

## BICARBONATE FL

BR F060 CH	6 x 10 ml
BR F245 CH	12 x 20 ml
BR F400 CH	4 x 100 ml

### INTENDED USE

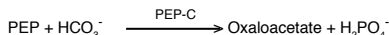
Reagent for quantitative *in vitro* determination of bicarbonate in biological fluids.

### SUMMARY OF TEST

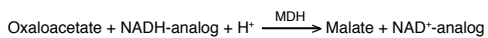
Bicarbonate is the second largest fraction of the anions in plasma. Total carbon dioxide (CO<sub>2</sub>) content of plasma consists of carbon dioxide dissolved in an aqueous solution (dCO<sub>2</sub>), CO<sub>2</sub> loosely bound to amine groups in proteins (carbamino compounds), HCO<sub>3</sub><sup>-</sup> and small amounts of carbonate (CO<sub>3</sub><sup>2-</sup>) ions, and carbonic acid (H<sub>2</sub>CO<sub>3</sub>).

### PRINCIPLE OF THE METHOD

Bicarbonate reacts with phosphoenolpyruvate (PEP), in the presence of phosphoenolpyruvate carboxylase (PEP-C), to form oxaloacetate and phosphate.



The oxaloacetate is then converted to malate by the action of malate dehydrogenase (MDH) and reduced nicotinamide adenine dinucleotide analog (NADH-analog).



The decrease in absorbance at 405 or 415 nm resulting from the oxidation of NADH analog is proportional to the amount of CO<sub>2</sub> in the sample.

### KIT COMPONENTS

For *in vitro* diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

<b>CO2 R1</b>	<b>F060:</b> 6 x 10 ml (liquid) blue cap
	<b>F245:</b> 12 x 20 ml (liquid) blue cap
	<b>F400:</b> 4 x 100 ml (liquid) blue cap

Composition: Buffer 0.1 M, PEP 10 mM, PEP-C > 100 U/l, MDH > 1000 U/l, NAD-analog 0.5 mM, stabilizer and preservative.

**Standard:** bicarbonate solution 30 mmol/l - 5 ml

Store all components at 2-8°C.

### MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micro-pipettes. Glass or high quality polystyrene cuvettes. Saline solution.

### REAGENT PREPARATION

Use single reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: preferably within 60 days at 2-8°C keep away from direct light sources.

### PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

### SPECIMEN

Serum, heparin plasma.

Specimens should be protected from direct exposure to light. Samples stored at 2-8°C in the dark and in closed vials are stable up to 3 days and 1 month at -20°C.

### TEST PROCEDURE

Wavelength:	415 nm (allowed 400 ÷ 415 nm)
Lightpath:	1 cm
Temperature:	37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml

incubate at 37°C for 5 minutes

water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 µl

Mix, incubate 1 minute at 37°C, then record absorbance against reagent blank as A<sub>1</sub>. After exactly 5 minutes, record again absorbance as A<sub>2</sub>.

### RESULTS CALCULATION

serum/plasma sample:

$$\text{Bicarbonate (mmol/l)} = \frac{A_2 - A_1 (\text{sample})}{A_2 - A_1 (\text{standard})} \times \text{standard value}$$

### EXPECTED VALUES

Newborn:	13 - 22 mmol/l - mEq/l
Infant, child:	20 - 28 mmol/l - mEq/l
Adults:	22 - 29 mmol/l - mEq/l
Adults > 60yr:	23 - 31 mmol/l - mEq/l

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

### QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose a suitable human based control sera has to be used.

Please contact Customer Care for further information.

### TEST PERFORMANCE

#### Linearity

the method is linear up to 50 mmol/l.

If the limit value is exceeded, it is suggested to dilute sample 1+4 with distilled water and to repeat the test, multiplying the result by 5.

#### Sensitivity/limit of detection (LOD)

the limit of detection is 0.7 mmol/l.

#### Interferences

no interference was observed by the presence of:

lipids	≤ 1700 mg/dl
bilirubin	≤ 70 mg/dl
hemoglobin	≤ 1000 mg/dl

#### Precision

intra-assay (n=10)	mean (mmol/l)	SD (mmol/l)	CV%
sample 1	13.78	0.12	0.87
sample 2	35.72	0.27	0.76

inter-assay (n=20)	mean (mmol/l)	SD (mmol/l)	CV%
sample 1	14.43	0.86	5.97
sample 2	35.59	1.09	3.05

#### Methods comparison

a comparison between Chema and a commercially available product gave the following results:

$$\begin{aligned} \text{Bicarbonate Chema} &= x \\ \text{Bicarbonate competitor} &= y \\ n &= 86 \end{aligned}$$

$$y = 1.037x - 0.191 \text{ mmol/l} \quad r^2 = 0.992$$

### WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.








### REFERENCES

- HU Bergmeyer - Methods of enzymatic analysis, third edition, Vol. VII (1987) p. 572.  
Norris K.A., Atkinson A.R. and Smith W.G. - Clin. Chem. 1093-1101, 21/8 (1975)  
Forrest R.L., Wataji L.J., Silverman D.A. and Pierre K.J. - Clin. Chem. 243-245, 22/2 (1976)  
Peled N. - Clin. Chem. 199-200, 27/1 (1981)

### MANUFACTURER

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### SYMBOLS

	<i>in vitro</i> diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use