

Roche launches new highly-sensitive test to more easily diagnose patients who may have B-cell lymphoma

- **The VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail assay is the first clinically approved in-situ hybridisation (ISH) test with the sensitivity to assess the full spectrum of B-cell lymphoma subtypes.^{1,2}**
- **The test helps differentiate a B-cell cancer from a normal, reactive immune response, providing diagnostic certainty for healthcare providers and their patients.**
- **B-cell lymphoma accounts for approximately 85 percent of non-Hodgkin lymphoma (NHL) cases, which is the tenth most common cancer worldwide.³**

Basel, 20 June 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the launch of the first clinically approved, highly-sensitive in-situ hybridisation (ISH) test, the VENTANA® Kappa and Lambda Dual ISH mRNA Probe Cocktail assay, in countries accepting the CE Mark. The test is designed to help pathologists differentiate a B-cell malignancy from a normal, reactive response to an infection.⁴

B-cell lymphoma is a type of cancer that typically develops in the lymphatic system. It accounts for approximately 85 percent of non-Hodgkin lymphoma (NHL) cases. NHL is the tenth most common cancer worldwide and each year more than 250,000 people die from this disease.³ In the early stages of NHL, patients may experience symptoms like swelling of the lymph nodes, fever, fatigue, loss of appetite or a red rash.

“It’s important to be able to provide patients with a definitive diagnosis as symptoms of lymphoma can appear similar to the body’s normal reactive response to an infection,” said Matt Sause, CEO of Roche Diagnostics. “This highly sensitive assay offers diagnostic certainty for patients with suspected B-cell lymphoma.”

With increased sensitivity, the new test enables assessment across the more than 60 B-cell lymphoma subtypes and plasma cell neoplasms on a single tissue slide. The test can assess small biopsies and formalin-fixed tissue, reducing the need for a fresh tissue sample, which may not be available especially if lymphoma was not originally suspected. These test properties preserve tissue, may result in fewer additional patient biopsies and make interpretation quicker and easier for the pathologist, helping create a faster diagnosis and access to treatment for patients.

This first-of-its-kind assay is a significant addition to Roche’s industry-leading hematopathology portfolio, which includes more than 65 biomarkers.

About the VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail

VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail is intended for the qualitative detection of Kappa mRNA and Lambda mRNA in formalin-fixed, paraffin-embedded (FFPE) human bone marrow and lymphoid tissue stained on a BenchMark IHC/ISH instrument using chromogenic in-situ hybridisation (ISH) and visualised using light microscopy. VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail is intended as an aid in the identification of B-cell lymphomas and plasma cell neoplasms. The results of the assay should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This product is intended for in vitro diagnostic (IVD) use.⁴

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

All trademarks used or mentioned in this release are protected by law.

References

- [1] Rimsza LM, et al. Kappa and lambda light chain mRNA in situ hybridization compared to flow cytometry and immunohistochemistry in B cell lymphomas. *Diagn Pathol.* 2014;9:144.
- [2] F. Hoffmann-La Roche Ltd. Joint Market Research. [Survey; Cited 2024 April 4]. Data on File.
- [3] Global Cancer Observatory. Non-Hodgkin Lymphoma Fact Sheet [Internet; Cited 11 April 2024]. Available from: <https://gco.iarc.who.int/media/globocan/factsheets/cancers/34-non-hodgkin-lymphoma-fact-sheet.pdf>
- [4] F. Hoffmann-La Roche Ltd. VENTANA Kappa and Lambda Dual ISH mRNA Probe Cocktail. [Method Sheet; cited 2024 April 16]. Data on file.

Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD

Phone: +41 79 407 72 58

Sileia Urech

Phone: +41 79 935 81 48

Nathalie Altermatt

Phone: +41 79 771 05 25

Simon Goldsborough

Phone: +44 797 32 72 915

Karsten Kleine

Phone: +41 79 461 86 83

Nina Mähltz

Phone: +41 79 327 54 74

Kirti Pandey

Phone: +49 172 6367262

Yvette Petillon

Phone: +41 79 961 92 50

Dr. Rebekka Schnell

Phone: +41 79 205 27 03

Roche Investor Relations

Dr. Bruno Eschli

Phone: +41 61 68-75284

e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber

Phone: +41 61 68-88027

e-mail: sabine.borngraeber@roche.com

Dr. Birgit Masjost

Phone: +41 61 68-84814

e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com