Media Release

Roche receives CE Mark for AI-based Kidney Klinrisk Algorithm[1] and launches new comprehensive chronic kidney disease (CKD) algorithm panel

- **Roche, in collaboration with KlinRisk, Inc, has received CE-mark for the first AI-based risk stratification tool for assessment of progressive decline in kidney function.**
- **This tool will be launched as part of Roche's new chronic kidney disease (CKD) algorithm panel to support care across the stages of the disease which affects 700 million people globally.**
- **Clinicians can use the CKD panel (Kidney Klinrisk Algorithm and Kidney KFRE Algorithm) to evaluate a patient's risk of kidney function decline, including in the early asymptomatic stages of the disease.**

Basel, 6 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY), in collaboration with KlinRisk, Inc., has received the CE-mark for the first AI-based risk stratification tool to assess progressive decline in kidney function. This milestone allows Roche to introduce the Chronic Kidney Disease (CKD) algorithm panel on its navify® Algorithm Suite to support care across all stages of the CKD care pathway. The panel includes the new Kidney Klinrisk Algorithm - for early risk assessment of adults diagnosed with CKD as well as adults with diabetes or hypertension at elevated risk for kidney function decline - alongside the established CE-marked Kidney KFRE Algorithm (KFRE) for managing later disease stages of CKD.

Chronic kidney disease (CKD) affects more than 700 million people worldwide and is broadly recognized as a global public health challenge.[2] With early diagnosis and appropriate treatment, it is possible to delay or prevent kidney function decline, and reduce cardiovascular risk and related healthcare costs.[3,5,7]

"The launch of the AI-based Kidney Klinrisk Algorithm as part of our chronic kidney disease algorithm panel, represents a significant advancement in the fight against this often silent, progressive disease," said Matt Sause, CEO, Roche Diagnostics. "The panel is designed to support physicians to make more informed decisions and manage patients' kidney function at every stage of the disease. Most importantly, this also includes the possibility to assess adults with diabetes and hypertension, who are at elevated risk for kidney function decline and not yet diagnosed with CKD."

Supporting clinicians in early and proactive care

Healthcare professionals now have easy access to a comprehensive risk assessment solution for managing CKD proactively in both diagnosed and undiagnosed adults at risk, including in

the early, often asymptomatic stages of the disease. This AI-based solution combines multiple input factors from routine blood and urine tests and aligns recommendations with clinical guidelines.

The new CKD algorithm panel, available on the **navify**® Algorithm Suite, marks a significant step in Roche's strategy to provide digital health solutions for the growing global burden of chronic kidney disease. This cloud-based platform seamlessly integrates with existing hospital systems, giving clinicians a single point of access to order and view algorithm results. The panel is available in Europe and the United Kingdom, with a later launch in the United States, the Middle East, and Asia.

About the Kidney Klinrisk Algorithm

The Kidney Klinrisk Algorithm, an *in vitro* diagnostic medical device software, is a machine learning (ML)-based tool to aid clinicians in making more informed, precise decisions on progressive kidney function decline. The algorithm is intended to be applied to adults diagnosed with Chronic Kidney Disease (CKD) in stages G1 to G4, and to diabetic and/or hypertensive adults who are at risk for CKD.

The Kidney Klinrisk Algorithm was developed in collaboration with KlinRisk Inc, a medical AI company founded by Dr. Navdeep Tangri, a leading physician in kidney health, building multiple prognostic tests for cardiovascular, kidney, and metabolic conditions to address the needs of patients, providers, and health systems.

About chronic kidney disease

Chronic kidney disease (CKD) is a progressive condition characterized by a gradual loss of kidney function over time. In its early stages, CKD is often asymptomatic, and many people are unaware they have the condition. If left untreated, CKD can progress to kidney failure, requiring dialysis or a kidney transplant. CKD is closely linked to other chronic conditions such as diabetes and hypertension.

The rising incidence of CKD is fueled by increasing cases of diabetes, hypertension, and obesity worldwide and CKD can be a major healthcare cost driver representing up to 2-3% of the annual budgets.[5] CKD increases hospitalizations, cardiovascular disease and can lead to early mortality.[6] Still, adherence to guideline-directed medical therapies (GDMTs) is often below target use.

About navify

The **navify** portfolio from Roche includes more than 130 digital solutions for labs, hospitals and patients worldwide in commercial or research phases. **navify** solutions connect the healthcare community with a robust digital infrastructure to integrate data efficiently and to accelerate clinician access to innovations as well as operational and medical insights. This work includes collaborating with other innovative companies such as Fortinet in

cybersecurity services. The **navify** platform is designed to deliver security at every step of the data analytical process with ISO/IEC 27001 certification for the Information Security Management System. All data is encrypted at rest and in transit. The solution is operated in compliance with applicable laws and regulations in the USA with HIPAA (Health Insurance Portability and Accountability) as well as with GDPR (General Data Protection Regulation) regulations in Europe.

Healthcare professionals can visit navify Marketplace to browse and request a growing number of next generation digital solutions from Roche and other companies – all designed to drive operational and clinical excellence, built on the foundational pillars of digital trust. More information is also available at navify.com.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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.

References

[1] European Union: EUR-Lex. Chronic Kidney Disease Algorithm Panel [Internet: accessed: August 2025] Klinrisk is an in-vitro diagnostic (IVD) medical device CE-marked (NB 0123) under the requirements laid out in the IVD regulation (EU) 2017/746 (IVDR).
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[5] N Tangri et al.: Impact of Improved Diagnosis and Treatment on Holistic CKD Burden. https://doi.org/10.1016/j.ekir.2025.05.039
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