MAYO CLINIC LABORATORIES

Test Definition: BIVAL

Bivalirudin, Ecarin, Plasma

Overview

Useful For

Monitoring of bivalirudin therapy for patients with prolonged baseline activated partial thromboplastin time

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Method Name

Chromogenic

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit

Ordering Guidance

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

Specimen Required

Specimen Type: Platelet-poor plasma

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

Submission Container/Tube: 13-mm x 75-mm, 5-mL, plastic vial (polypropylene preferred)

Specimen Volume: 1 mL Platelet-poor plasma

Collection Instructions:

1. Specimen should be collected 2 hours after initiation of continuous infusion of bivalirudin.
2. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing.
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, below -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

Platelet-poor plasma: 0.5 mL

Reject Due To

Thawing	Cold Reject; Warm reject

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 & Interpretive

Clinical Information

Bivalirudin, is a parenteral anticoagulant that directly inhibits thrombin (direct thrombin inhibitor), factor IIa. It is indicated for use in patients with unstable angina undergoing percutaneous coronary intervention (PCI), in those undergoing PCI with provisional use of glycoprotein IIb/IIIa inhibitor, or in those with, or at risk of, heparin- induced thrombocytopenia (HIT) or HIT and thrombosis syndrome (HITTS) undergoing PCI. In these indications, it is intended for use with aspirin.

Frequently, bivalirudin is used for prevention of treatment of thrombosis in patients with HIT with or without thrombosis and with kidney and/or hepatic dysfunction.

Bivalirudin is administered via continuous intravenous infusion, is removed by a combination of proteolytic cleavage by thrombin and renal clearance mechanisms and can inhibit both soluble and clot-bound thrombin.

Bivalirudin's effect is typically monitored using the activated partial thromboplastin time (aPTT) test with a target aPTT ratio of 1.5 to 2.5 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 bivalirudin is not reliable, and direct measurement of the effect of bivalirudin on factor IIa may be more reliable. For HIT, monitoring every 2 to 4 hours until in range and then once daily; for PCI, monitoring is unnecessary unless kidney failure is present.

Internal laboratory validation demonstrates that plasma concentrations of bivalirudin from 0.25 to 1.25 mcg/mL correspond to an aPTT ratio of 1.5 to 2.5 and plasma concentrations of bivalirudin from 0.25 to 2.00 mcg/mL correspond to an aPTT ratio of 1.5 to 3.0. Correlation of bivalirudin drug concentrations with aPTT ratios may vary with different aPTT reagents.

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

The recommended monitoring per product guidelines is with the activated partial thromboplastin time ratio; routine monitoring of bivalirudin drug levels is not indicated.

Bivalirudin concentration may be affected by drug interactions and liver and kidney disease.

Marked presence of hemolysis or bilirubin in the sample could falsely decrease bivalirudin levels. Marked presence of lipemia in the sample could falsely increase bivalirudin levels.

Clinical Reference

1. Linkins LA, Dans AL, Moores LK, et al. Treatment and prevention of heparin-induced thrombocytopenia: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):e495S-e530s
2. Love JE, Ferrell C, Chandler WL. Monitoring direct thrombin inhibitors with a plasma diluted thrombin time. Thromb Haemost. 2007;98(1):234-242
3. Van Cott EM, Roberts AJ, Dager WE. Laboratory Monitoring of Parenteral Direct Thrombin Inhibitors. Semin Thromb Hemost. 2017;43(3):270-276
4. Gosselin RC, Douxfils J. Ecarin based coagulation testing. Am J Hematol. 2020;95(7):863-869. doi:10.1002/ajh.25852
5. Gosselin RC, King JH, Janatpour KA, Dager WE, Larkin EC, Owings JT: Comparing direct thrombin inhibitors using aPTT, ecarin clotting times, and thrombin inhibitor management testing. Ann Pharmacother. 2004;38(9):1383-1388. doi:10.1345/aph.1D565
6. Beyer JT, Lind SE, Fisher S, Trujillo TC, Wempe MF, Kiser TH: Evaluation of intravenous direct thrombin inhibitor monitoring tests: Correlation with plasma concentrations and clinical outcomes in hospitalized patients. J Thromb Thrombolysis. 2020;49(2):259-267. doi:10.1007/s11239-019-01961-3

Performance

Method Description

The bivalirudin, ecarin chromogenic assay is performed on the Instrumentation Laboratory ACL TOP Family 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 para-nitroaniline from the chromogenic substrate resulting in a measurable colorimetric change.(Package insert: STA-ECA II. Diagnostica Stago S.A.S; Revision 04/2019)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 days

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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

80299

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BIVAL	Bivalirudin, Ecarin, P	104690-3

Result ID	Test Result Name	Result LOINC® Value
BIVA1	Bivalirudin, Ecarin, P	104690-3
BIVA2	Interpretation	69049-5
BIVA3	Cautions	62364-5