DRI® Primidone Assay

CE

Kit Configuration

P/N W150291	1 x 25 mL Antibody/substrate R1
	1 x 8 mL Enzyme Conjugate R2

Reagent Preparation

P/N 150291: PRIM R1: Ready to use.
PRIM R2: Ready to use.
Place the bottles into reagent tray.

In Use Stability

Stable until the expiration date shown on the vial when stored at 2-8°C. For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

Specimen

Serum or plasma.

Calibration

Use Primidone calibrator multipoint Cat. No 15100185. Recalibrate the instrument when new reagents are used. A reagent blank should be run daily before sample analysis.

Quality Control

Use TDM control 3 levels. Cat. No 15755095.

Calculation of Analytical Results

The results concentration is automatically calculated by the instrument against the Calibration curve. For detailed description, refer to the Instrument settings and to the ILab 600/650 Operator's Manual.

Therapeutic Range

In most patients, a serum primidone therapeutic range of 5-12 µg/mL (17-51µmol/L) can effectively suppress seizures without apparent side effects. Serum primidone concentrations above 15 µg/mL are often associated with toxicity.[2] The therapeutic range is provided only as a general guide.

References / Literatur / Bibliografía / Bibliographie / Bibliografia /

See package insert enclosed in the kit

Performance Characteristics

Limitation/Interfering Substances

No interference with hemolyzed, lipemic and icteric samples was found with hemoglobin, cholesterol and bilirubin up to a concentration of 800 mg/dL, 400 mg/dL and 34 mg/dL, respectively.
For a comprehensive review of interfering substances, refer to the publication by Young *et al*.[1]

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Instrument Settings

Photometric Test Parameters		***Serum***
Test No.		**
Test Name, Test Code		PRIM, PRIM
Sample Type		Serum
Reporting Unit, Decimal Points		µg/mL, 2
Reation Cycle		Standard
Twin Analysis		OFF
Methodology Type, Measuring Point		Rate, 21/25
Photometric Methodology		2 Wavelength
Primary/Secondary Wavelenght		340 - 510
Sampling Conditions		
Sampling 1	Sample Vol.	10
	Sample/Diluent Vol.	0/0
Sampling 2	Sample Vol.	5
	Sample/Diluent Vol.	0/0
Sampling 3	Sample Vol.	20
	Sample/Diluent Vol.	0/0
Sampling 4		0
Diluent Code		Water
Diluent Warning Limit		***
First Run		Sampling 1
Below/Above Normal Range		***
Panic L		Sampling 3
Panic H		Sampling 2
Noise		Sampling 1
Prozone		N/A
High!, ABS!		Sampling 2
Sample Volume Reduction		**
Reagent Volumes		
R1	Code	PRI 1
	Rgt/Dil. Vol. Stirring	210/0, ON
	Low Vol. Warning Limit	0
	Stability (days)	**
R2	Code	PRI 2
	Rgt/Dil. Vol. Stirring	70/0, ON
	Low Vol. Warning Limit	0
	Stability (days)	**

Ranges and Evaluation Criteria	***Serum***
Normal Range-Male	5 - 12
Normal Range-Female	5 - 12
Normal Range-Other	5 - 12
Valid Range	1 - 24
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	Above, 0, None, 0
Non Linear Limit	0
Slope/Intercept Correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	Multi Points,4PLog,2 Reps
Stability (days)	**
Calibrator, Concentration	Primi Std, *
R-Blank Limit (mAbs)	3500
Cal. Reps Range (%)	***
Min Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	***
Reagent Blank	ON
Auto R-Blank by Bottle	OFF

*	Lot dependent
**	operator definable
***	optional
N/A	not applicable to this test