

Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO2 in serum or plasma on DiaSys respons®910

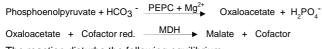
Order Information

Cat. No. 1 0950 99 10 923

4 twin containers for 200 tests each

Enzymatic test using phosphoenolpyruvate carboxylase (PEPC) and a stable NADH analog

Principle



The reaction disturbs the following equilibrium:

 $CO_2 + H_2O \longrightarrow H_2CO_3 \longrightarrow H^+ + HCO_3$ This results in a conversion of CO₂ to bicarbonate (HCO₃⁻) which then is included in the reaction. Therefore, the total CO2

concentration is measured.

The decrease of reduced cofactor concentration is measured at 405 nm and is proportional to the concentration of total carbon dioxide in the sample.

Reagents

Components and Concentrations

pH 7.5 Buffer Phosphoenolpyruvate (PEP) 12.5 mmol/L Phosphoenolpyruvate carboxylase (PEPC) > 400 U/I Malate dehydrogenase (MDH) > 4100 U/L NADH analog 0.6 mmol/L Activators, stabilizers, surfactant, preservative

Standard

30 mmol/L

Storage Instructions and Reagent Stability

Reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

The standard is stable up to the end of the indicated month of expiry, if stored at 2 - 25 °C and protected from light. Once opened, the standard is stable for 3 months, if recapped immediately after use.

Warnings and Precautions

- In very rare cases, samples of patients with gammopathy might give falsified results.
- Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent and standard are ready to use. The reagent bottles are placed directly into the reagent rotor.

Specimen

Serum or heparin plasma

Serum or plasma should be separated from cells immediately and stored at 2 - 8 °C. Exposure of samples to air should be avoided. Samples should be stored tightly sealed to prevent loss of carbon dioxide and assayed as soon as possible after collection.

Stability [1]:

20 - 25 °C 1 day at 4 - 8 °C 7 days at -20 °C 2 weeks at

Discard contaminated specimens. Freeze only once

Calibrators and Controls

For calibration DiaSys Bicarbonate Standard FS is recommended. This method has been standardized against a primary standard on basis of sodium carbonate. For internal quality control DiaSys TruLab Bicarbonate control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	K	it si	ze
Bicarbonate Standard FS	1 0950 99 10 030	6	Х	3 mL
TruLab Bicarbonate	5 9700 99 10 065	3	Χ	3 mL

Performance Characteristics

Measuring range up to 50 mmol/L bicarbonate				
(in case of higher concentrations re-measure samples after manual				
dilution or use rerun function).				
Limit of detection** 4 mmol/L bicarbonate				
On-board stability 3 weeks				
Calibration stability 2 weeks				

Interfering substance	Interferences < 10%	Bicarbonate [mmol/L]
Ascorbate	up to 30 mg/dL	18.3
Hemoglobin	up to 500 mg/dL	19.1
	up to 500 mg/dL	38.2
Bilirubin, conjugated	up to 60 mg/dL	22.7
	up to 60 mg/dL	42.6
Bilirubin, unconjugated	up to 55 mg/dL	17.6
	up to 55 mg/dL	38.8
Lipemia (triglycerides)	up to 1700 mg/dL	19.2
	up to 1700 mg/dL	34.7
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	19.5	30.7	44.7
Coefficient of variation [%]	1.44	1.62	1.63
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	19.5	29.3	41.7
Coefficient of variation [%]	3.63	4.70	2.53

Method comparison (n=1	09)
Test x	DiaSys Bicarbonate FS (Hitachi 911)
Test y	DiaSys Bicarbonate FS (respons®910)
Slope	0.983
Intercept	0.190 mmol/L
Coefficient of correlation	0.999

^{**} according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

Bicarbonate [mmol/L] = Bicarbonate [mEq/L]

Reference Range [3]

Adults: 22 - 29 mmol/L (mEq/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
- Müller-Plathe O. Acid base balance and blood gases. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 318-329.
- Norris KA, Atkinson AR, Smith WG. Colorimetric enzymatic determination of serum total carbon dioxide as applied to the Vickers multichannel 300 discrete analyser. Clin Chem 1975; 21: 1093-1101.
- US patent #5,801,006

Manufacturer

IVD

DiaSys Diagnostic Systems GmbH Alte Strasse 9 65558 Holzheim Germany

Reagent Information * fluid stable



Bicarbonate FS

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

Identification	
This method is usable for analysis:	Yes
Name:	HCO3
Shortcut:	
Reagent barcode reference:	017
Host reference:	

Technic	
Type:	Fixed Time Kinetic
First reagent:[µL]	200
Blanc correction	Yes
Second reagent:[µL]	0
Blanc correction	No
Main wavelength:[nm]	405
Secondary wavelength:[nm]	508
Polychromatic factor:	1.000
1 st reading time [min:sec]	0:36
Last reading time [min:sec]	7:48
Reaction way:	Decreasing
Linear Kinetics	
Substrate deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	0.16
Substrate deplation: absorbance limit	0.10
Endpoint	
Stability: largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	1.5
Concentration technical limits-Upper	50
SERUM	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	3
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	3
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume [µL]	3
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2
Normal dilution (factor)	1
Below normal volume[µL]	3
Below normal dilution (factor)	1
Above normal volume [µL]	2
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mmol/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=22.0 <=29.0
URINE	
PLASMA	>=22.0 <=29.0
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details			
Calibrator I	st	Concentration	
Cal. 1		0	
Cal. 2		*	
Cal. 3		*	
Cal. 4		*	
Cal. 5		*	
Cal. 6		*	
	Max delta abs.		
Cal. 1	0.015		
Cal. 2	0.025		
Cal. 3			
Cal. 4			
Cal. 5			
Cal. 6			
Drift limit [%]	0.8		
Calculation	S		
Model		X degree	
Degree		1	

^{*} Enter calibrator value

Application respons[®]910 March 2013/4