MAYO CLINIC LABORATORIES

Test Definition: ARGAT

Argatroban, Ecarin, P

Overview

Useful For

Measuring argatroban concentration in plasma

This assay is **not useful for** measurement of other direct thrombin inhibitors eg, dabigatran or bivalirudin.

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Method Name

Chromogenic Assay

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit

Ordering Guidance

This test measures argatroban only. For measurement of dabigatran direct thrombin inhibitor, see DABIE / Dabigatran, Ecarin, Plasma.

This test is **not indicated for** monitoring low molecular weight heparin (LMWH), unfractionated heparin (UFH), or oral direct anti-Xa inhibitors (eg, apixaban, rivaroxaban, edoxaban). For monitoring oral direct anti-Xa inhibitors, see APIXA / Apixaban, Anti-Xa, Plasma; EDOXA / Edoxaban, Anti-Xa, Plasma, or RIVAR / Rivaroxaban, Anti-Xa, Plasma.

Necessary Information

If priority specimen, mark request form, give reason, and request a call-back.

Specimen Required

Specimen Type: Platelet-poor plasma

Collection Container/Tube: Light-blue top (3.2% sodium citrate)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Specimen should be collected 2 hours after initiation of continuous infusion of argatroban.
2. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing in Special Instructions.
3. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
4. Aliquot plasma into a plastic vial leaving 0.25 mL in the bottom of centrifuged vial.
5. Freeze plasma immediately (no longer than 4 hours after collection) at -20 degrees C or, ideally, < or =-40 degrees C.

Additional Information:

1. Double-centrifuged specimen is critical for accurate results as platelet contamination may cause spurious results.
2. Each coagulation assay requested should have its own vial.

Forms

If not ordering electronically, complete, print, and send a Coagulation Test Request (T753) with the specimen.

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Minimum Volume

0.5 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma Na Cit	Frozen (preferred)	42 days	

Clinical & Interpretive

Clinical Information

Argatroban, a parenteral direct thrombin inhibitor (DTI) that directly inhibits factor IIa, is indicated for use in patients with heparin-induced thrombocytopenia (HIT). Argatroban is administered via continuous infusion, is eliminated by the liver, and can inhibit both soluble and clot-bound thrombin. Argatroban effect is typically monitored using activated partial thromboplastin time (APTT) measurements with a target of 1.5 to 3.0 times the patient's baseline value. However, in instances where patients have a prolonged baseline APTT (eg, lupus anticoagulants and factor XII deficiency), APTT monitoring of argatroban is not reliable and measurement of argatroban's effect on factor IIa may be more reliable.

There are no clinical studies directly correlating argatroban concentration to clinical outcomes. The available data suggest that plasma concentrations of argatroban 1.2 to 2.3 mcg/mL correspond to an APTT ratio of 1.5 to 3.0.(1)

Reference Values

<0.10 mcg/mL

Interpretation

Therapeutic reference ranges have not been established. See Clinical Information for activated partial thromboplastin time correlative information.

Cautions

Routine monitoring of argatroban drug levels is not indicated, the recommended monitoring per product guidelines is with the activated partial thromboplastin time.

Argatroban concentration may be affected by drug interactions, liver and renal disease.

Marked presence of lipemia or bilirubin in the sample could falsely decrease argatroban levels.

Supportive Data

The lower limit of detection of this assay is 0.10 mcg/mL.

Clinical Reference

1. Ahmad S, Iqbal O, Ahsan A, et al: Clinical laboratory monitoring of a synthetic antithrombin agent, argatroban, using

high performance liquid chromatography and functional methods. Int Angiol. 1999;18:198-205
2. Argatroban Injection. Package insert: Sandoz, Inc; 2019
3. Van Cott EM, Roberts AJ, Dager WE: Laboratory monitoring of parenteral direct thrombin inhibitors. Semin Thromb Hemost. 2017;43: 270-276
4. Gosselin RC, King JH, Janatpour KA, et al: Comparing direct thrombin inhibitors using aPTT, Ecarin clotting times, and thrombin inhibitor management testing. Ann Pharmacother. 2004;38:1383-1388
5. Gosselin RC, Adcock DM, Bates SM, et al: International Council for Standardization in Haematology (ICSH) recommendations for laboratory measurement of direct oral anticoagulants. Thromb Haemost. 2018 Mar;118(3):437-450
6. Lind SE, Boyle ME, Fisher S, Ishimoto J, Trujillo TC, Kiser TH: Comparison of the aPTT with alternative tests for monitoring direct trombin inhibitors in patient samples. Am J Clin Pathol. May 2014;141:665-674
7. Curvers J, van de Kerkhof D, Stroobants AK, van den Dool EJ, Scharnhorst V: Measuring direct thrombin inhibitors with routine and dedicated coagulation assays. Am J Clin Pathol. 2012;138: 551-558
8. Seidel H, Kolde HJ: Monitoring of argatroban and lepirudin: what is the input of laboratory values in "real life"? Clin Appl Thromb Hemost .2018 Mar;24(2):287-294
9. Fenyvesi T, Jorg I, Harenberg J: Monitoring of anticoagulant effects of direct thrombin inhibitors. Semin Thromb Hemost. 2002;28(4):361-368

Performance

Method Description

The argatroban, ecarin chromogenic assay is performed on the Instrumentation Laboratory ACL TOP 700 using the Diagnostica Stago ECA II kit. The STA ECA II kit is a chromogenic assay based on the cleavage of prothrombin by ecarin to meizothrombin which then enzymatically cleaves the paranitroanaline (pNA) from the chromogenic substrate resulting in a measureable colorometric change.(Package insert: STA-ECA II. Diagnostica Stago S.A.S; Revision 09/2015)

PDF Report

No

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test was developed, and its performance characteristics 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

80299