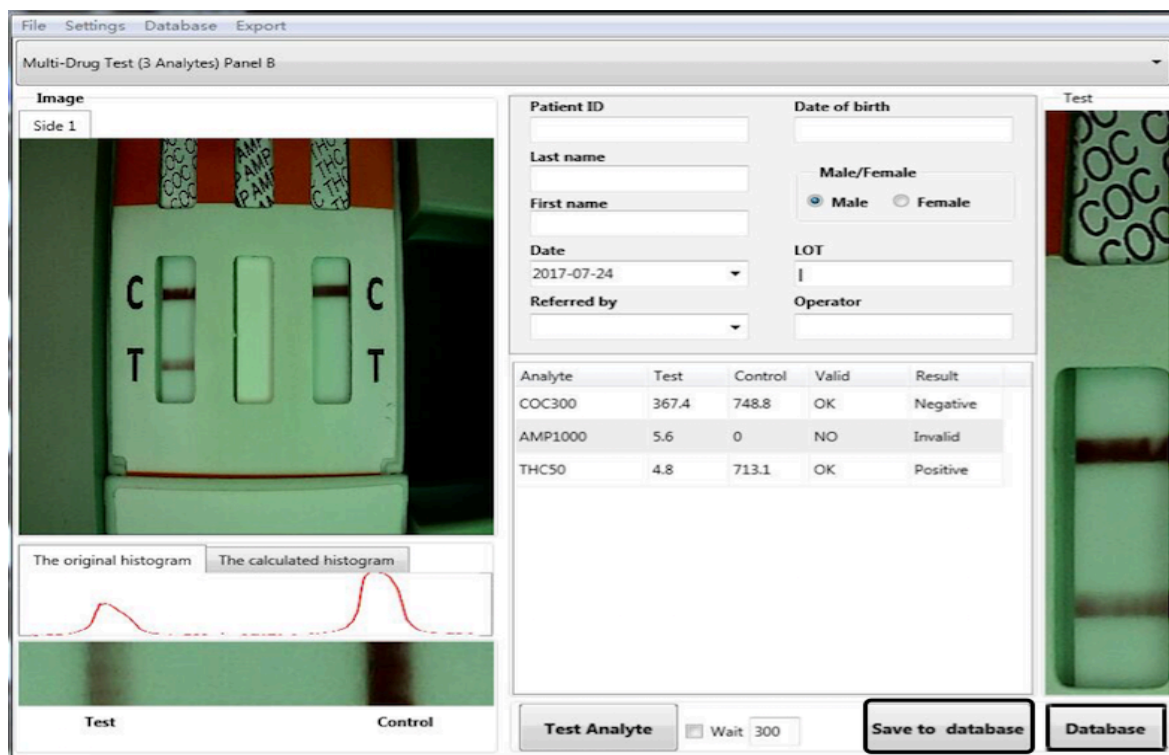
Fig.31 Screen view of Test results with option to save to database

7.5.4 Review database

Click **Database** on the menu screen **(Ref: Fig.31)**. You will see database window. You can print test report, or get report in PDF form for printing later and also export single data or all database to Excel report in database window by clicking appropriate tabs, such as Print, PDF, Export to Excel or Export database to Excel. **(Ref: Fig.32)**
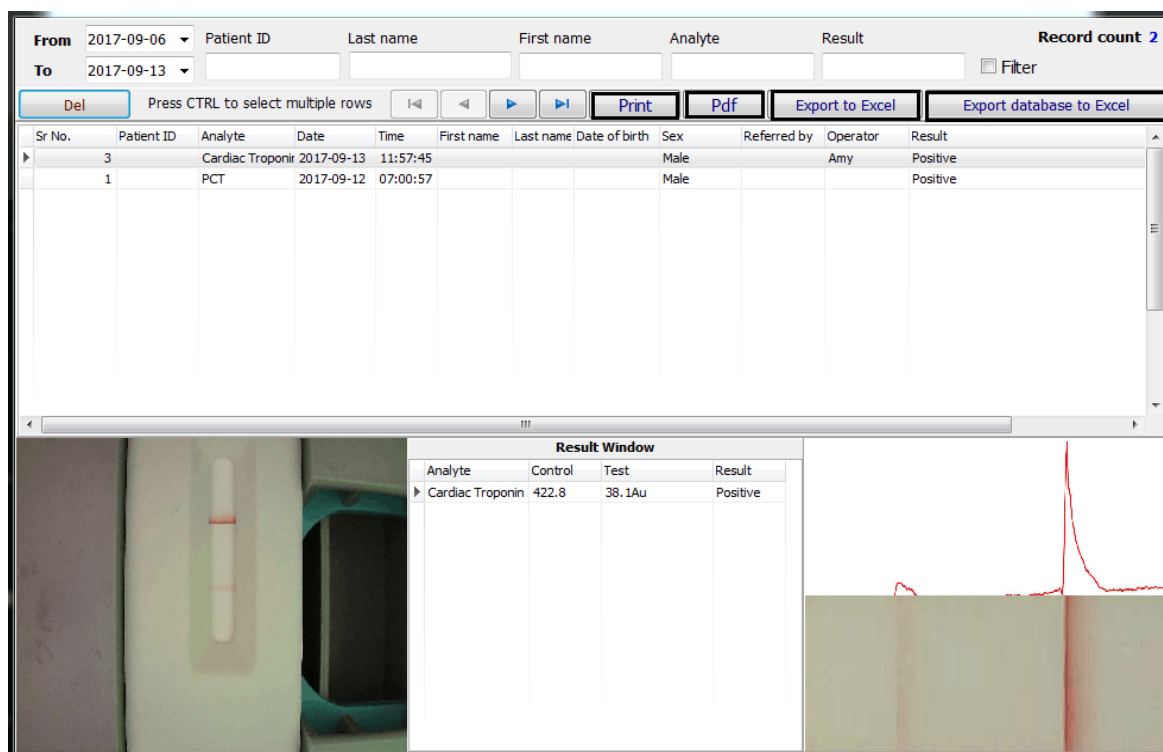
Fig.32 Screen view of database window

7.5.5 Delete data

If you want to delete data, please select the row to be deleted. If you want to delete multiple rows, press **Ctrl** and select multiple rows and click **Del** to delete the data **(Ref: Fig.33)**
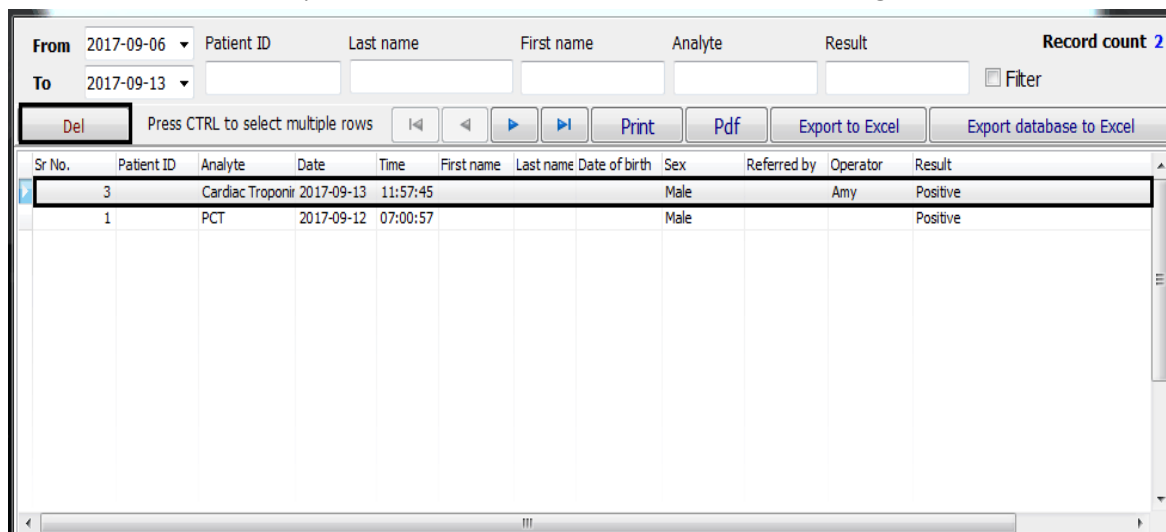

Fig.33 Screen view of data deletion

7.5.6 Filter data

Filter option helps you quickly arrange and view the data based on certain basis, such as Analyte or a person. This helps in finding all the tests performed on a person by LF Reader on a single screen. On the database window, fill in your requests in the search column, and click **Filter** to get the results you defined. **(Ref: Fig.34)**
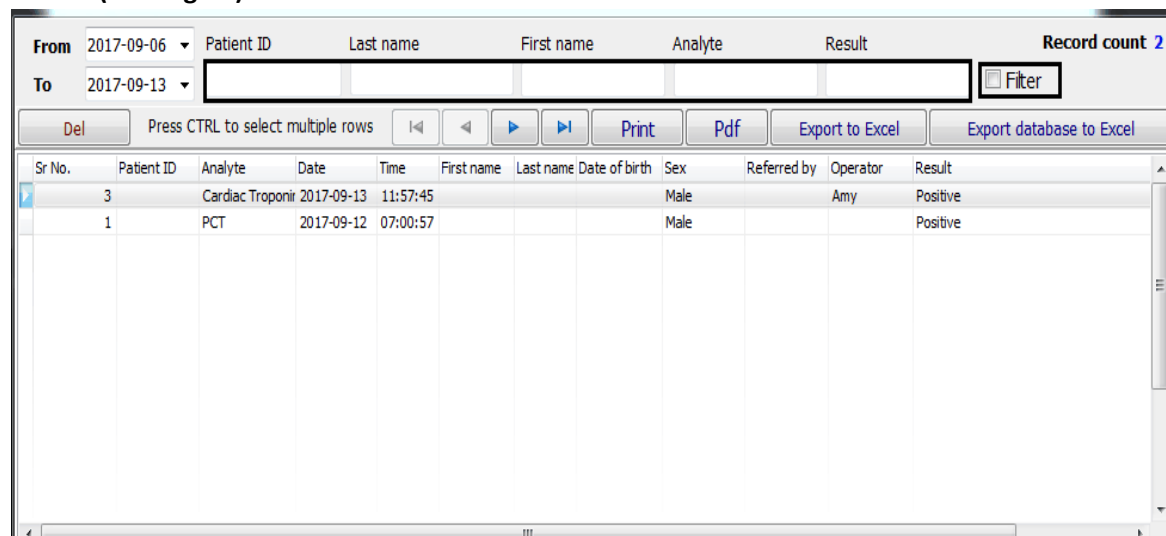

Fig.34 Screen view of option to filter the results

7.5.7 Export the test results

① Export the test results to Excel table.

A: On database window, click **Export database to excel** to export all the data to excel **(Ref: Fig.35)**.

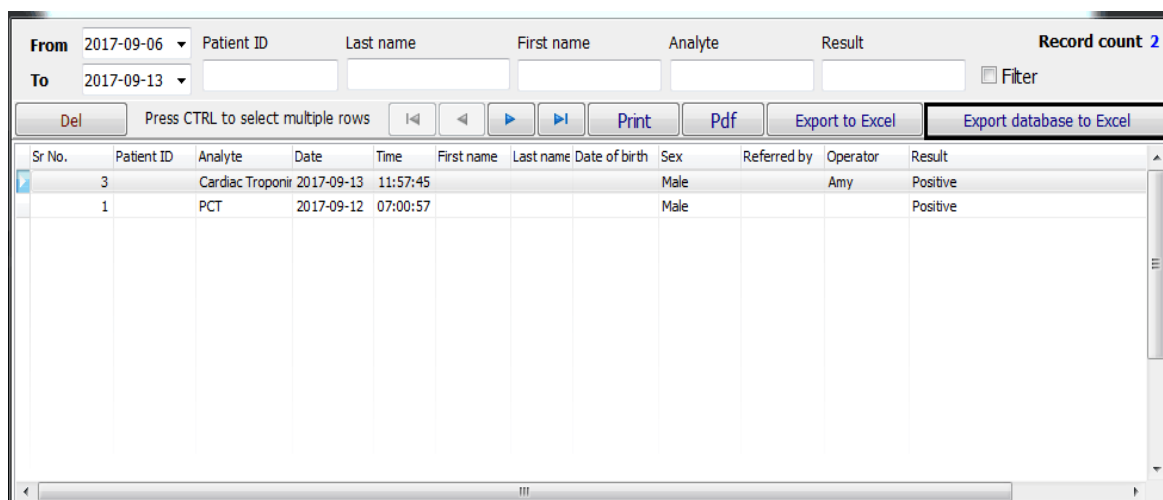B: On database window, click **Export to excel** to export the items you selected **(Ref: Fig.36)**.

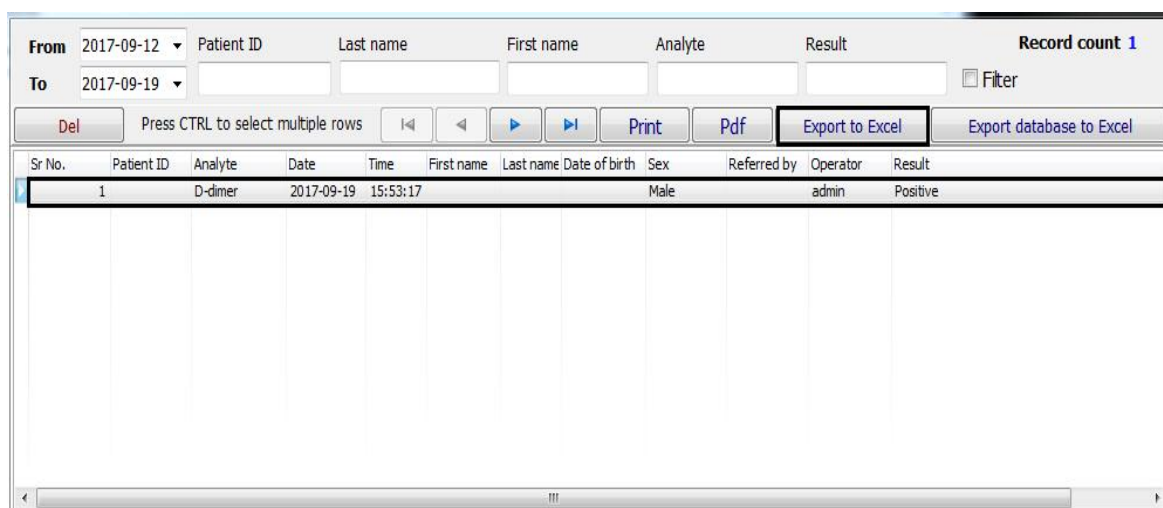**Fig.35 Screen view of selection of export database to excel**

Fig.36 Screen view of selection of export to excel

② Export the test results to PDF file.

On the database window, click **PDF** to export the result to PDF **(Ref: Fig.37)**.
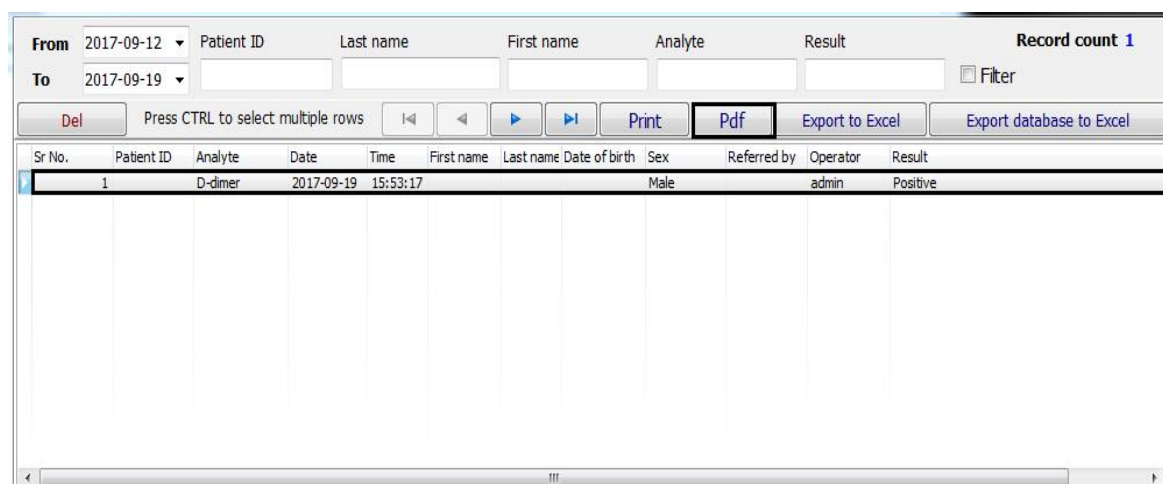

Fig.37 Screen view of Selection of PDF to see results in PDF format

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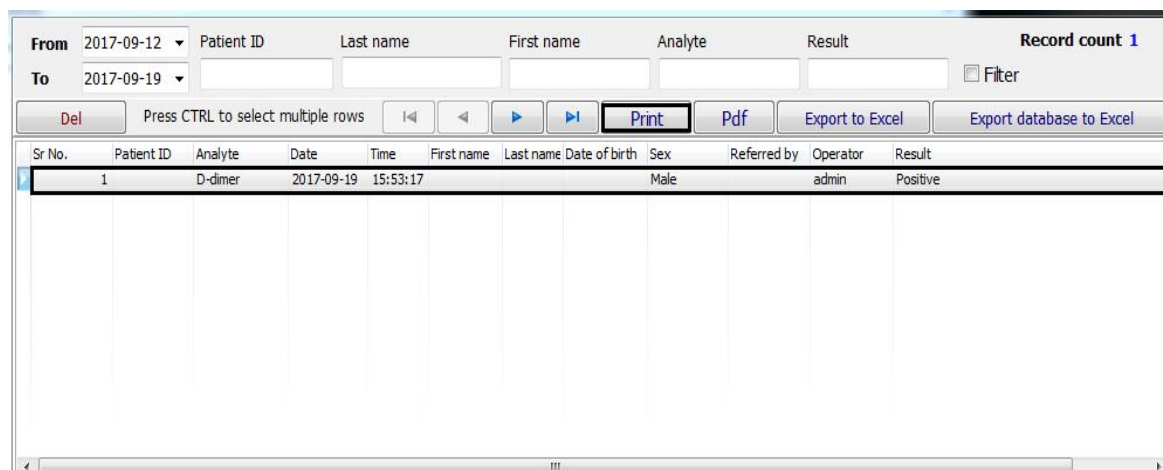**7.6 Print data**

Click **Print** on the Database window.

Fig.38 Screen view of selection of Print command

7.7 Exit the operation

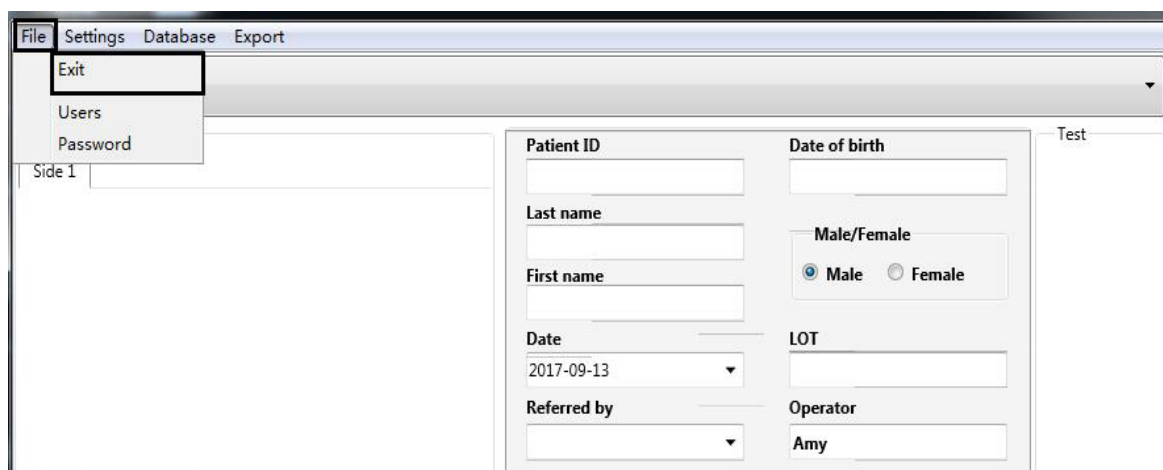Click **File➔ Exit** on the reading window **(Ref: Fig.39)**.

Fig.39 Screen view of Exit option

8. Daily Maintenance and Cleaning

Note: Reader's maintenance needs to be carried out by trained and qualified personnel

8.1. Maintenance

8.1.1.   To ensure the stability and accuracy of the reader, any interference to the optical system, including strong light near the reader should be avoided.

8.1.2.   Proper care should be taken such as no fluid, dust or other exogenous substances entering inside the reader in order to ensure proper functioning.

8.1.3.   **DO NOT** disassemble the reader and **DO NOT** touch optical system

8.2. Daily Cleaning

Wear disposable gloves and use disposable wet wipes and mild detergent to clean surface of reader.

9. Storage Condition

- Temperature: -10℃~60℃
- Relative humidity：≤80%RH
- Barometric pressure：86KPa~106KPa

10. Precautions

- The protection provided by the equipment may be impaired if used in a manner not defined in this user guide.
- Avoid strong magnetic field, vibration, shock, corrosive gas, direct sunlight, excessive humidity or high humidity during storing or operating. Refer to **5.4 Technical Specifications, 6.2 Environmental Requirement** and **9. Storage condition.**
- Put the reader on the working platform around 20cm away from the computer.
- Do not clean the unit with substances such as gasoline; paint thinner, benzene compounds or other organic solvents to avoid any damage to the reader.
- The cartridge must be kept clean. Wipe the cartridge with tissue soaked with fresh water daily.
- Follow all regulations when disposing the unit or its accessories.
- Do not use the reader or the rapid test out of the operating temperature ranges listed below:

  Reader: 15~30℃

  Rapid test: 15~30℃
- Only use QR code card provided along with the products from AllTest. Results obtained by using this equipment with test units manufactured by other manufacturers or with the visual test unit cannot be reliable.
- Do not depend on visual result.
- Strong light may lead to false results.


11. Errors and Warnings

This section provides trouble shooting steps for specific error and warning codes. If the warning or error persists after you have followed the instructions on this manual, contact AllTest Technical Support. Contact numbers can be found at the end of this User Manual.
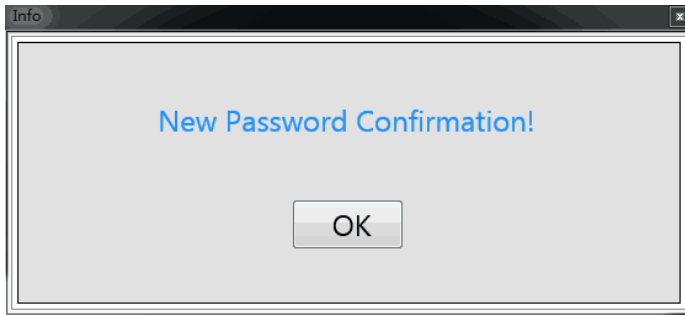
11.1 Errors
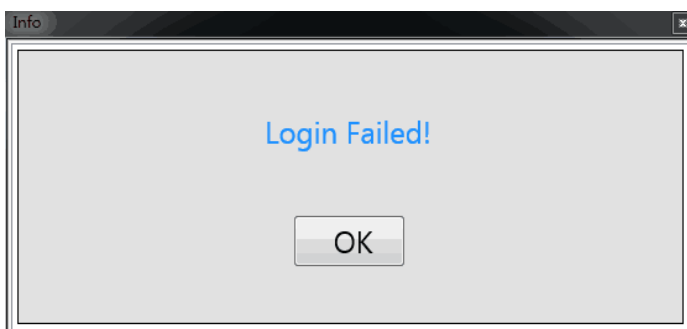
Error: Login failed.

Action: Tap **OK** and enter a correct user ID and password. If the error persists, contact the Admin or contact AllTest Technical Support.
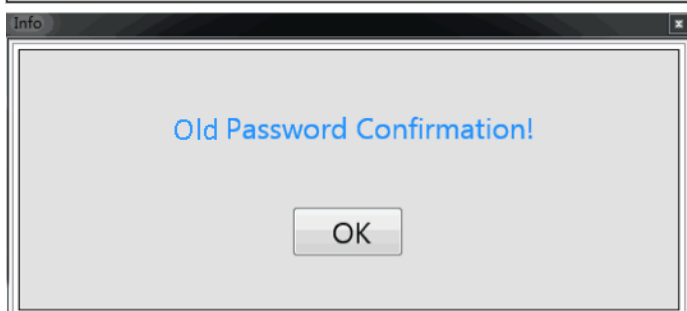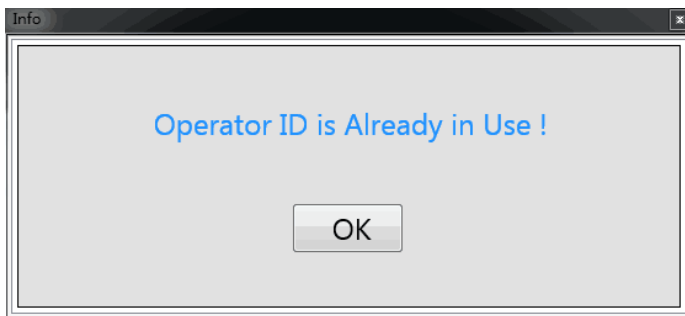

Error: Old Password do not match.

Action: Tap **OK** to try again. Make sure that old passwords are correct. If the error persists, contact the Admin or contact AllTest Technical Support.
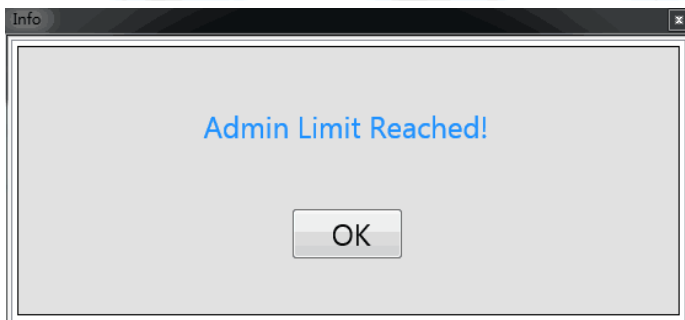
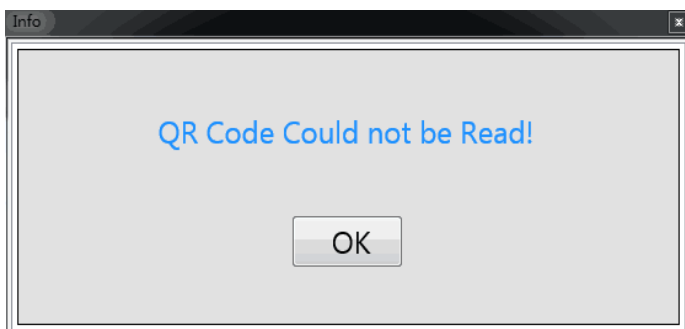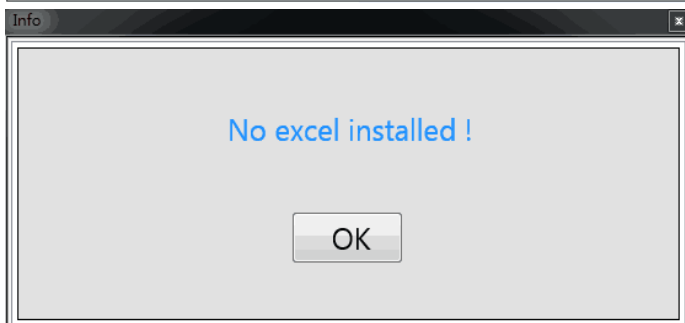|	
Info ☒ New Password Confirmation! OK	**Error**: "New Password" and "New Password Confirmation" do not match. **Action**: Tap **OK** to try again. Make sure that both passwords match. If the error persists, contact the Admin or contact AllTest Technical Support.
Info ☒ Operator ID is Already in Use ! OK	**Error**: Operator ID is already in use. **Action**: Tap **OK** to enter a different User ID. If the error persists, contact the Admin or contact AllTest Technical Support.
Info ☒ Admin Limit Reached! OK	**Error**: Admin cannot be created because the maximum admin limit has been reached. The maximum number of admin is 3. **Action**: Delete obsolete admin to create new admins. If the error persists, contact the Admin or contact AllTest Technical Support.
Info ☒ QR Code Could not be Read! OK	**Error**: QR code could not be read. **Action**: Open cartridge, check QR code card is not obscured, and make sure QR card are from test kits that in consistency with product. Close cartridge to try again. If problem persists, contact AllTest Technical Support.
Info ☒ No excel installed ! OK	**Error**: No excel installed **Action**: Check your computer and make sure it has installed Microsoft office.
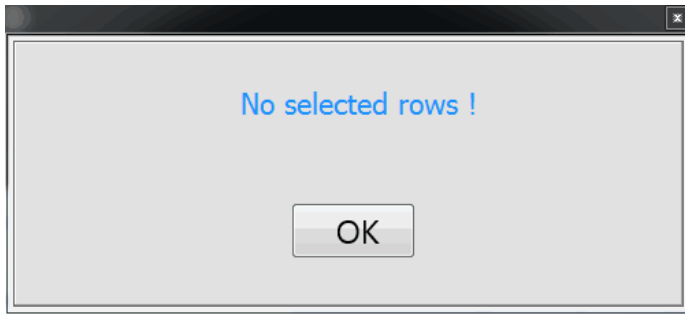
Error: No selected rows

Action: Before clicking export to excel, please choose target row that you want to export

11.2 Warnings
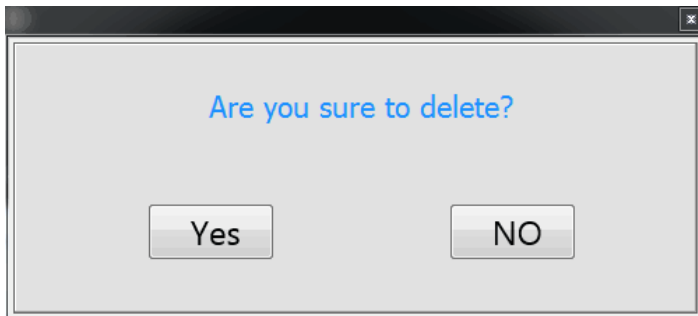
Warning: Single selected test result will be deleted.

Action: Tap **Yes** to delete single selected test result, or **No** to stop deletion. *Note: Once test history is deleted, results cannot be retrieved.*
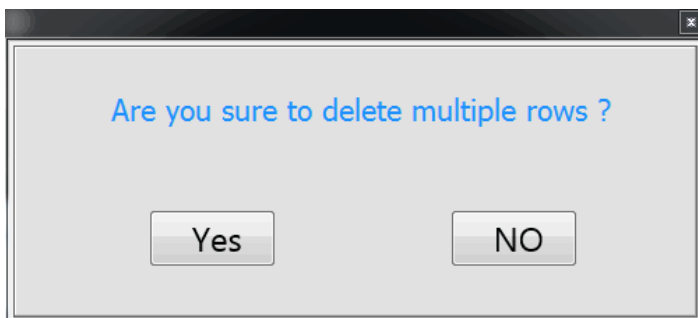
Warning: All selected test results will be deleted.

Action: Tap **Yes** to delete all selected test results, or **No** to stop deletion. *Note: Once test history is deleted, results cannot be retrieved.*
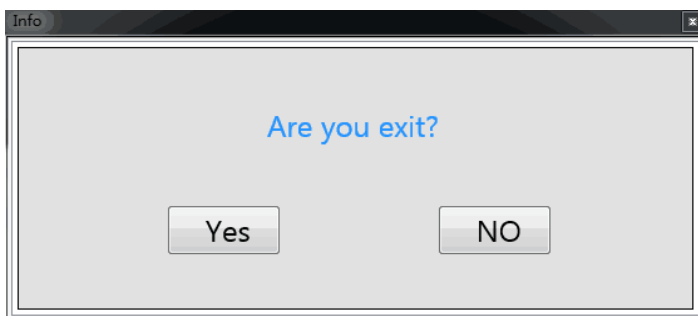
Warning: Are you exit.

Action: Tap **Yes** to exit, or **No** to continue using.

12. Manufacturer Information

Name：Hangzhou Alltest Biotech Co., Ltd
Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou-310018, P.R. China
Tel: +86-571-56267890
Fax: +86-571-56267856
Web: www.alltests.com.cn
Email: info@alltests.com.cn

Appendix I

Packing list

No.	Items	Amount
1	Reader	1
2	Connecting Cable	1
3	User Manual	1
4	Cartridges	5
5	Calibration Cassette	1

Index of Symbols

	Instruction for use		Test 1 kit		IVD		For in vitro diagnostic use only
	Store between -10-60°C	REF	Catalog #		EC | REP		Authorized Representative
	Manufacturer	CE	CE maker				Keep dry
	Fragile, handle with care		Keep away from sunlight				Protect from heat and radioactive sources

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CE

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