



AT THE FOREFRONT
UChicago
Medicine

TO: Medical Staff, House Staff, Patient Care Centers,
and Outpatient Clinics

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DATE: 8/21/2019

RE: New assays for monitoring direct thrombin inhibitors (argatroban and bivalirudin)

The UCM Coagulation Laboratory has validated an optimized argatroban assay as well as a new bivalirudin assay. These are both functional assays, using the dilute thrombin time methodology.

Please see UCM policies PC-148 and PGP-36 for direct thrombin inhibitor administration and monitoring. The aPTT can be used to monitor both argatroban and bivalirudin. However, in the setting of a prolonged baseline aPTT, DTI monitoring using the present dedicated assays is highly recommended.

As of 8/22/2019, these assays will be available 6AM-11PM, 7 days per week. If samples are sent during off-hours, they will be processed and frozen for analysis on the next shift.

The argatroban assay's current measurable range: 0.2 microg/mL to 2.05 microg/mL. Only an argatroban concentration in microg/mL will be reported; no derived aPTT value will be reported.

The bivalirudin assay's current measurable range: 0.1 microg/mL to 4.55 microg/mL. Only a bivalirudin concentration in microg/mL will be reported; no derived aPTT value will be reported.

Both of these assays are very sensitive to interference by hemolysis. All samples with visible hemolysis will be processed and frozen. If the patient with a hemolyzed sample is experiencing *in vivo* hemolysis, please request pathologist consultation by calling Coagulation laboratory at 773 702-1315. Absent a consultation, the sample will be credited and a re-draw will be requested.

No DTI therapeutic ranges using this methodology are available from the manufacturer. Below, we provide references from the literature for reported therapeutic target ranges:

Argatroban therapeutic target ranges

- 0.4-0.8 microg/mL (Colucci G et al. *J Transl Sci*, 2015. Volume 1(2): 37-42)
- 0.5-1.5 microg/mL (Seidel H et al. *Clinical and Applied Thrombosis/Hemostasis* 2018, Vol. 24(2) 287-294)
- 0.6–1.8 microg/mL (Van Cott EM et al. *Semin Thromb Hemost* 2017;43:270–276)
- Approximately 0.5 microg/mL (Warkentin et al. *Thromb Haemost.* 2005. 94:958)

Bivalirudin therapeutic target ranges

- Approximately 0.5 microg/mL (Warkentin et al. *Thromb Haemost.* 2005. 94:958)
- Approximately 1.0 microg/mL (Colucci G et al. *J Transl Sci.* 2015. 1:37)

For questions, please contact Krzysztof Mikrut, Laboratory Manager, at 773-702-1315, or Geoffrey Wool, MD PhD, Medical Director, at 773-926-1455.