Cat. No 7-382

ACCENT 300

CE CORMAY

ACCENT-300 GENTAMICIN

DIAGNOSTIC KIT FOR DETERMINATION OF GENTAMICIN CONCETRATION

INTRODUCTION

Gentamicin is an aminoglycoside antibiotic, used to treat many types of bacterial infections. It works by interrupting bacterial protein synthesis. Gentamicin is not absorbed from the alimentary tract and metabolized in the liver. It is eliminated unchanged in the urine (80-90%). Monitoring gentamicin concentration in serum is recommended because of the a narrow therapeutic range, oto- and nephrotoxic side effects occurring with prolonged (more than 7 days) treatment with high doses of gentamicin and also because of large intersubject variability in pharmacokinetic parameters.

METHOD PRINCIPLE

Immunoturbidimetric method; inhibition of agglutination.
Increase of absorbance measured at λ = 700 nm is inversely proportional to the concentration of gentamicin in the sample.
Gentamicin 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 gentamicin, agglutination is inhibited in proportion to gentamicin concentration in the sample.

REAGENTS

Package

1-Reagent	2 x 14.5 ml
2-Reagent	1 x 9.5 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 gentamicin, polistyrene latex particles coated with gentamicin, 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

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.	74	Prim.Wave.	700
Test	GENT	Sec.Wave.	
Method	Endpoint	Sample Vol.	3
Direction	Ascend	R1 Vol.	230
Unit	µg/ml	R2 Vol.	70
Decimals	2	Line. Limit	20
Incubation	10	Antigen Check	
Reaction	-2 | 30	Substrat	0
R1 Blank		**Mix. R Blank**	
Lower	0	Lower	0
Upper	0	Upper	0
Response		**Linearity**	
Lower	-2.5	Lower	
Upper	2.5	Upper	
S. volume	45	Full Name	Gentamicin
Ratio	5	Print No.	74

Calibration

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

THERAPEUTIC RANGE

Therapeutic concentration:

C_{max}*:	severe infections	8-10 µg/ml (16.7-20.9 µmol/l)
	less severe infections	5-8 µg/ml (10.4-16.7 µmol/l)
C_{min}*:	severe infections	< 2-4 µg/ml (< 4.2-8.4 µmol/l)
	moderate infections	< 2 µg/ml (< 4.2 µmol/l)
	less severe infections	< 1 µg/ml (< 2.1 µmol/l)

* maximum and minimum drug concentration in blood

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 GENTAMICIN CALIBRATORS (Cat. No 5-110) 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:** 0.07 µg/ml (0.15 µmol/l).

- **Linearity:** up to 10 µg/ml (20.9 µmol/l). If the gentamicin concentration exceeds 10 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**

Haemoglobin up to 0.5 g/dl, bilirubin up to 20 mg/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	3.06	0.037	1.21
level 2	6.09	0.121	1.98
level 3	7.69	0.269	3.50

Reproducibility (day to day) n = 10	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	3.05	0.070	2.28
level 2	6.11	0.126	2.06
level 3	7.87	0.290	3.69

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 50 samples gave following results:
$y = 0.9284x + 0.0365$ µg/ml;
$R = 0.9931$ (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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Date of issue: 11. 2009.

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

11/09/01/10