Published scientific study proves efficacy of Eurofins Viracor-IBT's ImmuKnow® test, improving patient survival rate

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Eurofins Scientific (EUFI.PA), the global leader in bio-analytical testing, and one of the world leaders in genomic services, is pleased to present the results from a recent study [1] published in Transplantation [2], showing that Viracor-IBT's ImmuKnow, the FDA-cleared immune cell function assay that detects cell-mediated immunity in immunosuppressed patients, helps improve outcomes in solid organ transplant (SOT) patients. The study demonstrated that the ImmuKnow assay provided additional data which helped optimize immunosuppression, and ultimately improve patient survival rate[3].

In solid organ transplantation, optimizing a patient's immunosuppressive therapy is critical in balancing the risk of organ rejection caused by an inadequately suppressed immune system, and the risk of infection, cancer and drug toxicity caused by over-immunosuppression. Results from the study show the ImmuKnow assay provides a useful biomarker which enables optimizing immunosuppression to improve patient outcomes by preventing bacterial and fungal infections, reducing immunosuppressant drug use and improving 1-year patient survival. The use of the ImmuKnow assay in a hospital's immunosuppression protocol can therefore increase the success rate in organ transplantation.

Specifically, the study showed that the use of the ImmuKnow assay helped **(1)** increase patient survival by 13% one year post-transplant **(2)** decrease infections over 2 weeks post-transplant; and **(3)** lower immunosuppressant drug dosage (tacrolimus). While there have been numerous retrospective and prospective studies over the years demonstrating the ability of ImmuKnow in identifying patients at risk of organ rejection and infection, this is the first interventional, outcomes-based study, which generated much discussion at the American Transplant Congress (ATC) in May 2015.

Comment from **Gilles Martin,** Eurofins Scientific CEO: "The ImmuKnow assay is just one of the specialized tests with fast turnaround time that Viracor-IBT, part of the Eurofins Scientific Group, offers to aid in the diagnosis and differentiation of SOT complications. The findings of this study, particularly the improvement in 1-year patient survival among transplant patients, are encouraging, and illustrate the positive impact that Eurofins aspires to across the Group. In line with its commitment to contribute positively to health, Eurofins promotes innovation across its laboratory network to develop technologies and analytical methods that take scientific advancements to benefit patients and consumers."

[1] Ravaioli M, Neri F, et al. Immunosuppression Modifications Based on an Immune Response Assay: Results of a Randomized, Controlled Trial. Transplantation. Epub* March 9, 2015.
[2] The official Journal of The Transplantation Society, published monthly.
[3] Refer to Summary of the findings of the study on p.2 of this press release

"Immunosuppression Modifications Based on an Immune Response Assay: Results of a Randomized, Controlled Trial". *Transplantation. March 9, 2015.* Summary of findings:

The prospective, randomized, controlled, blinded, interventional study involved 202 adult liver transplant recipients. Patients were divided into two groups; 102 patients received standard immunosuppressive therapy (control group) and 100 patients received adjustments to therapy based on their cell-mediated immune responses determined by the ImmuKnow assay (interventional group). In the interventional group, patients were tested with the ImmuKnow assay before liver transplantation, immediately after surgery and at each clinic visit occurring at approximately day 1, weeks 1 to 4, 6 and 8 and months 3 to 6, 9 and 12. The assay was repeated within 7 days of a suspected or confirmed rejection or infection, and again within one week after resolution of the event.

Based on immune function values, tacrolimus doses were reduced 25% when values were less than 130 (low immune cell response) and increased 25% when values were greater than 450 (strong immune cell response). This means that physicians are able to adjust the amount of the immunosuppressant drug, tacrolimus, to a more optimal, patient-specific level, helping maintain the critical balance between reducing organ rejection and patient infections. The study concludes that ImmuKnow provides a useful biomarker which enables optimizing immunosuppression to improve patient outcomes by preventing bacterial and fungal infections, reducing immunosuppressant drug use and improving 1-year patient survival.

ImmuKnow® is FDA cleared for the following intended use: Detection of cell-mediated immune response in populations undergoing immunosuppressive therapy for organ transplant.

For more information please visit http://www.eurofins.com or contact:

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Notes for the editor:

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