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# Waters achieves US FDA 510(k) clearance for ready-to-use flow cytometry clinical tests for Leukemia and Lymphoma

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**BD OneFlowâ?¢ LST and BD OneFlowâ?¢ B-CLPD T1 Tests now FDA 510(k)-cleared in US for identifying B-cell non-Hodgkin lymphoma (NHL)**



Waters Corporation has announced that the BD OneFlow LST Test and BD OneFlow B-CLPD T1 Test have received US Food and Drug Administration (FDA) 510(k) clearance. This clearance enables commercialisation in the US and provides pathologists and clinicians a standardised, ready-to-use flow cytometry testing solution that aids in identification and diagnosis of B-cell non-Hodgkin lymphoma (NHL), including chronic lymphocytic leukemia (CLL), for faster and reliable diagnostic insights.

The latest in a series of innovations delivered since Waters combined with BD's Biosciences & Diagnostic Solutions Businesses, the BD OneFlow Solution integrates reagents, instruments, defined staining protocols, pre-defined assay templates, and supporting consumables into a consistent, recurring workflow for immunophenotyping normal and abnormal cell populations. The solution significantly reduces hands-on time compared to liquid reagent cocktails, helping labs increase workflow efficiency, speed turnaround time, and lower the risk of human error.

In 2026, an estimated 79,320 people in the US will be diagnosed with NHL, including 22,760 cases of CLL, which is expected to cause approximately 4,350 deaths. CLL is the most common form of leukemia in adults, accounting for approximately one-third of new leukemia cases in the US. Expanding access to accurate, standardised diagnostic testing can help pathologists and clinicians identify disease and determine the appropriate path for further evaluation, monitoring, and treatment.