

Roche launches Elecsys Anti-p53 immunoassay to aid diagnosis of various cancer types

- **Anti-p53 antibodies are antibodies that mistakenly target a patient's own tissues, leading to a growth of solid tumors.**
- **Screening for Anti-p53 helps to diagnose throat, bowel and breast cancers earlier, thereby increasing the chances that a patient responds to a treatment**
- **The Elecsys Anti-p53 could be used to monitor cancer cell remnants in the patient's body**

Basel, 07 April 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of the Elecsys Anti-p53 immunoassay for the in vitro quantitative determination of anti-p53 antibodies. This test is used to aid physicians to diagnose throat cancer, bowel cancer and breast cancer in patients, in conjunction with other diagnostic tests. The assay is now available for all markets accepting the CE Mark.

“The addition of our Elecsys Anti-p53 immunoassay will help clinicians to quickly and reliably diagnose several prevalent cancers and might assist in leading to a better prognosis for many patients.”, said Thomas Schinecker, CEO Roche Diagnostics. “Beyond breakthrough cancer medicines, Roche also offers a growing number of testing solutions to help physicians diagnose and treat people with cancer.

p53 is protein which, when active, helps to regulate processes which stop tumors from developing. A mutation of p53 is present in half of solid tumor cancers and is the most common genetic change identified so far in human cancers.¹ Certain mutations of p53 can lead to a build up of p53 which results in the formation of anti-p53 autoantibodies. Autoantibodies are antibodies that mistakenly target and react with a person's own tissues. Between 20-50% of patients with mutated p53 will produce anti-p53 autoantibodies.² This mutation causes the tumor suppressive function of p53 to switch to a tumor-promoting function and thus cancer development.

Early appearance of anti-p53 antibodies during tumour development may have potential to detect malignant changes.³ The Elecsys Anti-p53 immunoassay detects these anti-p53 antibodies and, when used with other diagnostic tests, can help to diagnose certain cancers, at an earlier stage, which may help to improve patient outcomes. Determining the presence of anti-p53 antibodies may also be useful for monitoring cancerous cells that are still in the body following treatment.⁴ In addition, the Elecsys Anti-p53 test could aid in determining which patients may require less invasive treatment procedures, as part of their cancer treatment.

About Elecsys Anti-p53

Elecsys Anti-p53 immunoassay for the in vitro quantitative determination of anti-p53 autoantibodies in human serum and plasma. Elecsys Anti-p53 is a high precision immunoassay, with a low turn-around time for testing, complementing our overall tumor marker portfolio. The new Elecsys Anti-p53 immunoassay uses the well-established electrochemiluminescence immunoassay “ECLIA” technology and is intended for use on cobas e immunoassay analyzers.

For further information on Elecsys immunoassays visit [here](#).

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. More than 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 twelfth consecutive year, Roche has been recognised as one of the most sustainable companies 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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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] Yue X, et al. J Mol Biol 2017;429:1595-606
- [2] Suppiach et al. World J Gastroenterol 2013 August 7; 19(29): 4651-4670
- [3] Soussi T. Cancer Res 2000;60:1777-88
- [4] Kasthuber E & Lowe S. Cell 2017;170(6):1062-78

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