IMMUNOBIO

CE

Rapid Test Reader
Instruction for use

Thank you for purchasing a Rapid Test Reader Please carefully read the User Manual before using the nucleic acid extractor for correct use.Please properly keep the User Manual after read for always check when required.

◉ Preface

Thank you for purchasing a Rapid Test Reader

Please carefully read the User Manual before using the nucleic acid extractor for correct use.

Please properly keep the User Manual after read for always check when required.

Product name: Rapid Test Reader

Model: 152mm(L)×92mm(W)×35mm(H)

Manufacturer: Hangzhou Immuno Biotech Co., Ltd

Manufacturing address/address: Room401, 4F, Building 2, No.28, No.3 Street, Hangzhou Economic and Technological Development Zone, Hangzhou City,Zhejiang Province,China.

Tel.: +86571-85368996

Date of manufacture: See the nameplate of mainframe

Service life: 5 years

Prepared on: 08-2021

Version No.: A0

◉ Statement

Immunobio Company does not make any form of guarantee for this material, including (but not limited to) its implied guarantee of marketability and suitability for a specific purpose.

Immunobio only considers responsible for the safety, reliability and performance of the instrument under the following conditions, namely: The assembly operation, expansion, re-adjustment, improvement and repair are all carried out by personnel approved by Immunobio;

★ The extractor was used in accordance with the operation guidance;

★ Related electrical equipment complies with the national standards;

★ The extractor is not liquid-proof, and do not splash it with liquid during use.

If the following situations occur, Immunobio will not be responsible for the safety, reliability and operating conditions of the product:

★ The extractor is due for scrap;

★ Its components were disassembled & assembled, stretched and re-commissioned;

★ The extractor was failed to be correctly used in accordance with the User Manual.

◉ Warranty

Range of service and maintenance free of charge:

Free services are available for all equipment that meets the scope of the warranty service regulations of Immunobio.

◉ Brief introduction

Features:

Used in conjunction with adapter reagents for the qualitative and/or quantitative analysis of analytes in human, animal, and food samples.

Main purpose and scope of application:

The Rapid Test Reader is composed of a photoelectric detection module, a mechanical scanning control module, a control main board module, and an information acquisition module.



Type:152mm(L)×92mm(W)×35mm(H)

◉ Intended Use

The Rapid Test Reader is composed of a photoelectric detection module, a mechanical scanning control module, a control main board module, and an information acquisition module. The principle is generally that the reflectance signal of the detection reagent card is converted into a photoelectric signal through the sensor, and the photoelectric signal is converted into the corresponding concentration value or threshold value through the calibration information, and the test object is analyzed. Can automatically and accurately realize the interpretation from sample to result, and can detect the objects to be tested in various samples such as humans, animals, and food.

◉ Operation Manual

★ **Boot up**

（1）Power on: Press and hold the power button (about 2-3 seconds) in the off state to turn on the instrument. In the power-on state, press and hold the power button (about 2-3 seconds) to turn off the instrument.

★ **Boot up**

（2）When the instrument is turned on, the main interface displays two functional parts: [Record] and [Settings].

★ **Description of testing process**

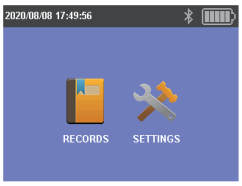
The entire workflow of the Rapid Test Reader is shown in Figure :



Starting up



Swipe IC card

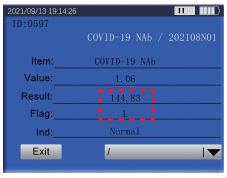




Insert test card



Test sample



Report results

★ Setting: Press the [Settings] button in the main interface to enter the system setting window as shown in Figure ①;

★ First use: the [Set Bluetooth] button in the setting window is shown in Figure ②, click the [Scan] button, as shown in Figure ③ , wait for the scanning to be completed, as shown in Figure ④ Show;

★ Select the Bluetooth device you are using, and click the [OK] button. After the connection is successful, when the instrument is turned on, turn on the Bluetooth, it will automatically connect, and there is no need to manually connect again.

★ Other settings: Click the [More Settings] button in Figure ⑤ interface to enter the more settings interface.

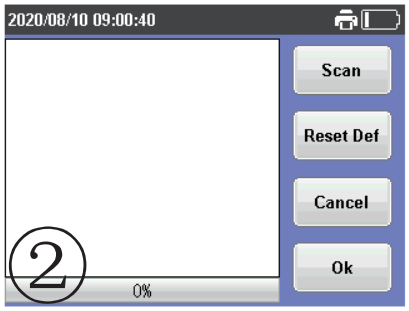
★ Clear data: Click the [Clear Data] button, and then click [OK] in the prompt box to clear all test data.

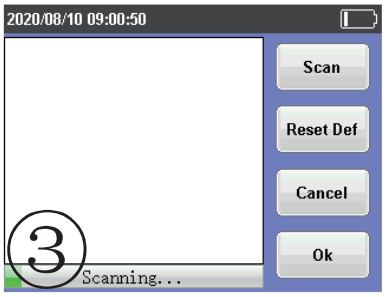
Import sample type: the sample information import list file is built in the TF card (the file is provided by the manufacturer), insert the TF card into the card slot, and click the [import sample] button to complete the sample type import operation.

System upgrade: TF card has a built-in system upgrade file (provided by the manufacturer), insert the TF card into the card slot, click the [System Upgrade] button, wait for the progress bar to finish, and automatically restart to complete the upgrade operation.

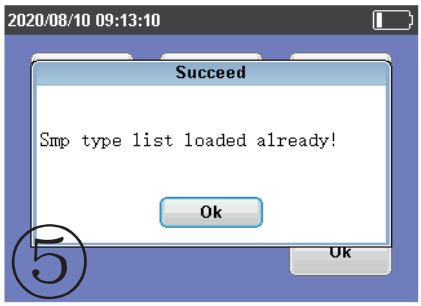
Set the system time and sample ID:It needs to be connected to the host computer app to operate. Please refer to the app manual for details.

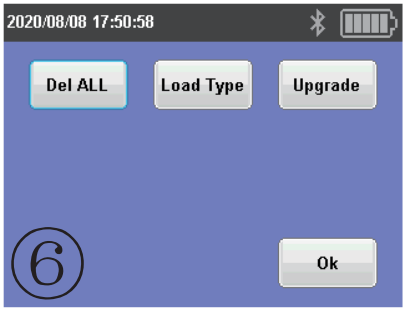






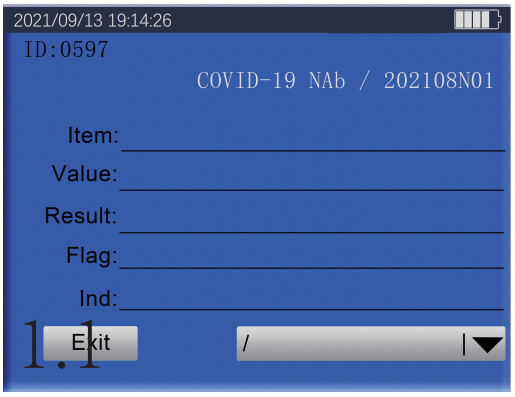


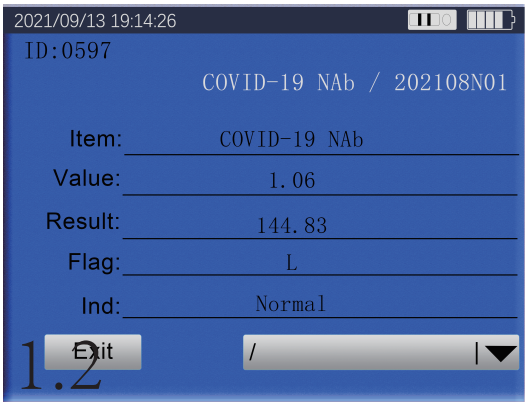




Swipe the IC card above the card pattern on the right side of the instrument, the instrument emits a long beep, and the interface shown in Figure 1.1 appears:

Select the type of sample to be tested, insert a reagent strip, the instrument will automatically recognize it, display the result and print it automatically. (As shown in the figure) (Automatic printing needs to be connected to a Bluetooth printer, see Bluetooth connection settings for the connection method) If you need to continuously test multiple samples, just continue to insert the reagent strip, without having to swipe the IC card multiple times as shown in Figure 1.2 .After the detection is completed, click the [Return] button to return to the main interface.





⚠ Cautions:

Cautions:

1.This system is only used by inspection professionals, doctors or experimenters who have been trained by Immunobio or the agents designated by Immunobio;

2.If the hospitals or institutions responsible for the use of this instrument cannot implement a satisfactory maintenance/repair plan, it may cause abnormal instrument failure and may endanger personal health;

3.Make sure to use the Rapid Test Reader under the conditions specified in the user manual. If the operating conditions are exceeded, the Rapid Test Reader may not operate normally, the measurement results will be unreliable, and it may damage the parts of the Rapid Test Reader and cause personal injury.

◉ Warning

★ This system is only used by inspection professionals, doctors or experimenters who have been trained by Immunobio or the agents designated by Immunobio;

★ If the hospitals or institutions responsible for the use of this instrument cannot implement a satisfactory maintenance/repair plan, it may cause abnormal instrument failure and may endanger personal health;

★ Make sure to use the Rapid Test Reader under the conditions specified in the user manual. If the operating conditions are exceeded, the Rapid Test Reader may not operate normally, the measurement results will be unreliable, and it may damage the parts of the Rapid Test Reader and cause personal injury.

◉ Attention

The User Manual is for professionals of Laboratory Department as follows:

a) Personnel who carry out daily operation of the system;

b) Personnel who perform system maintenance and troubleshooting;

c) Personnel who learn system operation.

◉ *Symbols*

Symbols used in the User Manual.

Symbols	Meaning
Warning	Prompt operators to operate following the steps below the symbol, or personal injury may be caused.
Attention	Prompt operators to operate following the notes below the symbol, emphasize on the important information or items requiring special attention from operators in operating steps.
	Prompt operators to operate following the steps below the symbol, or they are potential to be infected.

The following symbols may be seen on the Rapid Test Reader:

Symbols	Meaning
	Attention! Refer to the User Manual!
	Symbol of biological contamination
	Symbol of avoiding scalding from high temperature
	Serial number
	Period of validity
	Date of manufacture
	Manufacturer
	Storage temperature
	Refer to the User Manual
	Keep away from rain
	Fragile, handle with care

	Keep straight up during transport
	Stacking layers of mainframe
	In Vitro Diagnostic
	CE Symbol.

★ Installation: N/A

★ Instructions

Check the package situation, LOT number and expiry date before use.

Tear the small packages, take the product out and take samples.

★ Maintainance: single use only

★ Normal operating temperature: 10 ℃ - 30 ℃. Normal operating relative humidity: ≤80% (no condensation). Atmospheric pressure: 75 kPa - 106 kPa.

★ Storage conditions： The extractor shall be stored on a dry, clean and flat horizontal surface, without direct sunlight, mechanical vibration or intense electromagnetic interference.

★ Transportation type and mode:Normal shipping without cold chain， air or ground transport.

★ Expiry date: 5year

★ Packages and another

The packages are meeting requirement of ISO15223-1-2021 and ISO18113-1:2011 For medical device labeling.Symbols for marking and Providing Information Part 1 General Requirements

◉Specification

Bluetooth version	4
RFID	13.56MHz
LCD	2.8 inches reachable
Input voltage	5V 2A
Lithium battery capacity	5000mAh
Input/output interface	USB interface, TF storage expansion
Dimensions	152mm(L)×92mm(W)×35mm(H)



Manufacturer: Hangzhou Immuno Biotech Co., Ltd

Manufacturing address/address: Room401, 4F, Building 2, No.28, No.3 Street, Hangzhou Economic and Technological Development Zone， Hangzhou City,Zhejiang Province,China.



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