

## Overview

### Useful For

Monitoring therapy

Determining compliance

Assessing toxicity

### Method Name

Homogeneous Microparticle Agglutination Immunoassay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum Red

### Ordering Guidance

This test measures carbamazepine only. For assessment of its active metabolite, carbamazepine-10,11-epoxide, which is the predominant form in children, order CARBG / Carbamazepine-10,11-Epoxyde, Serum)

### Specimen Required

**Collection Container/Tube:** Red top

**Specimen Volume:** 0.5 mL

**Submission Container/Tube:** Plastic vial

**Collection Instructions:** Centrifuge and aliquot serum 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 Red     | Refrigerated (preferred) | 7 days   |                   |
|               | Frozen                   | 28 days  |                   |
|               | Ambient                  | 48 hours |                   |

**Clinical & Interpretive****Clinical Information**

Carbamazepine (Tegretol) is used in the control of partial seizures with both temporal lobe and psychomotor symptoms as well as for generalized tonic-clonic seizures. It is also used for analgesia in trigeminal neuralgia.

Carbamazepine exhibits a volume of distribution of 1.4 L/kg with an elimination half-life of 15 hours. Protein binding averages 70%.

Carbamazepine-10,11-epoxide (CBZ10-11) is an active metabolite that represents the predominant form of the drug in children. The volume of distribution of CBZ10-11 is 1.1 L/kg, and the half-life is 5 to 8 hours.

Aplastic anemia and agranulocytosis are rare side effects of treatment with carbamazepine; baseline hematologic data should be documented before treatment is initiated.

Toxicity associated with carbamazepine overdose occurs when the blood level is 15.0 mcg/mL or higher and is typified by irregular breathing, muscle irritability, and hyperreflexia; followed by hyporeflexia, tachycardia, hypotension, and impaired consciousness with coma in severe toxicity. The higher the blood level, the more severe the symptoms.

**Reference Values**

Therapeutic: 4.0-12.0 mcg/mL

Critical value: > or =15.0 mcg/mL

**Interpretation**

Dosage adjustments are usually guided by monitoring blood levels. Most patients respond well when the serum concentration is in the range of 4.0 to 12.0 mcg/mL. Toxicity often occurs when levels are greater than or equal to 15.0 mcg/mL.

**Cautions**

Carbamazepine-10,11-epoxide (CBZ10-11) is not reported. A separate orderable test for this active metabolite is available (CARBG / Carbamazepine-10,11-Epoxide, Serum). Optimal response occurs when the CBZ10-11 serum level is in the range of 0.4 to 4.0 mcg/mL.

**Clinical Reference**

1. Cereghino JJ, Meter JC, Brock JT, Penry JK, Smith LD, White BG: Preliminary observations of serum carbamazepine concentration in epileptic patients. *Neurology*. 1973 Apr;23(4):357-366. doi: 10.1212/wnl.23.4.357

2. Patsalos PN, Berry DJ, Bourgeois BF, et al: Antiepileptic drugs--best practice guidelines for therapeutic drug monitoring: a position paper by the subcommission on therapeutic drug monitoring, ILAE Commission on Therapeutic Strategies. *Epilepsia*. 2008 Jul;49(7):1239-1276. doi: 10.1111/j.1528-1167.2008.01561.x
3. Scheuer ML, Pedley TA: The evaluation and treatment of seizures. *N Engl J Med*. 1990 Nov 22;323(21):1468-1474. doi: 10.1056/NEJM199011223232107
4. Milone MC, Shaw LM: Therapeutic Drug Monitoring. In: Rifai N, Horvath AR, Wittwer CT, eds. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics*. 8th ed. Saunders; 2019:549
5. Patsalos PN, Zugman M, Lake C, James A, Ratnaraj N, Sander JW. Serum protein binding of 25 antiepileptic drugs in a routine clinical setting: a comparison of free non-protein-bound concentrations. *Epilepsia*. 2017 Jul;58(7):1234-1243. doi: 10.1111/epi.13802

## Performance

### Method Description

The ONLINE TDM Carbamazepine Gen.4 assay is a homogeneous microparticle agglutination immunoassay. It is a 2-reagent system used for the detection of carbamazepine in serum. Kinetic interaction of microparticles will be measured using automated analyzers. In this technology biotinylated drug hapten attached to streptavidin coated latex beads serves as the binding partner to anti-carbamazepine antibody. A competitive reaction to a limited amount of specific anti-carbamazepine antibody takes place between the latex bound hapten and free carbamazepine in the serum sample. A decrease in the apparent signal is proportional to the amount of drug present in the sample. (Package insert: ONLINE TDM Carbamazepine Gen.4. Roche Diagnostics; 04/2016)

### PDF Report

No

### Day(s) Performed

Monday through Sunday

### Report Available

Same day/1 day

### Specimen Retention Time

7 days

### Performing Laboratory Location

Rochester

## 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.

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- 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**

80156

**LOINC® Information**

| Test ID | Test Order Name       | Order LOINC® Value |
|---------|-----------------------|--------------------|
| CARTA   | Carbamazepine, Tot, S | 3432-2             |

| Result ID | Test Result Name      | Result LOINC® Value |
|-----------|-----------------------|---------------------|
| CARTA     | Carbamazepine, Tot, S | 3432-2              |