

Roche strengthens cancer diagnostic portfolio with launch of test for differential diagnosis of mesothelioma

- **The VENTANA® BAP1 (SP527) test helps confidently distinguish malignant mesothelioma from lung, breast and stomach cancers, as well as benign tissue growth in the chest or abdomen.**
- **Most patients are diagnosed with mesothelioma late, resulting in a median overall survival of just 12 to 18 months.¹**
- **Roche's comprehensive cancer diagnostic portfolio delivers end-to-end clinical answers across the patient journey, spanning advanced tissue diagnostics, core lab immunoassays, molecular testing and digital diagnostics.**

INDIANAPOLIS, October 28, 2026 – Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today the global launch of the VENTANA® BAP1 (SP527)* test. This automated, ready-to-use immunohistochemistry (IHC) assay provides a reliable, highly specific diagnostic tool to help clinicians and pathologists accurately identify mesothelioma and distinguish it from other malignancies, including non-small cell lung cancer (NSCLC). The BAP1 assay is registered as a Class I IVD with the U.S. Food and Drug Administration, has received IVDR approval as a Class C device, and is available globally.

BAP1 pinpoints malignant mesothelioma, a deadly, rare cancer that forms in the tissue that lines many internal organs.² More than 80% of mesothelioma cases are found in the pleural cavity,³ an area of thin, fluid-filled space between the two layers of tissue that surround each lung.

“Timely differential diagnosis of mesothelioma is critical to help deliver the best outcome for patients,” said Matt Sause, CEO of Roche Diagnostics. “Adding BAP1 to our portfolio underscores our commitment to developing innovative solutions that enable healthcare systems around the world to address diseases with high unmet need, such as mesothelioma.”

A major challenge in lung cancer and mesothelioma diagnostics is the preservation of limited patient tissue samples. Traditional approaches can exhaust tissue blocks through extensive antibody panels. Single markers with high specificity, such as BAP1 (SP527), along with the recently launched VENTANA® MTAP (SP530) and VENTANA® Claudin-4 (EP417) tests, allow pathologists to accurately differentiate cancers^{4,5} while minimizing tissue loss. By optimizing sample management, clinicians ensure sufficient tissue remains for essential molecular sequencing and precision medicine testing.⁶

Lung cancer is the leading cause of cancer death worldwide. Every year, more than 2.5 million people are diagnosed with lung cancer globally and up to 85% of these cases are NSCLC.⁷

Comprehensive Lung-Cancer Portfolio Leadership

Roche's comprehensive lung-cancer diagnostic portfolio delivers end-to-end clinical answers across the patient pathway. The portfolio spans advanced tissue diagnostics, including foundational H&E staining and high-medical-value IHC assays like ALK (D5F3), PD-L1 (SP263) and MET (SP44) to core lab immunoassays, molecular diagnostics (oncology PCR and CGP/NGS) and **navify**[®] digital software.

Launching assays like BAP1 (SP527) alongside Roche's existing portfolio helps address unmet clinical needs and bridge diagnostic gaps to enable more effective patient management. Acting as a powerful force multiplier, BAP1 combines with the newly launched MTAP and Claudin-4 assays to help distinguish malignant mesothelioma from benign and metastatic mimics.

This comprehensive and constantly evolving portfolio empowers medical practitioners to accelerate diagnostic certainty while maximizing pre-analytical sample stewardship to preserve precious patient tissue for critical downstream diagnostics like molecular sequencing.

About the VENTANA[®] BAP1 (SP527) Assay

The VENTANA[®] BAP1 (SP527) Rabbit Monoclonal Primary Antibody is designed for automated IHC testing to detect nuclear loss of BAP1 expression, a tumor suppressor marker located on chromosome 3p21. IHC loss of nuclear BAP1 is virtually 100% specific for malignancy in mesothelial proliferations,^{8,9} making it an indispensable tool for confirming mesothelioma in conjunction with mesothelial lineage markers such as WT1 and calretinin.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland, in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases, and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

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

*VENTANA® BAP1 (SP527) Rabbit Monoclonal Primary Antibody

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For Further Information

Roche Diagnostics U.S. Media Relations

us.mediarelations@roche.com

Krystina Monaco

1-317-850-7521

krystina.monaco@roche.com

Lori McLaughlin

1-463-207-2395

lori.mclaughlin@roche.com