Overview

Useful For
Assessing compliance
Monitoring for appropriate therapeutic levels of primidone and phenobarbital
Assessing toxicity

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIMD</td>
<td>Primidone, S</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>PBR</td>
<td>Phenobarbital, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Testing Algorithm
Includes phenobarbital determination.

Method Name
PRIMD: Immunoassay
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

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 aliquoted within 2 hours of collection.
Test Definition: PRMB
Primidone and Phenobarbital, S

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

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
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Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
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<tr>
<td></td>
<td>Frozen</td>
<td>28 days</td>
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<tr>
<td></td>
<td>Ambient</td>
<td>72 hours</td>
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Clinical and 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 <5 years of age.

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 <5 years of age.

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

**Cautions**

At the same time that the primidone level is monitored, one should also monitor the phenobarbital level, as phenobarbital is a metabolite of primidone.

**Clinical Reference**


**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 (G6PDH) 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 G6PDH 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., Newark, DE)

**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 the 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: Roche Phenobarbital reagent, Roche Diagnostic Corp, Indianapolis, IN)

**PDF Report**

No
Day(s) and Time(s) Test Performed
Monday through Sunday; Continuously

Analytic Time
Same day/1 day

Maximum Laboratory Time
1 day

Specimen Retention Time
1 week

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. 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

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<th>Order LOINC Value</th>
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<td>PRMB</td>
<td>Primidone and Phenobarbital, S</td>
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<th>Result LOINC Value</th>
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<tr>
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