Test Definition: DABIE

Dabigatran, Ecarin, P

Overview

Useful For

Measuring dabigatran concentration in plasma

This assay is **not useful for** measurement of other direct thrombin inhibitors eg, argatroban 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

Advisory Information

This test measures dabigatran only. For measurement of aragatroban direct thrombin inhibitor, see ARGAT / Argatroban, 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 drawn 1 to 3 hours (peak) after a dose or just prior (trough) to the next dose for dabigatran concentrations.

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.

Specimen Minimum Volume

0.5 mL

Reject Due To

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

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

Dabigatran, an oral direct thrombin inhibitor (DTI) that directly inhibits factor IIa, is indicated for use in patients with nonvalvular atrial fibrillation and venous thromboembolism. Dabigatran is administered orally twice daily, is eliminated primarily through the renal system, and can inhibit both soluble and clot-bound thrombin. Dabigatran does not require routine therapeutic monitoring. However, in selected clinical situations, measurement of drug level would be useful, eg, renal insufficiency, assessment of compliance, periprocedural, suspected overdose, advanced age, and extremes of body weight.

Observed dabigatran steady-state exposure concentrations

Nonvalvular atrial fibrillation(1)	**Median trough levels** (10-16 hours post dose)	**Median peak levels** (1-3 hours post dose)
110 mg twice daily	64.7 ng/mL (28.2-155)	126 ng/mL (52-275)
150 mg twice daily	91 ng/mL (39.8-215)	175 ng/mL (74.3-383)

Venous thromboembolism(2)	**Median trough levels** (10-16 hours post dose)	
150 mg twice daily	59.7 ng/mL (38.6-146)	

Reference Values

<20 ng/mL

Interpretation

Therapeutic reference ranges have not been established. See Clinical Information for peak and trough drug concentrations observed in clinical trials of dabigatran.

Cautions

Dabigatran concentration may be affected by drug interactions as well as liver and renal disease.

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

Supportive Data

The lower limit of detection of this assay is 20 ng/mL.

Clinical Reference

1. Reilly PA, Lehr T, Haertter S, et al: The effect of dabigatran plasma concentrations and patient characteristics on the frequency of ischemic stroke and major bleeding in atrial fibrillation patients: the RE-LY Trial. Am J Coll Cardiol. 2014;63:321-328

2. Pradaxa (dabigatran etexilate). Public Assessment Record. European Medicines Agency; 2008 Update January 23, 2020. Accessed June 19, 2020. Available at www.ema.europa.eu/en/medicines/human/EPAR/pradaxa

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.Â Am J Clin Pathol. 2012;138: 551-558

8. Fenyvesi T, Jorg I, Harenberg J: Monitoring of anticoagulant effects of direct thrombin inhibitors. Semin Thromb Hemost. 2002;28(4):361-368

9. PRADAXA (dabigatran etexilate). Package insert: Boehringer Ingelheim Pharmaceuticals, Inc; 2019

Performance

Method Description

The dabigatran, 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 -CA II. Diagnostica Stago S.A.S; Revision 09/2015)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; Varies

Analytic Time

1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

7 days

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 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 U.S. Food and Drug Administration.

CPT Code Information

80299

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
DABIE	Dabigatran, Ecarin, P	In Process

Test Definition: DABIE

Dabigatran, Ecarin, P

Result ID	Test Result Name	Result LOINC Value
DABI1	Dabigatran, Ecarin, P	74220-5
DABI2	Interpretation	69049-5
DABI3	Cautions	62364-5