

Roche receives FDA clearance for cobas pro integrated solutions designed to help labs deliver faster results to patients

- **cobas pro integrated solutions improves productivity in the lab and enhances reliability and turnaround times in delivering results to patients**
- **By simplifying operations in the lab, Roche is in-turn helping physicians provide evidence-based diagnostic and treatment decisions more cost-effectively and quickly for all patients**

Basel, 16 September 2019 - Roche Diagnostics announced today that the US Food and Drug Administration (FDA) has cleared its cobas pro[®] integrated solutions, a new generation of Serum Work Area (clinical chemistry and immunochemistry) laboratory solution, designed to optimize lab operations. With the cobas pro integrated solutions, laboratories are now able to run tests faster on less equipment, automate manual tasks and deliver results more quickly to aid in treatment decisions.

Diagnostic laboratories are a critical component of the global healthcare system with in vitro diagnostics influencing up to 70% of all clinical decisions while accounting for only about 2% of total healthcare spending.^{1,2} Together, medical and lab professionals play a key role in delivering optimal patient care, yet they face increasing pressure to manage a growing number of samples, while delivering quality results faster and rising profitability.

“We are excited about the accelerated FDA clearance of the cobas pro integrated solutions, our new generation of Serum Work Area solutions inspired by our mission to help improve speed and reliability of treatment decisions for patients and their families,” said Thomas Schinecker, CEO Roche Diagnostics. “Reliable, fast and sustainable diagnostic solutions are vital for optimal clinical care delivery for patients, and a key element in the evolution of general healthcare quality.”

The latest innovation from Roche allows for up to 2,200 tests per hour with three modules working in parallel and synchronized to improve efficiency.¹ Additionally, the cobas pro integrated solutions can boast up to 3¼ hours less operating time for a daily routine workload compared to cobas 6000^{2,3}, while 93% of Roche Immunoassays have reaction times of 18 minutes or less.^{4,5} Reducing the time in delivering results to physicians and patients across a number of therapeutic areas including pregnancy, core lab/HIV testing and blood screening, is vital to clinical decision making.

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 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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] Roche Diagnostics, Medical and Scientific Affairs (MSA); EAC / based on 2013 EAC interviews with cardiologists and oncologists in Germany and the US (N=40)
- [2] European Diagnostic Manufacturers Association (EDMA), 2009; based on: The Lewin Group, commissioned by Advamed, “The Value of Diagnostics”, 2005
- [3] cobas® pro integrated solutions product specifications. Data on file.
- [4] For a daily routine workload, as compared to cobas® 6000. Data on file.
- [5] Based on calculations with value calculation tool. Data on file.

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