Instrumentation Laboratory
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Press Release

Contact:
Eric Goodnow
Instrumentation Laboratory
egoodnow@ilww.com

FOR DISTRIBUTION TUESDAY, SEPTEMBER 22, 2020 AT 8:30AM ET

INSTRUMENTATION LABORATORY RECEIVES US FDA MARKETING AUTHORIZATION FOR THE FIRST APIXABAN DIAGNOSTIC TEST

— The First Direct Oral Anticoagulant Test Authorized for Clinical Use on Automated Hemostasis Systems —

Bedford, MA, September 21, 2020 – Instrumentation Laboratory (IL) announced today that the US Food and Drug Administration (FDA) granted De Novo marketing authorization for the HemosIL® Liquid Anti-Xa test kit to measure apixaban. This is the first direct oral anticoagulant (DOAC) test for automated Hemostasis analyzers authorized by the FDA.

The FDA indication for HemosIL Liquid Anti-Xa has been expanded from the current quantitative determination of unfractionated heparin and low molecular-weight heparin, to include apixaban measurement, when used with HemosIL Apixaban Calibrators. The test is intended to measure apixaban concentrations in patients on apixaban therapy in the following situations where measurement of apixaban levels could be useful to have as additional information: patients at risk for major bleeding and patients experiencing a bleeding episode.

"DOACs are essential treatment for hundreds of thousands of patients around the world. Providing a means for clinicians to assess appropriate patients who take apixaban is an important step in enhancing care," said Remo Tazzi, Director, Worldwide Marketing at IL. "We are very proud to add another milestone "first" to our 60-year history of innovation in *in vitro* diagnostics."

Fully validated for use on the ACL TOP® Family and ACL TOP Family 50 Series Hemostasis Testing Systems, HemosIL Liquid Anti-Xa assay for apixaban measurement delivers an automated result with excellent linearity, limit of detection, precision and accuracy, for reliable results and enhanced patient management.

The HemosIL Liquid Anti-Xa assay is not a stand-alone test and the results should be used in conjunction with other clinical and laboratory findings. Apixaban is a direct factor Xa (FXa) inhibitor, developed by Pfizer Inc. and Bristol-Myers Squibb Company, and is sold under the trademark Eliquis.

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Instrumentation Laboratory Receives US FDA Marketing Authorization for the First Apixaban Diagnostic Test

Instrumentation Laboratory (www.instrumentationlaboratory.com), founded in 1959, is a worldwide developer, manufacturer and distributor of *in vitro* diagnostic instruments, related reagents and controls for use primarily in hospitals and independent clinical laboratories. Based in Bedford, MA, USA, IL operates Technology Centers there, as well as in Orangeburg, NY, USA, San Diego, CA, USA, and Munich, Germany. IL is a company of Werfen, based in Barcelona (Spain). IL Acute Care Diagnostics product offerings include the new GEM® Premier™ ChemSTAT system with Intelligent Quality Management (iQM®), GEM Premier 5000 system with iQM2, GEM Premier 4000 and 3500 analyzers with iQM, GEMweb® Plus Custom Connectivity, ROTEM® viscoelastic testing systems, Hemochron™ systems, VerifyNow™ platelet-function testing system, and Avoximeter™ CO-Oximeters. The IL Hemostasis portfolio includes new ACL TOP® Family 50 Series and ACL TOP Family of Hemostasis Testing Systems, fully automated, high-productivity analyzers, HemoCell™ Specialized Lab Automation and HemoHub™ Intelligent Data Manager. IL also offers the ACL AcuStar®, ACL Elite®, and other Hemostasis analyzers, along with the comprehensive HemosIL® line of reagents.

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180 Hartwell Road, Bedford, MA 01730 • Tel 781-861-0710 • instrumentationlaboratory.com