Lab Dept: Coagulation

Test Name: FONDAPARINUX

General Information

Lab Order Codes:	FONDA
Synonyms:	Arixtra
CPT Codes:	85520 – Heparin assay
Test Includes:	Fondaparinux level reported in mcg/mL

Logistics

Test Indications:	Fondaparinux is a synthetic anticoagulant with selective inhibition of activated factor X (factor Xa). Fondaparinux induces a conformational change in Antithrombin and increases its affinity for factor Xa. Inhibition of factor Xa leads to decreased thrombin generation and thrombus development. Fondaparinux has a half-life of approximately 17 hours which allows once-daily dosing. It is almost completely excreted by the kidneys. Fondaparinux is approved for the prophylaxis and treatment of venous thromboembolic events.
Lab Testing Sections:	Coagulation
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours; Testing is performed at Minneapolis Laboratory only.
Turnaround Time:	2 hours
Special Instructions:	N/A

Specimen

Specimen Type:	Whole blood
Container:	Light Blue top (Buffered Na Citrate 3.2%) tube
Draw Volume:	1.8 mL blood (in 2 mL tube) or 2.7 mL blood (in a 3 mL tube).

Processed Volume: 0.9 mL plasma

Collection:

● A clean venipuncture is essential, avoid foaming.
● Entire sample must be collected with single collection, pooling of sample is unacceptable.
● Capillary collection is unacceptable.
● Patient's with a hematocrit level >55% must have a special tube made to adjust for the hematocrit; contact lab for a special tube.
● Mix thoroughly by gentle inversion. Deliver immediately to the laboratory at room temperature via courier or pneumatic tube.

Off campus collections:

● Must be tested within 4 hours.
● Do not refrigerate.
● If not received in our lab within 4 hours of collection, sample must be centrifuged and *platelet-poor plasma removed from cells and transferred to an aliquot tube. Freeze at -20°C and deliver to the lab on dry ice within 2 weeks.
*__Validation of your lab's centrifuge for platelet poor plasma is required__.

Special Processing: Lab staff: Centrifuge in Stat Spin for 5 minutes or 10 minutes at 3000 rpm at room temperature. For primary tube testing, leave plasma on cells OR remove plasma and place in a 4 mL plastic cup; allow for 100 mL of dead-space.

Test within:
● Four (4) hours when stored in the capped tube above the packed cells 18 to 24°C.
● Four (4) hours as plasma that has been separated from cells by centrifugation when stored 2 to 8°C or 18 to 24°C.
● Two (2) weeks when stored -20°C.
● Six (6) months when stored -70°C (rapidly frozen).
● Plasma must be frozen if testing cannot be completed within four (4) hours.
● Frozen plasmas are thawed at 37°C for three (3) minutes, test immediately.

Patient Preparation: None

Sample Rejection: Improper tube; clotted sample; under-filled tube; mislabeled or unlabeled specimens

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Interpretive

Reference Range: The therapeutic anti-Xa range for Fondaparinux (Arixtra) has not been established.

In patients treated with 2.5 mg Fondaparinux daily, the peak steady-state and plasma concentration is on average 0.39-0.50 mcg/mL approximately 3 hours post dose and the minimum steady-state concentration is 0.14-0.19 mcg/mL.

In patients treated with 5.0 mg (body weight <50 kg), 7.5 mg (body weight 50-100 kg), and 10.0 mg (body weight >100 kg), Fondaparinux once daily, the mean peak steady-state plasma concentration is approximately 1.20-1.26 mcg/mL and the mean steady-state plasma concentration is approximately

0.46-0.63 mcg/mL.

(Arixtra Prescribing Information version 9/20/2013, GlaxoSmithKline, Research Triangle Park NC and Garcia, et al. Chest 2012, 141:e24s-e43s)

Critical Values: N/A

Limitations: The test cannot distinguish between Fondaparinux unfractionated and low molecular weight heparin. The correct assay must be requested for the type of product the patient is receiving or the results will not be accurate.

Methodology: Laboratory monitoring of Fondaparinux is possible utilizing factor Xa inhibitory activity of the drug. Anti-Xa assay (used for monitoring heparin) is modified by using a standard curve constructed with Fondaparinux.

References:

Collection, Transport and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays (1991), 2nd edition, NCCLS Document H21-A2, Vol 11, No 23, December 1991
http://ajcp.ascpjournals.org/content/132/4/608.full

GlaxoSmithKline Product Monograph ARIXTRA® GlaxoSmithKline Inc, 7333 Missauga Road, Missauga Ontario, Canada L5N 6L4
http://www.gsk.ca/english/docs-pdf/product-monographs/Arixtra.pdf

The Reduced Anticoagulant Effect of Fondaparinux at Low Antithrombin Levels (2009) Copyright 2009 International Anesthesia Research Society DOI: 10.1213/ande.0b013e3181ae94b0

Coagulation Assays and Anticoagulant Monitoring (2012)
ASH Education Program Book
http://asheducationbook.hematologylibrary.org/content/2012/1/460.full?sid=102a721f-110a-4b9a-88f1-4e937c000755 ys and anticoagulant monitoring