respons®910

Bicarbonate FS*

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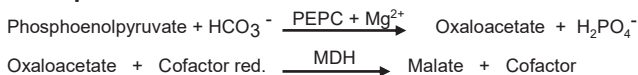
Order Information

Cat. No. 1 0950 99 10 923
4 twin containers for 200 tests each

Method

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

Principle

$$Phosphoenolpyruvate + HCO_3^- \xrightarrow{PEPC + Mg^{2+}} Oxaloacetate + H_2PO_4^-$$

$$Oxaloacetate + Cofactor\ red. \xrightarrow{MDH} Malate + Cofactor$$

The reaction disturbs the following equilibrium:

$$CO_2 + H_2O \longleftrightarrow H_2CO_3 \longleftrightarrow H^+ + HCO_3^-$$

This results in a conversion of CO_2 to bicarbonate (HCO_3^-) which then is included in the reaction. Therefore, the total CO_2 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

Buffer pH 7.5	
Phosphoenolpyruvate (PEP)	12.5 mmol/L
Phosphoenolpyruvate carboxylase (PEPC)	> 400 U/L
Malate dehydrogenase (MDH)	> 4100 U/L
NADH analog	0.6 mmol/L
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 – 8°C and protected from light. Once opened, the standard is stable for 12 months, if recapped immediately after use.

Warnings and Precautions

1. The reagent contains sodium azide (0.8 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagent contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. 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.
5. For professional use only!

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]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys Bicarbonate Standard FS is recommended for calibration. 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.	Kit size	
Bicarbonate Standard FS	1 0950 99 10 030	6 x	3 mL
TruLab Bicarbonate	5 9700 99 10 065	3 x	3 mL

Performance Characteristics

Measuring range up to 50 mmol/L bicarbonate (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) 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=109)	
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

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
2. 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.
3. 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.
4. 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.
5. US patent #5,801,006
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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respons®910

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
Twin reaction:	No
Name:	HCO3
Shortcut:	
Reagent barcode reference:	017
Host reference:	017

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	508
Polychromatic factor:	1.0000
1 st reading time [min:sec]	0:36
Last reading time [min:sec]	7:48
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance limit	0.1600
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	4.0000
Concentration technical limits-Upper	50.0000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	3.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	3.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	3.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	3.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	3.0
Below normal dilution (factor)	1
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mmol/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=22.0 <=29.0
URINE	
PLASMA	>=22.0 <=29.0
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	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 [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value