

ACCENT-300 CARBAMAZEPINE

DIAGNOSTIC KIT FOR DETERMINATION OF CARBAMAZEPINE CONCENTRATION

INTRODUCTION

Carbamazepine is an anticonvulsant used in generalized tonic - clonic and partial seizures. Also it is used to treat bipolar disorders, schizophrenia and neuralgias, especially trigeminal neuralgia. Carbamazepine is metabolized in the liver to more than 30 different metabolites, including pharmacologically active oksycarbamazepine. Monitoring carbamazepine concentration in serum is recommended because of a narrow therapeutic range, interactions with other drugs and also an influence of proteins disorders and patient's age and condition on therapeutic drug metabolism.

METHOD PRINCIPLE

Immunoturbidimetric method; inhibition of agglutination. Increase of absorbance measured at $\lambda = 600$ nm is inversely proportional to the concentration of carbamazepine in the sample. Carbamazepine which is present in the sample forms immune complexes with specific antibody contained in the first reagent. After adding a second reagent containing polystyrene latex particles coated with carbamazepine, agglutination is inhibited in proportion to carbamazepine concentration in the sample.

REAGENTS

Package

1-Reagent	2 x 14.5 ml
2-Reagent	1 x 8.5 ml

Unopened reagents stored at 2-8°C are stable up to the expiry date printed on the package. After opening the reagents are stable for 21 days on board the analyser at 2-10°C. Protect from light!

Reagents composition:

Bis-Tris buffer, monoclonal antibodies to carbamazepine, polystyrene latex particles coated with carbamazepine, sodium azide (< 0.1%).

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents should be used by suitably qualified laboratory personnel only in accordance with intended purpose.
- The reagents contain sodium azide as a preservative (< 0.1 %). Avoid contact with skin and mucous membranes. Sodium azide can form high explosive metal azide combinations with lead and copper. Drains should be flushed well with a large amount of water when discarding the solution.
- Mix well Reagent 2 before first use. Avoid foam formation.
- For optimal reagents stability it is recommended to remove them from the system and store in tightly closed bottles at 2-8°C.

SPECIMEN

Serum. Samples may be stored up to 3 days at 2-8 °C or longer at -20°C. Nevertheless it is recommended to perform the assay with freshly collected samples! Avoid repeated freezing and thawing. Mix well the samples before analysis.

PROCEDURE

This reagent may be used in automatic analyser ACCENT-300. 1-Reagent and 2-Reagent are ready to use. For reagent blank deionized water is recommended.

APPLICATION

Parameters

No.	71	Prim.Wave.	600
Test	CARB	Sec.Wave.	
Method	Endpoint	Sample Vol.	3
Direction	Ascend	R1 Vol.	220
Unit	µg/ml	R2 Vol.	60
Decimals	2	Line. Limit	20

Incubation	10	Antigen Check	
Reaction	-1 25	Substrat	0

R1 Blank

Lower	0	Mix. R Blank	
Upper	0	Lower	0
		Upper	0

Response

Lower	-2.5	Linearity	
Upper	2.5	Lower	
		Upper	

S. volume	45	Full Name	Carbamazepine
Ratio	5	Print No.	71

Calibration

Method	Spline
K Factor	
Replicates	1
Interval	0
Sensitivity	0
Coefficient	0
Rerun Error Limit	0 2.5
Blank Response	0 2.5
Difference Limit	0
SD	0

THERAPEUTIC RANGE

therapeutic concentration 4-12 µg/ml (16.9-50.8 µmol/l)

Some patients achieve the desired therapeutic response at levels outside this range, so it is recommended to consider the need to establish an individual therapeutic ranges for each patient.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY TDM CONTROLS (Cat. No 5-107) with each batch of samples. For the calibration of automatic analysers systems the CORMAY CARBAMAZEPINE CALIBRATORS (Cat. No 5-112) is recommended.

The calibration curve should be prepared every 7 days, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

Metrological characteristics may differ from values presented below with the instrument used.

- Sensitivity / Limit of Detection:** 0.33 µg/ml (1.4 µmol/l).
- Linearity:** up to 20 µg/ml (84.6 µmol/l). If the carbamazepine concentration exceeds 20 µg/ml, dilute the sample 1:8 with saline solution and repeat the assay. The dilution take into account when making the results.
- Specificity / Interferences**
Bilirubin up to 20 mg/dl, haemoglobin up to 0.5 g/dl, fatty acids up to 3 g/dl do not interfere with the test.

▪ **Precision**

Repeatability (run to run) n = 10	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.69	0.11	4.0
level 2	8.45	0.28	3.3
level 3	14.35	0.55	3.8

Reproducibility (day to day) n = 10	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.76	0.23	8.2
level 2	8.32	0.48	5.7
level 3	13.95	0.45	3.2

▪ **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 50 samples gave following results:

$$y = 0.9395x + 0.6698 \text{ µg/ml};$$

$$R = 0.9837 \quad (R - \text{correlation coefficient})$$

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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