MAYO CLINIC LABORATORIES

Test Definition: PRMB

Primidone and Phenobarbital, Serum

Overview

Useful For

Assessing compliance

Monitoring for appropriate therapeutic levels of primidone and phenobarbital

Assessing toxicity

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
PRIMD	Primidone, S	No	Yes
PBR	Phenobarbital, S	Yes	Yes

Testing Algorithm

Includes phenobarbital determination.

Method Name

PRIMD: Enzyme Immunoassay (EIA)

PBR: Kinetic Interaction of Microparticles in a Solution (KIMS)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged, and the serum aliquoted into a plastic vial within 2 hours of collection.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Neurology Specialty Testing Client Test Request (T732)
-Therapeutics Test Request (T831)

Specimen Minimum Volume
0.25 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	72 hours	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information
Primidone is used for control of grand mal seizures that are refractory to other antiepileptics and seizures of psychomotor or focal origin.

Primidone is initially dosed in progressively increasing amounts starting with 100 mg at bedtime to 250 mg 3 times a day after 10 days of therapy in adults.

Primidone exhibits a volume of distribution of 0.6 L/kg and a half-life of 8 hours.

When monitoring primidone and phenobarbital levels simultaneously, the specimen should be drawn just before the next dose is administered.

Primidone is not highly protein bound, approximately 10%. Phenobarbital is a metabolite of primidone. Like phenobarbital, there are no known major drug-drug interactions that affect the pharmacology of primidone. Toxicity associated with primidone is primarily due to the accumulation of phenobarbital. Diagnosis and treatment are as described for PBAR / Phenobarbital, Serum.

Reference Values
Primidone
Therapeutic: 5.0-12.0 mcg/mL
Critical value: > or =15.0 mcg/mL

Phenobarbital

Therapeutic: 10.0-40.0 mcg/mL
Critical value: > or =60.0 mcg/mL

Interpretation

At steady-state, which is achieved approximately 2 weeks after therapy is initiated, blood levels of primidone that correlate with optimal response to the drug range from 9.0 to 12.5 mcg/mL for adults and 7.0 to 10.0 mcg/mL for children younger than 5 years.

The corresponding levels for phenobarbital are 20.0 to 40.0 mcg/mL for adults and 15.0 to 30.0 mcg/mL for children younger than 5 years.

Dosage adjustment based on blood level information is the best way to obtain optimal response to the drug.

Cautions

The phenobarbital level should be monitored at the same time the primidone level is monitored as phenobarbital is a metabolite of primidone.

Clinical Reference

1. Lenkapothula N, Cascella M. Primidone. In: StatPearls [Internet]. StatPearls Publishing; 2024. Updated July 24, 2023. Available at www.ncbi.nlm.nih.gov/books/NBK562297/
2. Aronson J. Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions. 16th ed. Elsevier; 2016:927-932. doi.org/10.1016/B978-0-444-53717-1.01336-6

Performance

Method Description

Primidone
The assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in biological fluids. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PD) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD[+]) to NADH (the reduced form of NAD), resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PD does not interfere, because the coenzyme functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.(Package insert: Siemens Primidone reagent. Siemens Healthcare Diagnostics Ltd; 04/2020)

Phenobarbital
The assay is based on the kinetic interaction of microparticles in a solution (KIMS). Phenobarbital antibody is covalently coupled to microparticles and the drug derivative is linked to a macromolecule. The kinetic interaction of microparticles in solutions is induced by binding of drug-conjugate to the antibody on the microparticles and is inhibited by the presence of phenobarbital in a sample. A competitive reaction takes place between the drug conjugate and phenobarbital in the serum sample for binding to the phenobarbital antibody on the microparticles. The resulting kinetic interaction of microparticles is indirectly proportional to the amount of drug present in the sample.(Package insert: ONLINE TDM Phenobarbital reagent. Roche Diagnostics; 01/2024)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 day

Specimen Retention Time
1 week

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
PRIMD-80188
PBR-80184

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PRMB	Primidone and Phenobarbital, S	10547-8

Result ID	Test Result Name	Result LOINC® Value
PBR	Phenobarbital, S	3948-7
PRIMD	Primidone, S	3978-4