

Ex vivo test for early diagnosis of Acute Kidney Injury (AKI)

University of Chile has generated a method for early detection of AKI from blood samples, based on the markers FGF23, Klotho y Epo

THE CHALLENGE

AKI is an asymptomatic sudden episode of kidney failure associated with serious short-and long-term complications with high rates of morbidity and mortality; it has 20-67% of incidence in Intensive Care Unit (ICU) hospitalized patients. Diagnosis of AKI is usually done by measuring urine flow and blood levels of creatinine or electrolytes. However, these markers appear late in AKI progression after significant renal damage has already occurred, making it difficult to manage. An earlier method of diagnosis can lower the risks of kidney damage and allow specific therapies to improve outcomes. This new test would address this issue allowing early detection of patients that will develop AKI.

THE TECHNOLOGY

Ex vivo method for early detection of AKI from blood samples in hospitalized patients, based in a polynomial of plasma concentration of **direct markers of renal function Fibroblast Growth Factor 23 (FGF23), Klotho y Eritropoietin (Epo)**. This test provides information about location, type and severity of the damage in kidney tissue in AKI. Basic and clinical studies performed in septic patients of the CCU, with and without AKI, have demonstrated that this test allows **predicting with high accuracy AKI development, mortality and clinical outcomes**. These studies also showed that this test is applicable to septic patients, for whom the currently available AKI tests are not suitable.

STAGE OF DEVELOPMENT

- **Clinical studies** – >90 ICU hospitalized patients

COMPETITIVE ADVANTAGES

- **Fast response** – 1-2 hours after obtaining the sample
- **High accuracy** – >95% sensitivity and >96% specificity and high precision. Superior to currently available methods
- Performance **superior to leading biomarkers** in market NGal test[®] y NephroCheck[®]
- **Easy to sample and implement** – Blood samples allow testing even in patients not able to produce urine; it uses regular clinical procedures
- **Suitable for septic patients** – Competitor tests do not perform well with septic patients (specificity drops to 60% aprox.)
- **Use of direct biomarkers of kidney function** – Competitors use indirect biomarkers

APPLICATIONS

- Diagnostics of septic and non-septic hospitalized patients

OPPORTUNITY

University of Chile is searching for industry partners for **out-licensing** and/or **collaborating** in further validate and develop this technology (clinical studies and kit development).

INTELLECTUAL PROPERTY/REFERENCES

- US patent application 15/767,708 (PCT/CL2016/050056)
- Toro, L., *et al.* (2018). Erythropoietin induces bone marrow and plasma fibroblast growth factor 23 during acute kidney injury”, *Kidney Int.* 93(5):1131-1141