Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO_2 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

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 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

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 laboratory practice.
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 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

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
Alte Strasse 9 65558 Holzheim Germany

Bicarbonate FS

Chemistry code 100 12

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	HCO3	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Bicarbonate	MethodColor		R1	HCO3	172	
Sample Type	Serum			R2	Disable		
Unit	mmol/L			Diluent	Disable		
Assay Type	End			Sample Ppt. Wash	Disable		

Measuring points

	Start		End
1	2	–	3
2	37	–	38

Stirring Speed R1: Middle R2:

Wave Length: Prim. 415 Sec. 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) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐	Diluent	0.0 <	1.7 <	0.0		
	Rerun (High/Prozone)					
☐	Diluent	0.0 <	1.7 <	0.0		
	Rerun (Low)					
☐	Diluent	0.0 <	1.7 <	0.0		

Technical Range (Conc) 1.0 – 50.0; (mAbs/10) * – *

Previous Result Comparison (%) * * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * – *

Decimal Point 1 Profile SI Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name HCO3 Sample Serum

Limit Checks

- ✓ Duplicate Limit 50 mAbs/10
- ✓ Sensitivity Limit 1100 mAbs/10
- ☐ Linearity Limit %
  (mAbs/10)/min
- ☐ Prozone Limit Higher %
  SL1-S – SL1-F
  SL2-S – SL2-F
  Sensitivity mAbs/10
- ☐ Absorbance Limit
  Abs. in reaction Decrease
  Limit 25000 mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:

- ✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

Bicarbonate FS

Chemistry code 100 12

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name HCO3

Sample Type Serum

Replication Duplicate

Check Interval 28

Test without calibration
Disable

Calibration Type Linear

Reagent Lot New Add

Calibrator Name HCO3 Standard

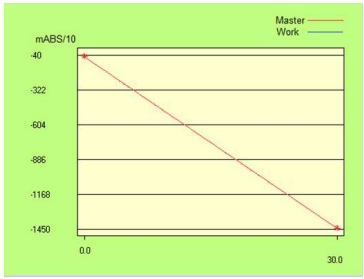
	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	0.0	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K Automatic entry

☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *

Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

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Bicarbonate FS

Chemistry code 100 12

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	HCO3		
Print Name	Bicarbonate			Reagent Name	Reagent (µL)	Water (µL)
Sample	Serum	R1		HCO3	200	
Unit	mmol/L	R2 ☐ Enable				
Assay Type	End	Diluent ☐ Enable				

Measuring points

		Start		End
	1	3	–	4
✓ Enable	2	54	–	55

Decimal Points: 1

Wave Length
Prim. 415 Sec ☐ Disable 510

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sampling	Sample (µL)	Diluent (µL)
☐ Dilution	2.0		
Rerun (High/Prozone)			
☐ Dilution	2.0		
Rerun (Low)			
☐ Dilution	2.0		

Technical Range
(Conc) 1.0 – 50.0
(mAbs/10) –

SPT Wash ☐ 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

✓ Duplicate Limit	50	mAbs/10	
✓ Sensitivity Limit	1100	mAbs/10	
☐ Linearity Limit		%	(mAbs/10)/min
☐ Prozone Limit		% Upper	
SL1-S		– SL1-F	
SL2-S		– SL2-F	
Sensitivity		mAbs/10	
☐ Absorbance Limit			
Reaction	Decrease		
Limit	25000	mAbs/10	

Blank measurement

Blank measurement:
Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 20 mAbs/10

Instrument Factor
a 1.00 b 0.00

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: HCO3

Sample: Serum

Sampling: Duplicate

Check Interval: 28 days

Auto: Change Lot Full Calibration

Auto Interval: hours

Type: Linear Lot: New

Material Name: HCO3 Standard

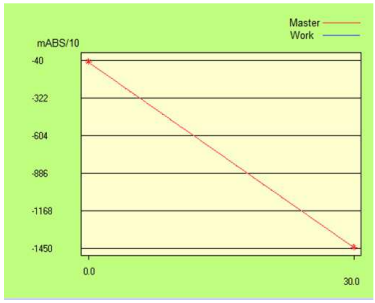
	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0.0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * Last:

R2: *



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation