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## **PerkinElmer's Oxford Immunotec Secures New Approval from U.S. FDA Expanding Instrumentation for Latent Tuberculosis Detection Workflow**

*Additional instrumentation for cell isolation expands automation options for laboratories to access the clinically superior T-SPOT®.TB test*

**WHAT:** PerkinElmer's Oxford Immunotec today announced that the U.S. Food and Drug Administration (FDA) has approved the use of two additional cell isolation instruments with the Company's [previously approved](#) T-Cell *Select*™ reagent kit, which is intended for *in vitro* diagnostic (IVD) use by certified laboratories with the T-SPOT®.TB test workflow. The two instruments included in this supplement approval are the Auto-Pure 24 and Auto-Pure 20B platforms manufactured by [Allsheng Instruments](#). Oxford Immunotec is the exclusive distributor of the Auto-Pure 10B, 20B and 24 products in North and South America.

**HOW:** The [T-Cell \*Select\* reagent kit](#) received initial FDA approval in September 2022 to simplify and streamline the preparation of cells for the Oxford Immunotec [T-SPOT.TB test](#), a globally regulated ELISPOT IGRA for detecting latent tuberculosis (TB) infection. The T-Cell *Select* reagent uses positive selection of peripheral blood mononuclear cells (PBMCs) with magnetic bead-based cell separation, providing for optimal cell purity without negatively impacting T cell function or the superior clinical performance of the T-SPOT.TB test.

With this latest approval, laboratories may now use Auto-Pure instrumentation that offers plate or strip-based sample preparation to meet variable throughput requirements. This versatility works to further optimize workflow efficiency, reduce hands-on time and minimize both labor and resource costs.

**WHY:** "Traditional methods for the detection of latent TB can be both time and labor intensive, with cell separation being one of the greatest bottlenecks for laboratories," said Phill Keefe, chief executive officer of PerkinElmer's Oxford Immunotec. "This supplement approval creates a wider portfolio of approved instrumentation labs may use to automate a clinically superior assay, ultimately meaning faster and more reliable results for more patients with a potentially life-threatening infection."

**MORE:** In addition to workflow efficiency, automation of the T-SPOT.TB test with the T-Cell *Select* reagent improves blood sample logistics, as samples may be stored at room temperature for up to 54 hours with no complex phlebotomy practices. The extended blood sample stability also enables easy centralization of sample processing, giving laboratories more flexibility with the potential for sample batching.

Outside of the United States, the T-Cell *Select* reagent kit is available throughout Europe where CE marking is accepted, in South Korea by the Ministry of Food and Drug Safety, in

China by the National Medical Products Administration (NMPA) and is quickly becoming available in more markets around the world.

**About The PerkinElmer Life Sciences and Diagnostics Company**

The PerkinElmer Life Sciences and Diagnostics company – which is to be renamed during the second quarter of 2023 – provides end-to-end solutions that help scientists, researchers and clinicians better diagnose disease and discover new and more personalized drugs. Its dedicated team of 11,000 collaborates closely with commercial, government, academic and healthcare customers to deliver reagents, assays, instruments, automation, informatics and strategic services that accelerate workflows, deliver actionable insights and support improved decision making. The Company is also deeply committed to good corporate citizenship through dynamic ESG and sustainability programs. The Company reported revenues of approximately \$3.3 billion in 2022, serves customers in 190 countries, and is a component of the S&P 500 index.

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