

Roche launches NGS AVENIO Tumor Tissue Analysis Kits for oncology research

- Ready-to-use kits determine genomic characteristics of solid tumours
- Optimized workflow to generate results in house
- Software analysis allows correlation to AVENIO ctDNA NGS kits

Basel, 15 October 2018 – Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the global commercial launch of three new next-generation sequencing (NGS) AVENIO Tumor Tissue Analysis Kits – the AVENIO Tumor Tissue Targeted Kit, Expanded Kit and Surveillance Kit.^[1] The kits, which detect all four mutation classes in solid tumours, complement Roche’s NGS ctDNA kits for oncology research. The AVENIO research-use-only (RUO) portfolio of ready-to-use kits provides reagents and software needed for labs to determine the genomic characteristics of solid tumours through a single DNA workflow.

“With the launch of these innovative assays we are pleased to further empower researchers around the world to continue to advance personalised oncology,” said Michael Heuer, CEO Roche Diagnostics. “These three ready-to-use AVENIO Tumor Tissue Analysis Kits enable researchers by providing relevant panel content that cover all four mutation classes to support the wide variety of cases that require genomic profiling, and complement the previously launched AVENIO ctDNA assays for liquid biopsy.”

Like the AVENIO ctDNA Analysis Kits launched in 2017, the AVENIO Tumor Tissue Analysis Kits are aligned with National Comprehensive Cancer Network (NCCN) guidelines to support oncology research.^[2] Researchers can now use the AVENIO family of NGS oncology assays to profile the genomic complexities of a variety of solid tumour types using formalin-fixed paraffin-embedded (FFPE) tissue or plasma to obtain detailed results from either workflow within five days.

“Cancer is a highly complex and dynamic disease, so the ability to obtain a detailed and accurate summary of the genomic profile of malignancies is critical. By combining the new AVENIO Tumor Tissue Kits with ctDNA kits containing exactly matched gene content, Roche has created an innovative new system not only for genomic profiling of solid tumours, but also to better understand how tumour heterogeneity and tumour burden change over time,” said Aadel Chaudhuri, MD, PhD, Assistant Professor of Radiation Oncology at Washington University School of Medicine.

About the AVENIO Tumor Tissue Analysis Kits

The AVENIO Tumor Tissue Analysis Kits are for research use only and not for use in diagnostic procedures. Three NGS tumour tissue assay kits are now available for oncology research:

- The AVENIO Tumor Tissue Targeted Kit is a 17-gene comprehensive genomic profiling assay for identifying guideline-related biomarkers

- The AVENIO Tumor Tissue Expanded Kit is a 77-gene comprehensive genomic profiling assay with both guideline-related and emerging biomarkers to profile well-characterised genetic mutations in addition to those identified in clinical studies
- The AVENIO Tumor Tissue Surveillance Kit contains 197 genes and is intended for baselining variants in longitudinal tumour burden monitoring applications.

Each kit includes the reagents necessary for DNA extraction and quality control (QC), library preparation and target enrichment. A proactive QC strategy is employed to help labs optimise sample inputs and detect variants in greater than 99% of FFPE samples that pass QC.^[3] When paired with secondary analysis software running on the Oncology Analysis Server, labs can analyse sequencing data and generate sequencing QC, variant and analytical concordance reports. The AVENIO kits utilize Roche's enhanced hybrid capture target enrichment techniques to analyse all four mutation classes in a single DNA workflow: single nucleotide variants (SNVs), insertions or deletions (indels), fusions and copy number variants (CNVs). With the AVENIO family of NGS oncology assays, Roche aims to make sequencing simple and accessible for everyday use.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the tenth consecutive year, Roche has been recognised as the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 billion. 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.

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References

- [1] For research use only. Not for use in diagnostic procedures.
 [2] National Comprehensive Cancer Network. <http://www.nccn.org>. August 31, 2018.
 [3] Data on file.

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