Low CVs, High precision

With less than 1% CVs, H50 delivers more precise and reliable results of HbA1c, especially around 6.5%, which is the internationally accepted criteria for diagnosis of diabetes.



Traceability to NGSP and IFCC

HbA1c results generated by H50 are traceable to the international reference method as certified by "National Glycohemoglobin Standard Program (NGSP)" & "International Federation of Clinical Chemistry (IFCC)"

Certificate of Traceability	fice.
Manufacturer Certification This certifies that <u>Mindray</u> , using <u>Ion-exchange HPLC on H50/H50P</u> has participated in and successfully completed the NGSP certification for manufacturers and is inceable to the Diabetes Control and Complications Trial Reference method. The	Traceability of Manufacturers to the IFCC Reference Measurement Procedure for Hb
comparison was performed with: Reference Material Institute for Clinical Chemistry Standards (ReCCS) ASRU#] The system evaluated was: Instrument Instrument Calibrator Lot: Isources Column Lot: Labbrator Lot: Column Lot: Labbrator Asternol Values:	<u>HbA1C</u> participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Program the following performance was seen: at 30 mmol HbA1c/mol Hb : 0.9 at 60 mmol HbA1c/mol Hb : 0.9 at 60 mmol HbA1c/mol Hb : 1.7 at 90 mmol HbA1c/mol Hb : 2.4 Reproducibility, coefficient of variation 0.32%
2014001101, 2014001201, 2014001201 [55%, 11.3%] Date of Certification: May 1, 2015 Certification: Certification Expires: Marking Marking More Marking Marking Notes Seeing Constant Set Marking Set Marking Notes Set Marking Set Marking Set Marking Set Marking Set Marking Set Marking	Linearity, correlation coefficient 0.9997 Date of issue: 9.July 2015 Certification expires: 11 December 2016
	IFCC Networks. Coordinator

H50 Automated HPLC Analyzer

Technical Specifications

Principle High Performance Liquid Chromatography (HPLC)

Parameters and Units

HbF % HbA1c % and mmol/mol HbA1 eAG mmol/L and mg/dL

Sampling mode

Autoloader - Whole blood mode Autoloader - Prediluted mode Closed tube - Whole blood mode

Sample Volume Whole blood mode: 16uL Prediluted mode: 4µL

Throughput Up to 50 samples per hour

Reagents and Consumable Hemolysis solution Eluent A Eluent B Analytical column Probe cleanser Hemoglobin A1c Calibrator (CAL-1、 CAL-2) Hemoglobin A1c Control (CRL-1、 CRL-2)

Data Storage Capacity

Up to 50,000 results including numeric and chromatograms information

Power requirement Voltage: 100V-240V Frequency: 50Hz/60Hz

> Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China Tel: +86 755 8188 8998 Fax: +86 755 26582680 E-mail: intl-market@mindray.com www.mindray.com

P/N: ENG-H50-21285x6-20150728

Mindray is listed on the NYSE under the symbol"MR"

Operating Environment

Ambient temperature:	10°0
Relative humidity:	20%
Atmospheric pressure:	70k

°C - 32°C % - 85% kPa - 106kPa

Dimension and Weight Width×Height×Depth: 560mm×530mm×572mm Weight: <65kg

Mo Ana Tub	de: AL-V lysis Tin e Pos.: 3	VB ne: 3-5	2015-07	# -07 15:3	0	
Name: Test-01# Gender: Male Age: 36						
Parameter			Result	Unit		
HbA	HbA1c H		11.0	%(NGSP)		
HbA	HbA1c H		96	mmol/mol		
HbF			0.9	%	%	
HbA1		13.1	%	%		
*eAG		14.9	mmol/L			
Name		RTime	Area	%		
Ρ1	A1a		10	1	0.8	
P2	A1b		12	2	1.3	
Р3	F		19	2	0.9	
Ρ4	L-A1c		23	5	2.9	
Р5	S-A1c		39	14	11.0	
P6	A0		57	154	86.0	
TotalArea: 179						
25	mOD		•	П		



Representative chromatogram of a diabetic patient

H50 mindray Sample ID: 3#0707-CFX-WHH-NS29-19 Mode: CT-WB Analysis Time: 2015-07-07 11:07 Tube Post

> H50 Automated HPLC Analyzer



Gold standard for HbA1c analysis



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H50 Automated HPLC Analyzer

- HPLC method for HbA1c testing
- Method traceability certified by NGSP & IFCC
- 4 parameters: HbF, HbA1c, HbA1, eAG
- Less than 1% CVs
- 8.4 inch large-size LED touch screen
- Up to 50 samples per hour
- First sample result reported within 3 minutes
- 2 sampling modes: autoloader and closed tube
- 40 tubes autoloader with random access
- Intelligent tube rack recognition
- Easy to replace analytical column
- Radio Frequency (RF) technology to read reagent information
- Data storage capacity: 50,000 results with chromatograms
- Supports bi-directional LIS



H50 features include the Gold-standard High Performance Liquid Chromatography (HPLC) method, a 50 tests/hour rapid throughput and high precision to measure glycosylated hemoglobin (HbA1c).

The ability of H50, to directly measure HbA1c, HbF as well as other fractions, assists clinicians take quick & confident therapeutic decisions. This greatly improves patient care.

Reagents 3 built-in reagents RF* detection Reagents saving

> Sample mixing Better mixing by inversion More accurate results







Closed tube STAT sample

Cap-piercing