Cat. No 4-234 and 4-434

PRESTIGE 24i CARBAMAZEPINE

DIAGNOSTIC KIT FOR DETERMINATION OF CARBAMAZEPINE CONCETRATION

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 λ = 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 polistyrene latex particles coated with carbamazepine, agglutination is inhibited in proportion to carbamazepine concentration in the sample.

REAGENTS

Package

	Cat. No 4-234 (24-TRAY)	**Cat. No 4-434 (36-TRAY)**
1-Reagent	2 x 19.5 ml	2 x 18.5 ml
2-Reagent	2 x 6.5 ml	2 x 6 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, polistyrene 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 cooper. 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

These reagents may be used in automatic analysers Prestige 24i, Biolis 24i and Sapphire 400.
1-Reagent and 2-Reagent are ready to use.

1-Reagent put on basic position in reagent tray.
2-Reagent put on start position in reagent tray.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Item name	**CARB**

Data information

Units	**µg/ml**
Decimals	**2**

Analysis

Type	**END**
Main W.Length1	**600**
Sub W.Length2	
Method	**Immunoturbidymetric**

Corr

	Slope		Inter
Y=	**1.000**	X+	**0.000**

Calibration

Type	**Linear**
Factor	

Standard

#1	*	#4	*
#2	*	#5	*
#3	*	#6	*

Normal Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Aspiration

Kind	**Double**

	Volume	
Sample	**3**	µl
Reagent1	**300**	
Reagent2	**80**	

Third Mix.	**OFF**
R1 Blank	**Water-B**

Monitor

0 Level Point	**1**
Span	**3.000**

Data Process

Read			**Absorbance Limit**	
	Start	End		
Main	**53**	**54**	Low	**0.000**
Sub	**34**	**35**	High	**3.000**

Factor		Endpoint Limit	**2.000**
Blank correction:	**1.0000**	Linear Check (%)	**90%**

Dilution

Diluent	**100 : Dil2**

Prozone Check

	Start	End	Limit (%)	
First				
Second				**Low**
Third				**Low**

Auto Rerun SW

ON

Auto Rerun Range (Result)

	OFF	**OFF**
	Lower	Higher
Serum		
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range		
	Lower	**OFF**
	Higher	**OFF**
Prozone Range		**OFF**

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) 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 µg/ml;
R = 0.9837 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Oellerich, M. Therapeutic drug monitoring. In: Thomas L, ed. Clinical Laboratory Diagnostics. Use and Assesment of Clinical Laboratory Results. 1st Edition. TH-Books, Frankfurt/Main, Germany, 1998.
2. Biosafety in Microbiological and Biomedical Laboratories, Richmond JY, McKinney RW, eds. US Department of Health and Human Services, 4th Edition, 1999.
3. Westgard JO, Barry PL. Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes, AACC Press, 1986.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th Edition, AACC Press, 2000.
5. Tietz NW. Clinical Guide to Laboratory Tests. WB Saunders Company, Philadelphia, 1990.
6. Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 1456 (2006).

Date of issue: 09. 2012.

MANUFACTURER

PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLAND
tel.: +48 (0) 81 749 44 00
fax: +48 (0) 81 749 44 34
http://www.pzcormay.pl

09/12/09/12