

Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO₂ in serum or plasma on DiaSys respons[®]920

Order Information

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

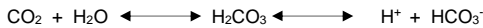
Method

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

Principle



The reaction disturbs the following equilibrium:



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

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

- The reagent contains sodium azide (0.8 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagent contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons[®]920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- 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.
- 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. DiaSys TruLab Bicarbonate control should be assayed for internal quality control. 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**	2 mmol/L bicarbonate
On-board stability	3 weeks
Calibration stability	3 weeks

Interfering substance	Interferences < 10%	Bicarbonate [mmol/L]
Ascorbate	up to 30 mg/dL	18.3
Hemoglobin	up to 1000 mg/dL	23.2
	up to 600 mg/dL	42.0
Bilirubin, conjugated	up to 60 mg/dL	15.0
	up to 60 mg/dL	34.5
Bilirubin, unconjugated	up to 60 mg/dL	16.4
	up to 70 mg/dL	35.6
Lipemia (triglycerides)	up to 2000 mg/dL	16.4
	up to 1900 mg/dL	41.5

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]	20.0	34.3	46.2
Coefficient of variation [%]	1.05	1.19	1.17
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	17.4	26.7	44.3
Coefficient of variation [%]	3.48	2.86	1.57

Method comparison (n=114)	
Test x	DiaSys Bicarbonate FS (Hitachi 917)
Test y	DiaSys Bicarbonate FS (respons [®] 920)
Slope	1.047
Intercept	-1.328 mmol/L
Coefficient of correlation	0.998

** 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-Platze 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.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD  DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Bicarbonate FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: HCO3			Auto Rerun	<input type="checkbox"/>
Report Name	: BICARB			Online Calibration	<input type="checkbox"/>
Unit	: mmol/L	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 405	Secondary	: 505	Total Reagents	: 1
Assay Type	: 2-Point	Curve Type	: Linear	Reagent R1	: HCO3 R1
M1 Start	: 2	M1 End	: 2	Reagent R2	:
M2 Start	: 24	M2 End	: 26	Consumables/Calibrators:	
Sample Replicates	: 1	Standard Replicates	: 3	Blank	: 0
Control Replicates	: 1	Control Interval	: 0	Calibrator	: *
Reaction Direction	: Decreasing	React. Abs. Limit	: 0.0000		
Prozone Limit %	: 0	Prozone Check	: Upper		
Linearity Limit %	: 0	Delta Abs. / Min.	: 0.0000		
Technical Minimum	: 0.0000	Technical Maximum	: 60.0		
Y = aX + b	a= 1.0000		: 0.0000		

* Please enter standard value.

Test Details		Test Volumes		Reference Ranges	
Test	: HCO3				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 2.00 µL	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 10.00 µL	Dilution Ratio	: 1 X		
Decrease	: 2.00 µL	Dilution Ratio	: 6 X		
Standard Volume	: 2.00 µL				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 200 µL	R1 Stirrer Speed	: Medium		
RGT-2 Volume	:	R2 Stirrer Speed	:		

Test Details		Test Volumes		Reference Ranges	
Test	: HCO3				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit (mmol/L)	Upper Limit (mmol/L)			
Normal	: 22.0	: 29.0	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other		
Panic	: 0.00	: 0.00			