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Roche submits filing to FDA for HbA1c testing solution to help meet increasing demand for HbA1c testing of people with diabetes

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced that it has submitted the cobas c 513 analyzer as a 510(k) to the U.S. Food and Drug Administration (FDA) as a dedicated, high-throughput HbA1c testing solution for people with diabetes.

“As the prevalence and incidence of diabetes continues to grow, it’s estimated that by the end of this decade 15 percent of American adults—or roughly 39 million people will be affected. This staggering number is not only a major cause for concern for healthcare providers, but for healthcare organizations as well,” said Dr. Alan Wright, Chief Medical Officer, Roche Diagnostics Corporation. “With the submission of the cobas c 513 analyzer to the FDA for 510(k) clearance, Roche is dedicated to helping address the need to quickly identify, diagnose and monitor people with diabetes.”

Upon receiving FDA clearance for the cobas c 513 analyzer, Roche plans to replace its existing analyzer, the COBAS INTEGRA® 800 CTS, which has been a successful and well-established solution. The cobas c 513 analyzer will further increase laboratory efficiency by doubling the already market-leading throughput of the COBAS INTEGRA® 800 CTS from 200 to 400 patient results per hour. Additionally, the cobas c 513 analyzer will achieve this performance with the same footprint.

The cobas c 513 analyzer features direct results reporting, thereby minimizing the risk of result misinterpretation and eliminating the need to perform time-consuming, manual result interpretation. This feature will help save valuable time and laboratory resources, while ensuring high-quality results.

Furthermore, the cobas c 513 analyzer will provide a higher on-board test capacity. This will enable laboratories to load the analyzer with more tests at a time, save laboratory space, minimize lab resources and ensure a smooth workflow. The new analyzer will also offer closed tube sampling, which will reduce hands-on time, prevent sample contamination and ensure operator safety for laboratory personnel.

About Diabetes
The prevalence of diabetes has increased significantly in recent years, with estimates of as many as 566 million people with diabetes worldwide, of which 32% may still be undiagnosed. The total number of people with diabetes is anticipated to increase by 53% until 2035, putting a significant strain on healthcare providers. More than half of all cases of diabetes are preventable.

About the cobas c 513 analyzer and the HbA1c test

HbA1c is a longer term measurement of blood sugar levels, which is used to determine if a person has diabetes or is at risk of developing diabetes. Set to run on the established Tina-Quant HbA1c A1cDx Gen.3 test, which is also used across the Roche laboratory HbA1c portfolio, the cobas c 513 will ensure high-quality results and comply with current guidelines and recommendations for HbA1c testing and measures A1c as defined by the IFCC.

The cobas c 513 analyzer is based on the proven and trusted cobas technology developed in cooperation with Hitachi High-Technologies (HHT).

About Roche

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

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine 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. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 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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