

# Ortho Clinical Diagnostics

## Ortho Clinical Diagnostics Launches New MicroTip Partnership Assays with Diazyme Laboratories, Inc., ARK Diagnostics, Inc., and Sekisui Diagnostics LLC

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**Kappa Free Light Chain and Lambda Free Light Chain MPAs cleared for use in diagnosing and monitoring plasma cell disorders, neoplastic diseases; Methotrexate MPA cleared for use in monitoring therapeutic levels of methotrexate**

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, is continuing to expand its menu by offering three new assays to customers. Through its MicroTip Partnership Assay (MPA) program, Ortho will offer Kappa Free Light Chain and Lambda Free Light Chain in collaboration with Diazyme Laboratories, Inc. In addition, the company will offer the Methotrexate assay through collaboration with ARK Diagnostics, Inc and Sekisui Diagnostics LLC. The MPA program enables Ortho to offer high value, esoteric testing, in step with the evolving needs of today's labs.

"Our successful MicroTip Partnership Assay program helps us expand our reach in delivering innovative and critically important new assays to our customers," said Jennifer Paine, Chief Product Portfolio and Quality, Regulatory and Compliance Officer at Ortho. "Through collaborations with other leading organizations, Ortho is fully committed to expanding its assay offerings in the oncology portfolio."

Kappa Free Light Chain and Lambda Free Light Chain assays are recommended for the diagnosis and monitoring of plasma cell disorders such as multiple myeloma, lymphoid neoplasms, and amyloidosis. The Diazyme polyclonal Kappa Free Light Chain and Lambda Free Light Chain assays are considered superior to monoclonal assays due to the ability to recognize serum free light chains through variable epitopes. Both assays have a rapid turnaround time (10 minutes) and have excellent accuracy and precision. In addition, the assays' long extended linear range reduces the need for off-board manual dilutions.

The Methotrexate assay is used to monitor levels of Methotrexate, a therapeutic drug prescribed to patients who have certain neoplastic diseases (osteogenic sarcoma, leukemia, non-Hodgkin's lymphoma, and lung and breast cancer), adult rheumatoid arthritis, and severe psoriasis.

These MPAs have been validated for use on Ortho's VITROS® 5600 Integrated System and Ortho's VITROS® 4600 Chemistry System. Kappa Free Light Chain and Lambda Free Light Chain assays will be available in the United States and EMEA, and the Methotrexate assay will be available in the United States.

### About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

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