

Novel Viscoelastic Coagulation Monitor (VCM) Granted FDA Breakthrough Designation for Assessing Preterm Neonates

VCM to be Used to Assess Coagulation Status from Whole Blood of Preterm Neonates Aged 28 or More Weeks, Full Term and Newborns up to Six Months Post-Birth

DURHAM, NC, UNITED STATES, May 27, 2025 /EINPresswire.com/ -- Entegriion, Inc., a leading developer of innovative solutions for clinical diagnosis and management of hemostasis, announced today that the [VCM™](#), [viscoelastic coagulation monitor](#), has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) to assess

coagulation status using native whole blood collected via standard venipuncture or heel sticks from preterm [neonates](#) older than 28 weeks, full-term neonates, and newborns up to six months post-birth. The Breakthrough Device Designation allows Entegriion to work collaboratively with the FDA to develop the first-in-class diagnostic solution for assessing coagulopathies in neonates.

“

Entegriion is excited to have the ability to collaborate with the FDA to create a diagnostic solution tailored to neonatal needs.”

*Christopher Rumana MD,
Chairman of the Board at
Entegriion*

Christopher Rumana MD, Chairman of the Board at Entegriion, stated, “Entegriion is excited to have the ability to collaborate with the FDA to create a diagnostic solution tailored to neonatal needs.”

When the marketing authorization application is approved “Entegriion will offer for the first time in the United States a diagnostic test specific to this extremely vulnerable patient

population.” said Bert Valada, President and CEO of Entegriion. “Our CE marked whole blood heel stick diagnostic test gives the care giver a global understanding of a neonate hemostasis



VCM Analyzer

condition patient side and is currently demonstrating improved patient outcomes in Europe.”

About the Viscoelastic Coagulation Monitor (VCM)

The Entegriion VCM is a compact, portable device that performs a viscoelastic analysis of the coagulation-fibrinolysis process utilizing glass surface activation of untreated whole blood. The wide surface area of contact between the blood and the glass inside the cartridge accounts for the rapid initiation of clotting, eliminating the need for activating factors. VCM has made viscoelastic measurements of the hemostasis of whole blood samples rapid and accurate at the site of patient care. The VCM™ system is robust, reliable, totally automated and easy to use. It has demonstrated the ability to be used in transit, harsh and austere environments, and acute care settings, taking a once complex diagnostic test to the site of trauma.



About Entegriion

Entegriion is a life sciences development company that is focused on improving the safety and availability of blood diagnostics. Many of Entegriion's advances in diagnostics are based on close collaborations with leading medical research institutions. Visit www.entegriion-vcm.com for more information.

MEDIA CONTACT: Info@entegriion-vcm.com

Bert Valada

Entegriion, Inc.

+1 919-536-1500

[email us here](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/816209893>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2025 Newsmatics Inc. All Right Reserved.