

FloBio bleeding risk Dx gets FDA breakthrough device designation

November 2023—FloBio announced that the FDA has granted breakthrough device designation for its rapid bleeding risk diagnostic test. The point-of-care test is designed for in vitro diagnostic use to determine blood clotting status and whether a patient is on a direct oral anticoagulant.

The automated hemodynamic assay aims to give a complete picture of a patient's blood clotting status, including anticoagulation caused by DOACs. The novel device platform combines hemodynamic flow and discrete clot activation to mimic physiological blood clotting and produce a comprehensive DOAC drug assessment at the patient's bedside.

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