
Preface

Shenzhen Genius Electronics Co. Ltd. has a Medical Device Manufacturing License with the number: **GDFDA-MD No. 20041046**.

Executive standard of CA51 Blood Coagulation Analyzer: YZB/GD 0114-2012 Blood Coagulation Analyzers

The number of the Medical Device Registration Certificate for CA51 Blood Coagulation Analyzers: GDFDA-MD (app.) 2012 No. 2400332

This Manual is applicable to CA51 Blood Coagulation Analyzers.

In order to facilitate its use, we compiled the Operating Manual of CA51 Blood Coagulation Analyzers based on our experts' opinions, to provide a reference for clinical technicians when using this instrument to perform clinical tests. Some assays may be different from this Manual during actual practice due to using reagents from different manufacturers, therefore please read the reagent IFU [Instructions for Use] carefully and then carry out the assays as per the specific requirements of the IFU and this Manual.

This Manual describes how to install, operate, maintain, and repair the CA51 Blood Coagulation Analyzer, as well as the relative precautions. Please read this Manual carefully before operating the instrument.

We provide a series of technical services for you, including: a) Free technical training about instrument operation and maintenance; b) Supplying a complete set of reagents; 3) Establishing a superior after-sales team to ensure you can enjoy high-quality and rapid reparation service.

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Chapter I: Instrument Introduction

Section 1: Overview

This CA51 Blood Coagulation Analyzer is a type of single-channel instrument. Its measurement principle is optical colorimetry. After mixing the reagents with plasma, fibrinogen converts into fibrin and coagulates, thus the optical density of the test sample changes and the analyzer can detect the coagulation end-point.

1. Product structure and composition: It mainly consists of microprocessors, a detection system, LCD screen, printer, and pipette.
2. Scope of application: This instrument is mainly applicable to determine prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB), and other blood-coagulation factors in clinical coagulation tests.

Section 2: Technical Parameters

Sample-preheating positions: 5

Reagent-preheating positions: 2

Timer: 1

Testing channels: 1

Wavelength: 470nm

Temperature of testing positions: $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$

Temperature of preheating positions: $37.0^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$

Reagent volume: At least 20 μL

Sample volume: 20 - 40 μL

Repeatability: When testing normal QC plasma, the CVs (coefficient of variance) of prothrombin time (PT), activated partial thromboplastin time (APTT), and fibrinogen (FIB) are $\leq 5\%$; that of thrombin time (TT) is $\leq 8\%$.

Channel deviation: $\leq 5\%$

Accuracy: For FIB measurement, the relative bias (B) $\leq \pm 8.0\%$

Linearity: The linear regression coefficient (r) ≥ 0.980

Calculation: Able to calculate with measuring units of S, %, PTR, INR, and g/L

Power supply: A.C. 100 - 240V; 50/60Hz

Power rating: $\leq 80\text{VA}$

Built-in printer: 24-digit heat-sensitive printer (58 mm wide)

Appearance size: 289mm(L) $\times$ 275mm(W) $\times$ 133mm(H)

Working environment: Temperature $10^{\circ}\text{C} - 30^{\circ}\text{C}$ Relative humidity $\leq 85\%$

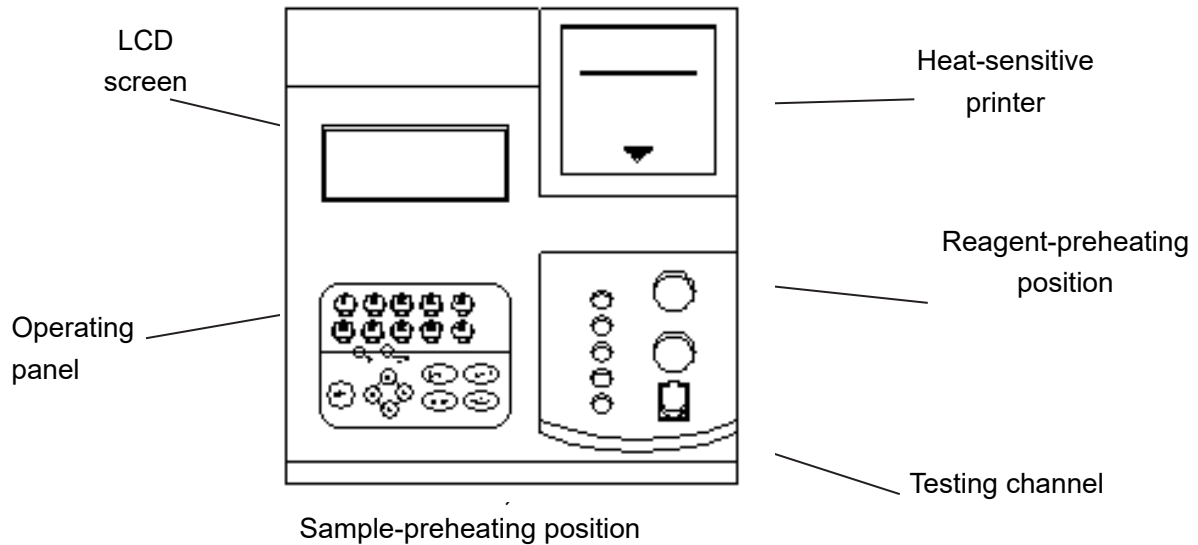
Weight: About 2 kg

Expected service life: Eight years

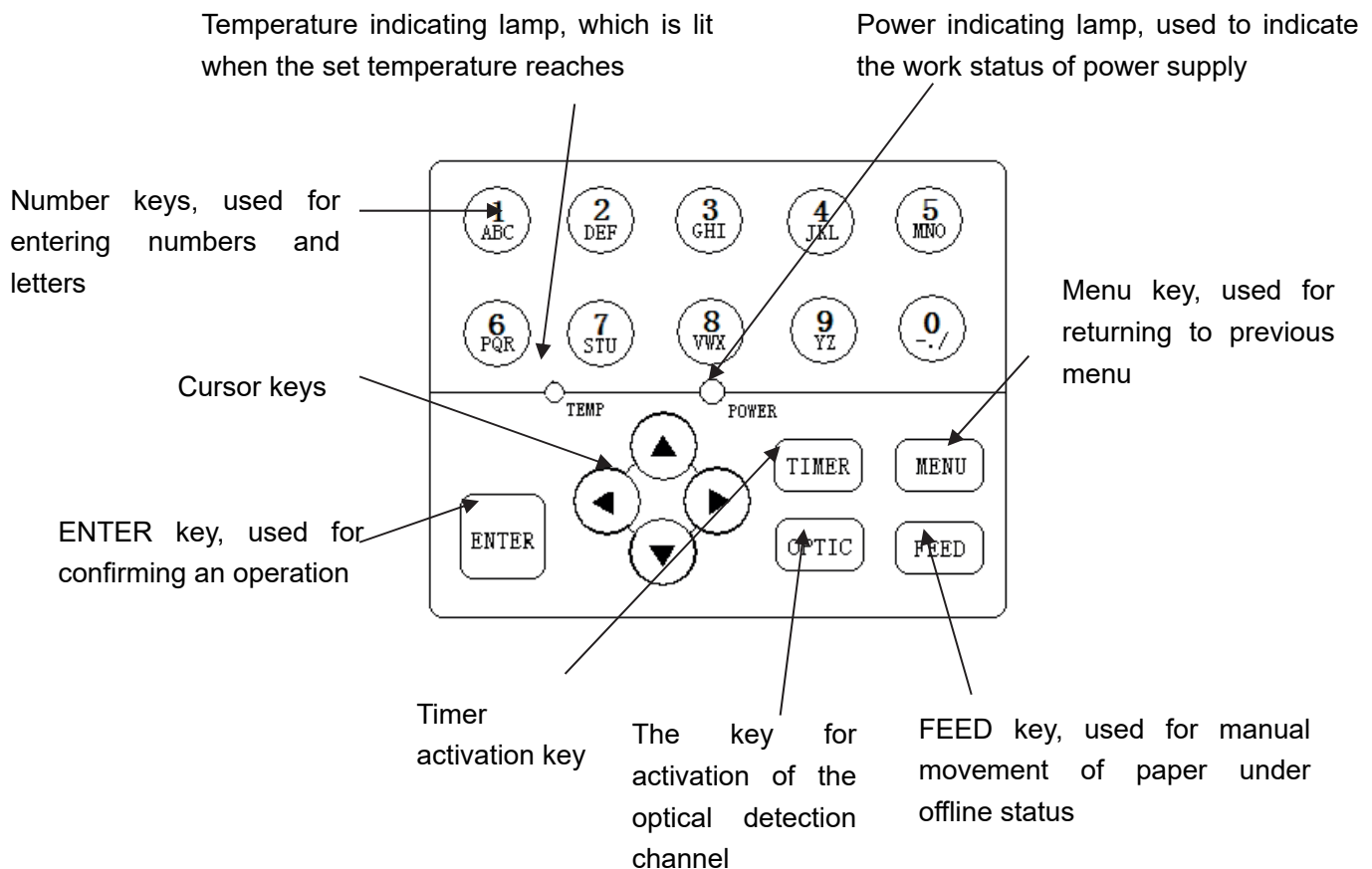
Section 3: Structure Description

1. Diagram of Main Components

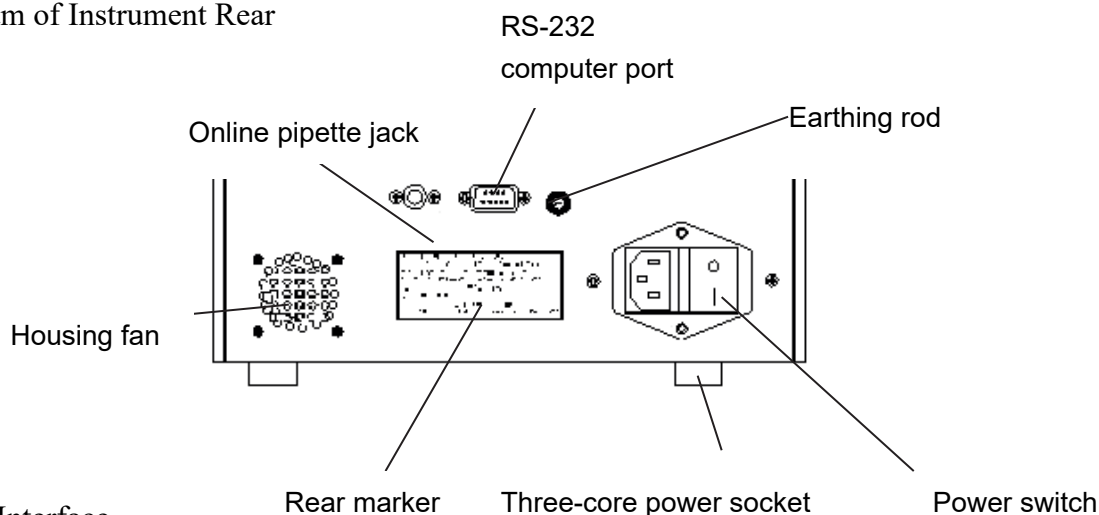
The entire principal machine is illustrated as follows:



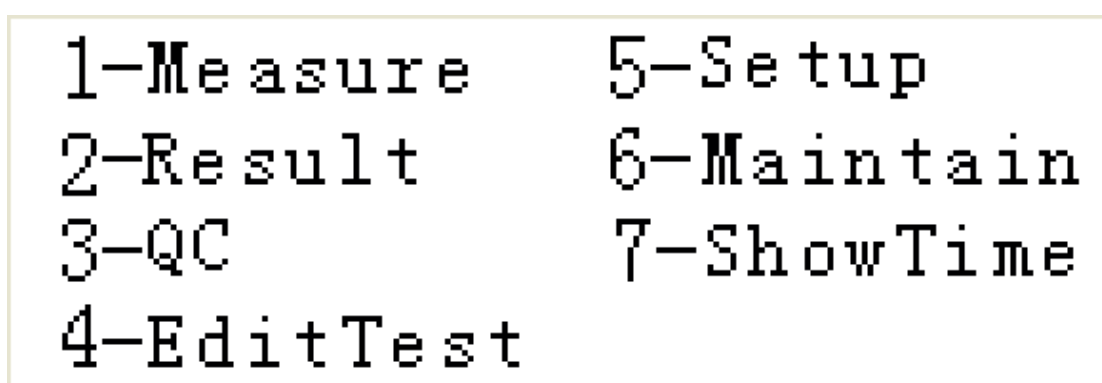
2. Diagram of Operating Panel



3. Diagram of Instrument Rear



4. Menu Interface



As illustrated in the Figure above, the main interface displayed after instrument startup has seven submenus, which can be selected with the number keys on the keyboard by operators.

During routine work, operators mainly use Items 1, 2 and 3; Item 1 can conduct the sample testing, Items 2 and 3 can help you print a report, and Item 7 can display the current time and date.

Section 4: Symbols, Stencils, Labels and Figures

1. Symbol

The following symbols listed in the table below are applicable to this Manual.

Symbol	Meaning
	Caution! 1. The analyzer may be damaged or the test results may be compromised 2. Please refer to this Manual
	Biological harm; please do not directly contact
	May cause electric shock
	The print head or the metal part around it may be very hot and you may be scalded if touched. After stopping the printout, please wait at least 20 minutes prior to replacement of the printing paper.

Symbol	Meaning
	Personal injury; the components, such as the fan, may cause personal injuries and you should be careful during use
	The operation interfaces included in this Manual may not be consistent with various software versions or instrument models. Please operate based on the actual interface on your analyzer.

2. Stencils and Labels

The following stencils and labels listed in the table below are applicable to this Manual.

Label	Meaning
	Serial number of the product
	Isoelectric grounding rod
	Manufacturing date
	A device for in vitro diagnosis, only assisting to perform in vitro diagnosis
~ or AC	Alternating current
	Power ON
	Power OFF
PIPETTE	Connecting to the pipette compatible with the instrument
POWER	Main power supply
COM RS-232	Communication port, which can exchange data with this kind of analyzing system in the testing department or other instrument systems and equipment

3. Figures

All the figures in this Manual are only used for illustration or examples; they cannot be used for other purposes. Specific operations should be based on the actual instrument; changes may occur without notification.

Section 5: Warranty and Service

The whole instrument will be warranted for one year from the date of installation. However, this warranty does not cover the damage caused by the following situations:

- (1) Used in an environment that cannot meet the requirements in this Manual;
- (2) Damage caused by not using the specified power supply or having abnormalities in the power supply;
- (3) Man-made damage;
- (4) Damage due to reparation by personnel that do not acquire the authorization from Genius;
- (5) Damage caused by other irresistible natural factors such as earthquakes, fire, and war;

If you have any concern or question during the use of this instrument, please do not hesitate to contact us.

Section 6: Training

We will hold free training periodically at different places for you, to facilitate the correct use of the CA blood coagulation analyzer series and the maximization of its performance. For the training schedule, please visit our website or consult our local office in your region.

This instrument can only be used by personnel who have received training by Genius or its authorized representatives; otherwise, the protection provided by this instrument may be impaired.

Please read this Manual and the IFU of related reagents carefully before use; otherwise, the protection provided by this instrument may be impaired or the test results may be significantly compromised.

Section 7: Summary of the Operating Manual

This Manual mainly helps you learn about the safety, installation, structure, analysis principles, operation procedures, maintenance and care, and faults and troubleshooting of the blood coagulation analyzer. Please operate the instrument as per this Manual.

This Manual mainly includes:

Chapter I	Instrument Introduction
Chapter II	Safety and Precautions
Chapter III	Instrument Installation
Chapter IV	Measurement Flowchart
Chapter V	Routine Operations
Chapter VI	Software Operation
Chapter VII	Daily Use and Maintenance
Chapter VIII	Commonly-Used Consumable Materials and Ordering Information
Chapter IX	Transportation and Storage
Chapter X	Annex

Chapter II: Safety and Precautions

The following items are warning symbols related to this analyzer. If you do not pay attention to them, there may be a risk of death or serious injury. The following warning symbols are not ordered as per importance; all the symbols are equally important.

Section 1: Safety

	Electric Shock (1) When the power is ON, any person except authorized service technicians are prohibited to open the analyzer panel; (2) Avoid spilling any liquid onto the instrument tabletop. If some liquid splashes into the analyzer, please cut off the power supply immediately and contact Genius promptly.
	Biological risk (1) All the test samples and quality controls should be regarded as infectious. Please wear gloves when contacting them; (2) The components touched with a test sample, such as pipetting tips and measuring cups, should be regarded as infectious; so, you should wear gloves when contacting them; (3) All the wastes are potentially infectious, and should be regarded as medical waste and disposed of according to the current regulatory requirements; (4) When the service life of the instrument ends, it should be disposed of as per local requirements for environmental protection, and it cannot be disposed of and discarded as common wastes.

Section 2: Precautions

	Scope of Application (1) This instrument is applicable to determine prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), and fibrinogen (FIB) in clinical coagulation tests. (2) When making a clinical judgment based on the test results, please consider the patient's clinical examination results, other test results or clinical symptoms as well.
Operators (1) Personnel who have been trained by Genius or its authorized engineers.	
	Actions in Case of Breakdown (1) If the instrument has a hazardous breakdown, such as fire, strange smell, smoke or other dangerous situations, someone should directly cut off its electricity or the main power supply, and then contact Genius.

	Application Environment (1) Please correctly install the instrument as per the environmental conditions specified in this Manual. Otherwise, the test results obtained may be inaccurate and the analyzer may be damaged.
	Electromagnetic Interference (1) The analyzer is susceptible to electromagnetic interference during running, which may influence assay results and lead to improper operations. During its running, please do not use devices generating electromagnetic waves, such as electric drills, mobile phones, or the intercom; (2) The analyzer can emit electromagnetic waves during running. Please do not install or use electromagnetic-sensitive equipment near the analyzer.
	Poor Grounding (1) The power supply must be correctly grounded; otherwise, there is the risk of electric shock. (2) The grounding impedance must be lower than 0.1 Ω; poor grounding can cause unstable test results and housing leakage, and thus there is the risk of electric shock.
	Device Connection (1) For a device not permanently connected, please do not place it at a location that is hard to disconnect; (2) For all the external switches or breakers and external overcurrent-protection systems, it is recommended to place them near the analyzer; (3) The devices connecting with the input and output ports of this analyzer (COM RS-232 or USB port) should satisfy the requirements in the National Standards GB4793 and GB4943 of <u>China</u> as well as IEC60950.
	Inflammation (1) Please do not use inflammable hazardous materials such as alcohol and ether near the analyzer.

以上内容仅为本文档的试下载部分，为可阅读页数的一半内容。如要下载或阅读全文，请访问：<https://d.book118.com/918033052052006123>