MAYO CLINIC LABORATORIES

Test Definition: CARFT

Carbamazepine, Free and Total, Serum

Overview

Useful For

Monitoring carbamazepine (free and total) therapy in patients who are uremic

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
CARTA	Carbamazepine, Tot, S	Yes	Yes
CARF	Carbamazepine, Free, S	Yes	Yes

Method Name

CARF: Ultrafiltration Followed by Homogeneous Microparticle Agglutination Immunoassay

CARTA: Homogeneous Microparticle Agglutination Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum Red

Specimen Required

Container/Tube: Red top (serum gel/SST are not acceptable)

Submission Container/Tube: Plastic vial

Specimen Volume: 2 mL

Collection Instructions: Centrifuge and aliquot serum into a plastic vial within 2 hours of collection.

Forms

If not ordering electronically, complete, print, and send a Therapeutics Test Request (T831) with the specimen.

Specimen Minimum Volume

1 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum Red	Refrigerated (preferred)	7 days	
	Ambient	48 hours	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Carbamazepine (Tegretol) is an effective treatment for complex partial seizures, with or without generalization to tonic-clonic seizures. It is frequently administered in conjunction with other antiepileptic agents, such as phenytoin and valproic acid.

Under normal circumstances, 75% of the carbamazepine that circulates in blood is protein bound. In severe uremia, carbamazepine may be displaced from protein, resulting in a higher free (unbound) fraction of the drug circulating in blood. Since neurologic activity and toxicity are directly related to the circulating free fraction of drug, adjustment of dosage based on knowledge of the free carbamazepine level may be useful in patients with severe uremia.

Reference Values

CARBAMAZEPINE, TOTAL
Therapeutic: 4.0-12.0 mcg/mL
Critical value: > or =15.0 mcg/mL

CARBAMAZEPINE, FREE
Therapeutic: 1.0-3.0 mcg/mL
Critical value: > or =4.0 mcg/mL

Interpretation

In patients with normal kidney function, optimal response is often associated with free (unbound) carbamazepine levels greater than 1.0 mcg/mL, and toxicity may occur when the free carbamazepine is greater than or equal to 4.0 mcg/mL.

In uremic patients, the free carbamazepine level may be a more useful guide for dosage adjustments than the total level. In patients with severe uremia, subtherapeutic total carbamazepine levels in the range of 1.0 to 2.0 mcg/mL may be associated with therapeutic free levels. Toxicity may occur in these patients when the free carbamazepine level is greater than or equal to 4.0 mcg/mL (even though the total carbamazepine concentration is <15.0 mcg/mL).

As with the serum levels of other anticonvulsant drugs, total and free carbamazepine levels should be correlated with the patient's clinical condition. They are best used as a guide in dose adjustment.

Cautions

Fresh serum with normal protein content is required for optimal analysis.

Specimens subjected to significant heat or other factors that cause protein denaturation demonstrate an artifactually increased free carbamazepine.

If hemolysis, lipemia, or icterus exceed the analytical interference threshold, the testing will be canceled.

Clinical Reference

1. Svinarov DA, Pippenger CE. Relationships between carbamazepine-diol, carbamazepine-epoxide, and carbamazepine total and free steady-state concentrations in epileptic patients: the influence of age, sex, and comedication. Ther Drug Monit. 1996;18(6):660-665
2. Bernus I, Dickinson RG, Hooper WD, Eadie MJ. The mechanism of the carbamazepine-valproate interactions in humans. Br J Clin Phamacol. 1997;44(1):21-27
3. Dasgupta A, Volk A. Displacement of valproic acid and carbamazepine from protein binding in normal and uremic sera by tolmetin, ibuprofen, and naproxen: presence of inhibitor in uremic serum that blocks valproic acid-naproxen interactions. Ther Drug Monit. 1996;18(3):284-287
4. Moyer TP: Therapeutic drug monitoring. In: Burtis CA, Ashwood ER eds. Tietz Textbook of Clinical Chemistry. 4th ed. WB Saunders Company; 2005: 1237-1285
5. 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;49(7):1239-1276
6. Kanner A.M, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(2):74-81

Performance

Method Description

Carbamazepine:
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 anticarbamazepine antibody. A competitive reaction to a limited amount of specific anticarbamazepine 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: Carbamazepine reagent. Roche Diagnostics; 09/2021)

Free Carbamazepine:
Free carbamazepine is isolated from serum by ultrafiltration. 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 anticarbamazepine antibody. A competitive reaction to a limited amount of specific anticarbamazepine 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: Carbamazepine reagent. Roche Diagnostics; 09/2021)

PDF Report

No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 day

Specimen Retention Time
7 days

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
80156
80157

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CARFT	Carbamazepine, Free and Total, S	34545-4

Result ID	Test Result Name	Result LOINC® Value
CARTA	Carbamazepine, Tot, S	3432-2
CARF	Carbamazepine, Free, S	3433-0