

Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO₂ in serum or plasma on Sysmex BX-Series

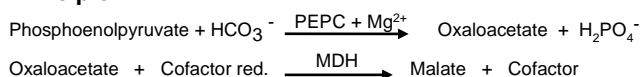
Order Information

Cat. No.	Kit size	Number of tests
1 0950 99 10 971	R1 3 x 18.3 mL	BX-3010 3 x 90 tests BX-4000 3 x 78 tests

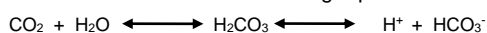
Method

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 415 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

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagent! The standard is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C. Once opened, the standard is stable at least 12 months, if recapped immediately after use. Protect reagent and standard from light!

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 laboratory practice.
- 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 minimized. 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

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.	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**	1.00 mmol/L bicarbonate
On-board stability	6 weeks
Calibration stability	4 weeks

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	19.3 mmol/L
Hemoglobin	up to 500 mg/dL	20.4 mmol/L
Bilirubin, conjugated	up to 60 mg/dL	20.0 mmol/L
Bilirubin, unconjugated	up to 40 mg/dL	19.9 mmol/L
Lipemia (triglycerides)	up to 2000 mg/dL	19.0 mmol/L
	up to 2000 mg/dL	29.5 mmol/L

For further information on interfering substances refer to Young DS [2].

Precision (BX-4000)

Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L] [mEq/L]	9.95	21.3	31.0
Coefficient of variation [%]	1.00	2.56	0.604
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L] [mEq/L]	15.4	26.0	30.0
Coefficient of variation [%]	1.42	0.979	1.97

Method comparison (n=114)

Test x	Bicarbonate FS (BioMajesty 6010C)
Test y	Bicarbonate FS (BX-4000)
Slope	0.927
Intercept	0.688 mmol/L
Coefficient of correlation	0.997

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

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="HCO3"/>	Reagent Name	Reagent (µL)	Water (µL)	
Print Name	<input type="text" value="Bicarbonate"/>	MethodColor		R1	<input type="text" value="HCO3"/>	<input type="text" value="150"/>	
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="Disable"/>		
Unit	<input type="text" value="mmol/L"/>			Diluent	<input type="text" value="Disable"/>		
Assay Type	<input type="text" value="End"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>		
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2	<input type="text"/>
		1	<input type="text" value="2"/> - <input type="text" value="3"/>				
		2	<input type="text" value="37"/> - <input type="text" value="38"/>				
Wave Length	Prim. <input type="text" value="415"/>	Sec. <input type="text" value="510"/>		Normal Range			
				No.	Normal Range Name	Min	Max
				1	Male-G1	*	*
				2	Male-G2	*	*
				3	Male-G3	*	*
				4	Female-G1	*	*
Normal	Sample Volume (µL)	Diluted Sample (µL)	Diluent (µL)	Technical Range	(Conc)	<input type="text" value="1.0"/>	- <input type="text" value="50.0"/>
	Low	Normal	High		(mAbs/10)	*	- *
<input type="checkbox"/>	Diluent <input type="text" value="0.0"/>	< <input type="text" value="1.5"/>	< <input type="text" value="0.0"/>				
	Rerun (High/Prozone)			Previous Result Comparison (%)	<input type="text" value="*"/>		<input type="text" value="*"/> %
<input type="checkbox"/>	Diluent <input type="text" value="0.0"/>	< <input type="text" value="1.5"/>	< <input type="text" value="0.0"/>				
	Rerun (Low)			Abnormal Range	(Conc)	<input type="text" value="*"/>	- <input type="text" value="*"/>
<input type="checkbox"/>	Diluent <input type="text" value="0.0"/>	< <input type="text" value="1.5"/>	< <input type="text" value="0.0"/>				
				Panic Range	(Conc)	<input type="text" value="*"/>	- <input type="text" value="*"/>
				Decimal Point	<input type="text" value="1"/>	Profile SI	<input type="text" value="Disable"/>

*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters			
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="HCO3"/>	Sample	<input type="text" value="Serum"/>		
Limit Checks	Blank measurement						
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	mAbs/10		Blank measurement:			
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="1100"/>	mAbs/10		<input type="text" value="Disable reagent blank and C1 blank"/>			
<input type="checkbox"/> Linearity Limit	<input type="text"/>	%		Measurement of Reagent Blank during Run:			
	<input type="text"/>	(mAbs/10)/min		<input type="text" value="None"/>			
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%		Reagent blank measurement at calibration:			
	<input type="text"/>			<input type="text" value="Reagent blank (No sample)"/>			
	SL 1-S	-	SL1-F	The number of measurement:			
	<input type="text"/>		<input type="text"/>	<input type="text" value="Duplicate"/>			
	SL 2-S	-	SL2-F	Reagent blank limit checks:			
	<input type="text"/>		<input type="text"/>	<input checked="" type="checkbox"/> Duplicate Limit <input type="text" value="20"/> mAbs/10			
Sensitivity	<input type="text"/>	mAbs/10		Instrument Factor			
<input type="checkbox"/> Absorbance Limit	Abs. in reaction <input type="text" value="Decrease"/>			a	<input type="text" value="1.00"/>	b	<input type="text" value="0.00"/>
	Limit	<input type="text" value="25000"/>	mAbs/10				

Calibration Registration

**Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters**

Method No.

Method Name

Sample Type

Replication

Check Interval

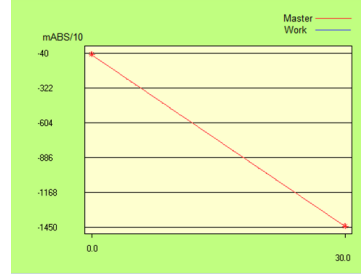
Test without calibration

Calibration Type

Reagent Lot

Calibrator Name

Reagent Lot No.
(R1)
(R2) Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	0.0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10

K C1 Blank
 Reagent Blank for C1

*Entered by user

Bicarbonate FS

Chemistry code 100 12

Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters																						
Method	*	Name	HCO3	Reagent Name	Reagent (µL)	Water (µL)																				
Print Name	Bicarbonate			R1	HCO3	200																				
Sample	Serum			R2 <input type="checkbox"/>																						
Unit	mmol/L			Enable																						
Assay Type	End			Diluent <input type="checkbox"/>																						
				Enable																						
Measuring points	Start	End	Decimal Points	1																						
	1	3 - 4																								
<input checked="" type="checkbox"/> Enable	2	54 - 55																								
Wave Length	Normal Range																									
Prim. 415	Sec <input type="checkbox"/> Disable	510	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Normal Range Name</th> <th>Min</th> <th>Max</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male-G1</td> <td>*</td> <td>*</td> </tr> <tr> <td>2</td> <td>Male-G2</td> <td>*</td> <td>*</td> </tr> <tr> <td>3</td> <td>Male-G3</td> <td>*</td> <td>*</td> </tr> <tr> <td>4</td> <td>Female-G1</td> <td>*</td> <td>*</td> </tr> </tbody> </table>				No.	Normal Range Name	Min	Max	1	Male-G1	*	*	2	Male-G2	*	*	3	Male-G3	*	*	4	Female-G1	*	*
No.	Normal Range Name	Min	Max																							
1	Male-G1	*	*																							
2	Male-G2	*	*																							
3	Male-G3	*	*																							
4	Female-G1	*	*																							
Normal	Sampling	Sample (µL)	Diluent (µL)	Technical Range																						
<input type="checkbox"/> Dilution	2.0			(Conc)	1.0	- 50.0																				
	Rerun (High/Prozone)			(mAbs/10)		-																				
<input type="checkbox"/> Dilution	2.0																									
	Rerun (Low)																									
<input type="checkbox"/> Dilution	2.0			SPT Wash	<input type="checkbox"/> Enable	Reagent Name																				
				Stirring Speed	R1 Middle	R2																				

*Entered by user

Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method No.	*	Name	HCO3	Sample	Serum	
Limit Checks	Blank measurement					
<input checked="" type="checkbox"/> Duplicate Limit	50	mAbs/10		Blank measurement:		
<input checked="" type="checkbox"/> Sensitivity Limit	1100	mAbs/10		Disable reagent blank and S1 blank		
<input type="checkbox"/> Linearity Limit		%	(mAbs/10)/min	Measurement of Reagent Blank during Run:		
<input type="checkbox"/> Prozone Limit		%	Upper	None		
SL1-S		-	SL1-F	Reagent blank measurement at calibration:		
SL2-S		-	SL2-F	Reagent blank (No sample)		
Sensitivity		mAbs/10		The number of measurement:		
<input type="checkbox"/> Absorbance Limit				Duplicate		
Reaction	Decrease			Reagent blank limit checks:		
Limit	25000	mAbs/10		<input checked="" type="checkbox"/> Duplicate Limit	20	mAbs/10
	Instrument Factor					
	a	1.00	b	0.00		

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer Analytical Parameters

Method Name

Sample

Sampling

Check Interval days

Auto

Auto Interval hour

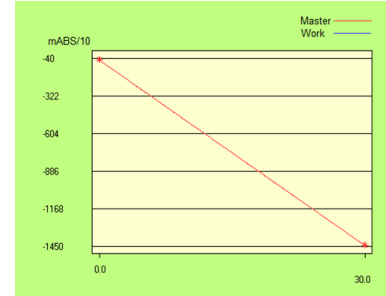
Type Lot

Material Name

R Lot No.
R1

R2

Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Lot No. (S)	<input type="checkbox"/> All
S1	0.0	Automatic entry	Automatic entry		
S2	*	Automatic entry	Automatic entry		
S3	*				
S4	*				
S5	*				
S6	*				
S7	*				

Reagent blank mAbs/10 Last

Blank mAbs/10 Last

Type Conc.

Absorbance mAbs/10

K S1 Blank Reagent Blank for S1

*Entered by user