

**Runda**  
MEDICAL

**MEDCONN**  
MEDICAL TECHNOLOGY



## Runda Group

Instrument manufacturer:

Shanghai Huizhong Medical Science and Technology Co., Ltd

Reagent manufacturer:

Shanghai Huachen Biochemistry Reagent Co.,Ltd

Sales Company:

**Shanghai Kangxiang Medical Co., Ltd**

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Website: [www.rundamedical.com](http://www.rundamedical.com)

# MQ-2000PT(HPLC)

## Automatic HbA1c Analyzer

*Your HbA1c Testing Total Solution...*

## company profile

Runda Medical Group is founded in 1999, with over 550 employees nowadays. The Group existing business is focusing on medical laboratory. The business covers the whole east region of China. For a decade, the Group has built a strong long term relationship with the business partners.

Besides product distribution, Runda Medical Group owns self manufactured products which including blood gas, Hemoglobin analyzer and chemistry reagents.



Kangxiang Medical founded in January 2006, appointed IVD products operator by Runda Group in 2009. The company is mainly focusing on the sales and marketing for the self manufactured products in domestic and international markets.

The company takes "Sincerity, Communication and Creativity" as its enterprise culture, and takes care for the needs of customers. Service creates value as its management belief, in order to provide high quality products and professional service for the development of IVD industry.

Global Leading HPLC Principle

HPLC is a recommended principle by WHO. It is recognized as a 'Gold Standard' for HbA<sub>1c</sub> measurement as it has a high sensitivity and stable performance.

- ▶ Eliminate unstable HbA<sub>1c</sub> interferences
- ▶ Eliminate variant Hb interferences
- ▶ HbA<sub>1c</sub> (NGSP&IFCC) %, eAG also can be reported at the same time

Performance Characteristics

- ▶ Automatic identify the sample type
- ▶ Automatic sample load: on board capacity 50 samples, continuously
- ▶ Cap piercing function
- ▶ Barcode reading
- ▶ Auto-mixing function

Operation System & Software

- ▶ English operating software
- ▶ Touch screen input
- ▶ Data storage > 20000
- ▶ Pressure, temperature, test quantity display
- ▶ Pressure, temperature monitor
- ▶ LIS data output

Cutting-edge Technology

- ▶ Adopting High Pressure plunger Pump (Micro-pump) to provide a hydrodynamic force, without the influence of any resistance from the rest of the entire chromatographic system ensure to provide a constant velocity.
- ▶ Using 24 AD high-precision detector allows to detect the sample absorbance with a high-precision and a high resolution.



International Certifications.....

- √ CE approved product
- √ IFCC certified product
- √ ISO qualified organization

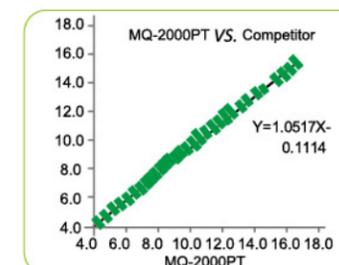
MQ-2000PT – IFCC Certificate

ISO 13485



**Specifications**

Principle	Ion exchange chromatography with HPLC principle
Throughput	Sample cycle $\leq 160s/T$
Sample	Sample aspirate volume: whole blood 10 $\mu$ l; diluted blood 150 $\mu$ l
	Automatic sample entry: on board capacity 50 samples, Non-stop
Testing	Wave length: 415nm
	Measuring range (NGSP value): HbA <sub>1c</sub> 4%-17%, $r \geq 0.99$
	Precision: $CV \leq 2.0\%$
Operating Condition	Temperature: 10 °C - 30 °C
	Humidity: $\leq 80\%$
	Pressure: 79-106kPa
Power Requirement	Voltage: 220V
	Frequency: 50-60Hz
	Power: < 100VA
Dimension	Length: width: height = 610mm*500mm*410mm
	Net weight: 28kg

**Performance Data**
**Correlation**


Sample distribution range			
Sample Range(%)	Percentage	Sample required	Sample Qty.
4-4.5	5%	10	10
4.6-6.0	25%	50	61
6.1-8.0	25%	50	62
8.1-10.0	25%	50	68
10.1-12.0	15%	30	33
>12.1	5%	10	15

Correlation data	
Model	MQ-2000PT VS. Competitor
a	1.0517
b	-0.1114
r	0.9963

**Reproducibility**

	Intra-assay precision(n=20)		Inter-assay precision(n=20)	
	Mean	SD	Mean	SD
Mean	5.67	0.0813	5.75	0.14
SD	0.0813	0.1046	0.14	0.21
CV	1.43	1.20	2.36	2.15

**Stability**

QC	L	H
Mean(%)	5.68	9.96
SD	0.08	0.13
CV(%)	1.41	1.33

**Effects of coexisting substances**

Bilirubin • F	~ 19.7 mg/dL
Bilirubin • C	~ 21.0 mg/dL
Hemolytic hemoglobin	~ 488 mg/dL
Chyle	~ 1550 FTU
Ascorbic acid	~ 50 mg/dL
Glucose	~ 1200 mg/dL
Acetaldehyde	~ 60 mg/dL

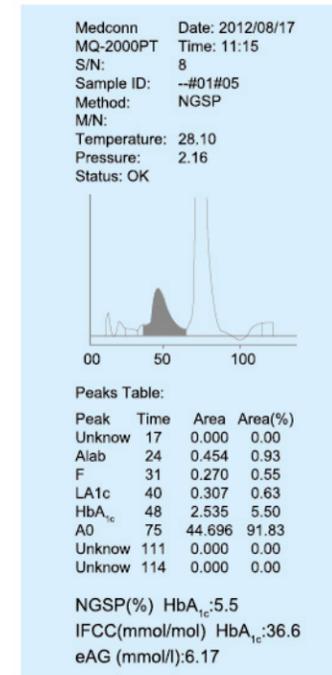
No interference from coexisting substances up to above concentrations

**Reagent Allocation**

COMPOSITION	SPECIFICATIONS	QUANTITY
Reagent A	1800ml/bottle	2
Reagent B	1400ml/ bottle	1
Haemolyser	1800ml/ bottle	4
Column	Unit	1
Vials	Unit	100
Paper rolls	roll	6
Filter	400T	2

\* Each pack of reagent contains 800 tests

Storage and Stability: 18 months before opening, 2 months after opening at 4°C to 30°C.



**Calibrator and Control**

Product	Specification
lyophilized calibrator (2 levels)	0.25ml*2
Liquid control (2 levels)	1ml*2

Storage and Stability: over 24 months before opening at 2°C - 8°C.



#### Recommendation

HbA1c can be used as a diagnostic test for diabetes providing that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement.

#### HbA1c targets

An HbA1c of 6.5% is recommended as the cut point for diagnosing diabetes. A value of less than 6.5% does not exclude diabetes diagnosed using glucose tests.

#### When should HbA1c level be tested?

1. Once per 3 months if trying to get better control.
2. Once per 6 months if good control achieved and maintained.

#### How does HbA1c return an accurate average measurement?

- For non-diabetics, the usual reading is 4-5.9%.
- For people with diabetes, an HbA1c level of 6.5% is considered good control, although some people may prefer their numbers to be closer to that of non-diabetics.
- People at greater risk of hypoglycemia may be given a target HbA1c of 7.0-7.5%.

#### A1C Shows Predictive Advantage

The HbA1c test can more accurately identify people at risk for a variety of health conditions than the fasting plasma glucose test. American Diabetes Association has recommended HbA1c as an official screening test for diagnosing diabetes and detecting prediabetes since 2010.

Research shows that controlling blood glucose levels helps to prevent serious diabetes-related complications, such as kidney disease, nerve damage and problems with the eyes and gums.

#### The advantages of HbA1c include:

- Only a single, non-fasting blood sample required (instead of the fasting, 2-hr and maybe 1-hr samples for blood glucose).
- Very small day-to-day variability
- Gives an overlook 'view' of glucose in the blood during the previous weeks or even months.
- Already the most common way to guide the management of diabetes.

