CytoChip Receives FDA Clearance and First CLIA Waiver for a Cartridge-Based Complete Blood Count Test

The CLIA-waived CitoCBC® expands patient access to quick CBC results in physician offices, pharmacies, and home care, enabling data-driven diagnostics.

IRVINE, CA, UNITED STATES, February 25, 2025 /EINPresswire.com/ -- CytoChip proudly announces that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance and a CLIA Waiver for its CitoCBC®, making it the first cartridge-based CBC test to achieve this milestone. This breakthrough significantly expands access to Complete Blood Count (CBC) testing in physician offices, pharmacies, home care, and other decentralized healthcare environments.

CBC is one of the most commonly requested lab tests, essential for disease diagnosis, therapy monitoring, and routine health screening. However, over 90% of U.S. physician offices lack the infrastructure for on-site CBC testing, often leading to delayed results and missed diagnostic opportunities during patient consultations. With the CLIA Waiver, CitoCBC® eliminates this barrier by enabling fast, reliable CBC results within a small footprint, improving patient care and clinical decision-making.

A recent study published in Nature (Dec. 11, 2024) by researchers from Harvard Medical School at Massachusetts General Hospital highlights the value of personalized CBC testing for the early intervention of common diseases. A CLIA-waived solution like CitoCBC® is crucial for delivering personalized CBC testing routinely in primary care, enabling proactive patient management.

CitoCBC® is engineered for both ease of use and high performance. Its self-contained cartridge simplifies the testing process while delivering a state-of-the-art 5-Part Differential CBC with a turnaround time of eight minutes. The FDA clearance with CLIA Waiver (510(k) number K240402 and CLIA Waiver CW240006) validates its accuracy and reliability, ensuring that even non-laboratory personnel can operate the system effectively.

"Achieving CLIA Waiver for a CBC test is a major step forward in improving access to diagnostics at the point of care," said Dr. Wendian Shi, CEO of CytoChip. "This milestone not only fills a critical gap among CLIA Waived testing but also expands diagnostic accessibility in underserved areas."

This product will launch first in the United States, followed by select European countries upon receiving CE Marking.

For more information, visit www.cytochipinc.com.

About CytoChip

CytoChip is a diagnostic company specializing in microfluidic innovations and committed to empowering healthcare professionals with data-driven, point-of-care solutions. Its proprietary OneChip® platform miniaturizes fluorescent flow cytometry into a cartridge-based format, making advanced diagnostics more accessible.

Sirun Qiu
CytoChip Inc.
sirun@cytochipinc.com
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