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BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES

BioPharma Services News

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Study shows ImmuKnow® test improves patient survival rate

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As a member of the Eurofins Scientific Group, Viracor-IBT Laboratories is committed to contributing positively to global health through its specialised clinical diagnostic testing, such as its ImmuKnow assay.

Results from a recent study[1] published in *Transplantation*[2], show that 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 assay provided additional data which helped physicians optimise immunosuppression, and ultimately improve patient survival rate.

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 two 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.

In solid organ transplantation, optimising 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. Study results show the ImmuKnow assay provides a useful biomarker which enables optimising 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.

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

To learn more, please visit:
www.viracoribt.com/immuknow

[1] Ravaioli M, Neri F, Lazzarotto T, Bertuzzo VR, et al. Immunosuppression Modifications Based on an Immune Response Assay: Results of a Randomized, Controlled Trial. Transplantation. 2015 Aug;99(8):1625-32.

[2] The official Journal of The Transplantation Society, published monthly.

GLP Certification for high quality sequencing services within the regulatory field

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Good Laboratory Practice (GLP) is the worldwide gold standard to conduct non-clinical health studies, including pharmacology and toxicological studies. Additionally, for pre-clinical safety studies GLP compliance is required for the development of pharmaceuticals (small molecules) and biologics (monoclonal antibodies, therapeutic proteins, vaccines and gene therapeutics). GLP standards are also critical for the development of diagnostic kits and device validation (FDA and patent submissions), as well as an array of other products including agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, and detergents.

Extended GLP certifications for Sequencing (Sanger & Next Generation)

Good Laboratory Practice is the highest QA standard Eurofins offers to their pharma and diagnostics customers. GLP ensures that test data is reliable, repeatable and auditable and is easily recognised by scientists and authorities worldwide.

As a result, in 2014 Eurofins Genomics added Next Generation Sequencing (NGS) to their ISO 17025 accredited testing portfolio. At the same time the company achieved GLP certification for DNA sequencing services, the first genomic service provider in Germany to attain such qualification.

Some months later AROS, a member of the Eurofins Genomics Group, has extended GLP certification for (NGS) services as one of the first service providers in Europe.

AROS has already been GLP certified since 2005 for their DNA and RNA extraction services, qPCR (Gene Expression and Genotyping) and microarrays (Illumina and Affymetrix). In 2015 they also added the certificate “non-clinical safety studies for medical products on NGS under GLP” to their GLP certified platforms.

With this comprehensive set of GLP certifications for sequencing services, Eurofins customers yield the combined full benefits of highly skilled staff, formal quality management and quality assurance systems and long-term experience. For more information, visit *www.eurofinsgenomics.eu*

Update on current revisions of ISO 10993 medical device standards and their implication for testing

By Dr. Albrecht Poth, Scientific Director, Eurofins Medical Device Testing, albrechtpoth@eurofins.com

A large number of experts including Eurofins key scientists met in June 2015 in Lund, Sweden, to discuss new scientific developments and challenges to be included in the revision of the ISO 10993 standards, used in the biological evaluation of medical devices.

Three major standards, ISO 10993-1, -17 and -18 are to be revised. For ISO 10993-1 “Evaluation and testing within a risk management process” it was discussed to change the flow-chart describing the systematic approach to the biological evaluation of medical devices, with a strong focus on the chemical characterisation of the medical devices. By including additional requirements, chemical characterisation and cytotoxicity testing will be mandatory while all other toxicological endpoints will be evaluated within a toxicological risk assessment.

A major revision of ISO 10993-17 on allowable limits for leachable substances is in the works. Risk assessment approaches to use the concept of Threshold of Toxicological Concern (TTC), already established and accepted for genotoxic pharmaceutic impurities, are in discussion. If it can be shown that an impurity is below the TTC, then it is assumed that the chemical substance is of no significant risk.

A major revision will be made to ISO 10993-18 to incorporate the technical and scientific experience developed during the last 10 years since its publication, including a more detailed description of experimental requirements for the investigation of extractables and leachables and a revision of the stepwise chemical characterisation process, including the setting of the analytical evaluation thresholds (AETs) in alignment with the TTC-concept.

Based on the proposed revisions, it can be foreseen that in the future chemical characterisation will be a key parameter in the risk management process of medical devices. Eurofins laboratories are already aligned to the new requirements and biological evaluations, including biocompatibility studies, chemical characterisations, and toxicological assessment performed on a regular basis by our experts.

To receive advice and support, contact:
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Eurofins Experchem helps global pharma companies enter the Canadian marketplace

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In Canada, medical device and drug regulations are similar to those in other countries, but have their own very specific requirements. Classification of a product in Canada might differ from the US or Europe. For example, sunscreen products are classified as drugs in Canada and require a licence, like other drugs, but are cosmetics in Europe. Also, certain creams and liquids regulated as medical devices in Europe or the US are in many cases regulated as drugs or Natural Health Products (NHPs) in Canada.

Regulations affecting dietary supplements or NHPs differ greatly in Canada compared to other countries. In the US, the Food and Drug Administration (FDA) regulates most dietary supplements as foods, which are not evaluated for safety or efficacy prior to release in US markets. In Canada, however, dietary supplements such as botanical formulations, vitamins, minerals, amino acids, enzymes and homeopathies are regulated as NHPs following guidelines similar to drugs.

When a product is regulated as a NHP, the manufacturer must demonstrate to Canadian authorities that the product is safe and effective before a licence is issued and the product can be marketed. A site licence is required to manufacture, label and/or import a NHP in Canada. To receive a site licence, the company must demonstrate compliance with Good Manufacturing Practices (GMPs).

If a company's products are already marketed in the USA, Europe or other countries, now could be a good time to look at entering the Canadian marketplace and expanding global reach. Eurofins keeps manufacturers and distributors connected globally, and now the company is pleased to offer regulatory support services to get your product on the shelf in Canada.

Experchem Laboratories, is located in Toronto, Ontario, Canada and was recently acquired by Eurofins. The company has a thriving regulatory affairs department that helps Eurofins clients enter the Canadian market place.
For more information, visit the website: *www.experchemlab.com*.

Meeting the needs of changing research priorities

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The paradigm for drug discovery has been changing in recent years. Fewer blockbuster drugs are anticipated to be developed, and many existing blockbuster drugs have gone off-patent. As a result, most pharmaceutical companies are looking to evolve their approach to drug discovery. Part of this evolution is for Big Pharma to rely on acquisition of smaller companies with promising early stage pipelines while streamlining their own operations. As a result, internal capacity and know how is contracting. This means these companies are looking to supplement their internal capabilities by outsourcing more of their reagent production, assay development and testing.

As a market leading provider of products and services supporting early stage drug discovery, Eurofins Pharma Discovery Services (EPDS) is well suited to support the changing needs of biotech and pharmaceutical companies. The aim of early drug discovery is to identify molecules that interact with a target of interest and optimise their potency, safety and pharmacokinetic properties to obtain a candidate drug for IND submission for clinical trials. Along with custom service capabilities, EPDS has the largest portfolio of off-the-shelf products and services to test these properties.

A critical component that drove EPDS to its current market leadership position is the flexibility it provides their clients to transfer projects between internal and external resources. EPDS provides the same recombinant proteins and cell lines used in its screening services as reagents that clients can purchase. This means that researchers can perform the same assays with identical reagents in their own laboratories. This dual capability of assay services and reagent supply adapts to the customers evolving outsourcing priorities and reduces the risk when the decision to run assays in-house or at a service provider changes. Having both services and corresponding reagents available, means that customers can enjoy greater flexibility while being assured of more consistent data.

For more information on EPDS products and services, visit:
www.eurofins.com/pharmadiscovery

New DNA sizing and barcoding methods are robust molecular alternatives to Isoenzyme analysis

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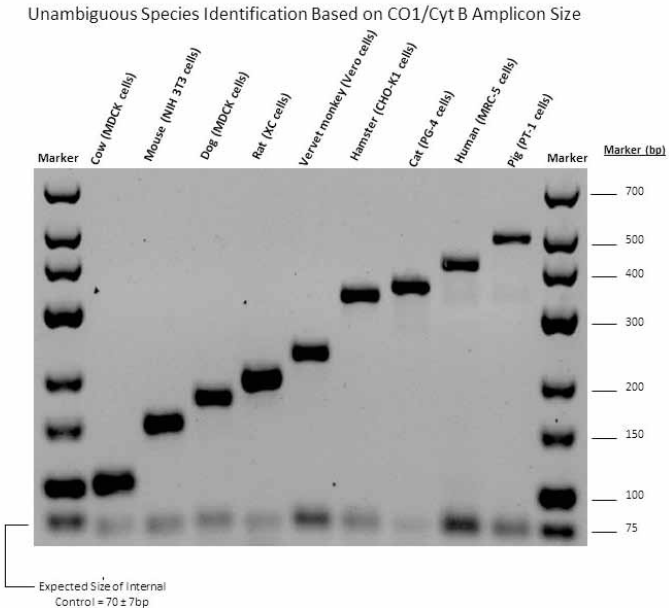
Cell line identity testing is a critical regulatory requirement for recombinant cell lines in order to confirm the cell line's species of origin, as well as to assist in detecting contamination from other cell lines.

Biochemical analysis of isoenzyme polymorphism has been considered the standard test for mammalian and insect cell line identification. However, the methodology suffers several limitations. With limited species coverage, insufficient sensitivity, and reagent supply shortages of the historically standard isoenzyme ID test, Eurofins Lancaster Laboratories has developed DNA Sizing and Barcoding methods to combat these challenges. For species identification, these robust methods utilise the mitochondrial genes Cytochrome Oxidase 1 (CO1) and Cytochrome B (Cyt B) as targets for the molecular identification of cell lines commonly used in biopharmaceutical production.



Why are the DNA Sizing and Barcoding methods superior? For CO1/Cyt B Sizing, genomic DNA is isolated from the cells being tested and amplified using a set of species specific primers. Species identification and detection of cross contamination can be determined based upon the presence/absence of PCR amplification by given sets of primers and the size of the PCR amplicon. Cell lines of cow, mouse, dog, rat, monkey, hamster, cat, human and pig origin can be tested using CO1/Cyt B Sizing. Identification of cell lines derived from a wider variety of animal and insect species can be made by CO1 DNA Barcoding. The comparison between the determined CO1 sequence of tested cell lines and the confirmed species specific sequences deposited in the Consortium for the Barcode of Life database allows for unambiguous genetic identification.

The Sizing and Barcoding methods are based on a more robust technology than that of the isoenzyme assay and can provide more accurate speciation. They can also be easily implemented in a quality control environment. Further, the PCR amplification and DNA sequencing techniques used for the Sizing and Barcoding methods decrease dependency on a single supplier for test reagents. And the Sizing and Barcoding methods are more sensitive with regard to the detection of cell line cross contamination than isoenzyme analysis.

To see how Eurofins Lancaster Laboratories' comprehensive cell line characterisation services, along with its cell banking capabilities, provide clients with a single-source solution for all cell line needs, visit *www.EurofinsLancasterLabs.com*

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