

# HAEMONETICS®

## Haemonetics Welcomes New FDA Guidance on Viscoelastic Testing During COVID-19 Pandemic

January 22, 2021

### FDA recognizes importance of increased availability of devices such as market leading TEG® hemostasis analyzers

BOSTON, Jan. 22, 2021 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE) ("Haemonetics"), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, affirms its support of [new guidance](#) issued by the U.S. Food and Drug Administration (FDA) related to the use of viscoelastic testing for the duration of the public health emergency related to COVID-19. Haemonetics is working expeditiously on fulfilling the requirements to modify the indications for the TEG® 5000 and TEG® 6s hemostasis analyzers and all related assays by amending product labeling and instructions for use, in line with the FDA guidance. This will allow healthcare professionals to begin using TEG® products for improved patient care during the pandemic.



Haemonetics' TEG® 5000 and TEG® 6s hemostasis analyzers provide market leading viscoelastic tests. TEG® analyzers use whole blood, including platelets, and provide functional insights into the entire blood clotting process. For this reason, viscoelastic testing, such as the TEG® technology, has been recognized by the FDA as a potential adjunctive diagnostic to help better characterize COVID-19 associated coagulopathy (CAC) and to inform patient management, including personalized anticoagulation to reduce the risk of bleeding.

CAC is characterized by hypercoagulability resulting from increased blood clot formation and impaired fibrinolysis, or the body's ability to resolve blood clots. This condition is common among COVID -19 patients and can lead to potentially deadly complications, such as venous thromboembolism, pulmonary embolism or stroke.

"While leading symptoms of COVID-19 include fever, cough and shortness of breath, it has become apparent that blood coagulation and clotting issues play a critical role in this disease," said Jan Hartmann, MD, Haemonetics' VP Medical Affairs, Clinical Development & Medical Safety.

"COVID-19 is a healthcare and humanitarian crisis of unprecedented dimensions," said Stewart Strong, Haemonetics' President, Global Hospital. "As a market leader, we have worked closely with our partners at hospitals across the country to provide our support with tools to optimize use of scarce blood resources. We remain committed to making our innovative technologies available to healthcare professionals at the front line of fighting this pandemic."

#### About Viscoelastic Testing

Viscoelastic testing is used to analyze the ability of patients to form blood clots and to resolve them, and it provides holistic and unique insights beyond the information gained from conventional coagulation tests that each only look at one step in this process. This unique testing reviews the entire process, from the activation of the coagulation to the clot formation and ultimately to its resolution. In addition, viscoelastic testing uses whole blood from patients, as opposed to platelet-poor plasma like conventional tests, so it can provide more and valuable information, including about the contribution of platelets.

#### About Haemonetics

Haemonetics (NYSE: [HAE](#)) is a global healthcare company dedicated to providing a suite of innovative medical products and solutions for customers, to help them improve patient care and reduce the cost of healthcare. Our technology addresses important medical markets: blood and plasma component collection, the surgical suite and hospital transfusion services. To learn more about Haemonetics, visit [www.haemonetics.com](http://www.haemonetics.com).

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