bioMérieux receives FDA clearance for BPA and BPN culture bottles used with BACT/ALERT® VIRTUO® for quality control testing of platelets

Marcy l'Étoile (France) – December 18, 2018 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces that its culture bottles BACT/ALERT® BPA and BPN have received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for quality control testing of leukocyte-reduced apheresis platelet (LRAP) units with the BACT/ALERT® VIRTUO® fully automated blood culture system.

This innovative FDA cleared and CE marked system is commercially available to blood banks and transfusion services in the United States and in countries that recognize CE marking.

BACT/ALERT® VIRTUO® is a fully automated microbial detection system with motion-activated loading and unloading of bottles. It offers powerful proprietary algorithms, high thermal stability and sensitive optics which enhance performance for more rapid time to detection if microbial contaminants are present. This innovative system enables blood banks and transfusion services to streamline their workflow by reducing hands-on time and increasing efficiency.

Patient safety is at the heart of bioMérieux's solutions, driven by a commitment to enhance detection of specific pathogenic bacteria in platelets in order to avoid the risks associated with bacterial contamination of life-saving platelet transfusions. As platelets have a short shelf life and the highest contamination risk of any transfusable blood component, reliable quality control methods are essential to protect patients from the risk of septic reactions.

In addition, in accordance with FDA clearance for secondary safety measure testing with BACT/ALERT® BPA and BPN culture bottles, and existing global customer validated practices like large volume delayed sampling, bioMérieux quality control solutions can be used to extend platelet shelf life up to a total of seven days, increasing the safety and availability of platelets, which are precious and often scarce life-saving resources.

"*The FDA clearance and CE marking of BPA and BPN culture bottles used with BACT/ALERT® VIRTUO® illustrate bioMérieux's commitment to the protection of patients' health. We are thrilled that our innovative solution can now be used by blood banks to increase the safety and availability of life-saving platelets,*" said Mark Miller, MD, Executive Vice President, Chief Medical Officer of bioMérieux.

BACT/ALERT® BPA and BPN culture bottles support the growth of aerobic and anaerobic microorganisms in two types of leukocyte reduced units: apheresis platelet units and both single and pools of up to six units of whole blood platelet concentrates.

The BACT/ALERT® technology is in routine use by blood collection and transfusion facilities in over 25 countries worldwide and has a long proven track record for testing platelets. With VIRTUO®, bioMérieux offers a state-of the-art integrated microbiology solution to provide faster reliable and actionable results for in-process quality control of platelets.

BACT/ALERT® VIRTUO® uses the same reagents (BPA and BPN culture bottles) as the BACT/ALERT® 3D systems.

PRESS RELEASE

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 43 subsidiaries and a large network of distributors. In 2017, revenues reached €2.3 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products

bioMérieux is listed on the Euronext Paris stock market
Symbol: BIM - ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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