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BioPharma Services
News

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Eurofins' US Clinical Diagnostics delivers complete solutions for transplant patients

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Determining what's happening inside the body of a transplant patient is a constant balancing act for physicians. Is it rejection, infection, toxicity?

With the recent launches of Transplant Genomics' TruGraf® and Viracor's TRAC™ Kidney to the US Clinical Diagnostics' transplant portfolio, Eurofins is now uniquely positioned to serve kidney transplant patients with complete testing solutions for managing rejection, infection, and immunosuppression to support successful outcomes.

TruGraf® Blood Gene Expression Test is the first and only biomarker-guided blood monitoring assay to rule out "silent" or subclinical rejection for patients with stable renal function. For kidney patients with no symptoms, this is a game-changing alternative to invasive and costly organ surveillance biopsies. TruGraf® is covered by Medicare.

Viracor TRAC™ Kidney is a noninvasive donor-derived cell-free DNA (dd-cfDNA) blood test for evaluating "active" or acute rejection. The current gold standard method of rejection diagnosis is biopsy. TRAC™ utilises a liquid biopsy to measure the percentage of dd-cfDNA in the transplant recipient's plasma and eliminates potential complications that biopsies can cause for the patient. Viracor has secured a Proprietary Laboratory Analyses (PLA) code for Viracor TRAC™.

In the simplest terms, if you were a transplant patient, you would want to have TruGraf® ordered for you to make sure your immune system is not "silently rejecting" your new kidney without any outward indication. Silent rejection impacts up to 25% of kidney transplant recipients, so it's a substantial consideration. In similar fashion, if you had indications that active rejection of your kidney had already begun – possibly through a high creatinine test result – you would want to have TRAC™ Kidney ordered for you, as the acute rejection could be confirmed with a blood test instead of a biopsy procedure, which would include taking biopsies of your kidney undergoing rejection.

In striving for diagnostic efficiency and improved cost of care, these advances in transplant testing will make a big difference for the constituencies they serve – transplant patients, healthcare providers and payers. Moreover, offering vanguard testing that impacts transplant patient care further enhances our reputation in the market for innovation, scientific expertise and exceptional service.

Additionally, the diagnostic power of Eurofins' VRL pre-transplant laboratory and Viracor's robust infectious disease and therapeutic drug monitoring options will provide hospitals, physicians and organ procurement organisations with the most comprehensive transplant testing menu available in the U.S. Healthcare providers can now partner with a single diagnostic source for their transplant patients' continuum of care. For more information visit: *www.eurofins.com/clinical-diagnostics/*

Eurofins Discovery as part of CiPA initiative to form future industry regulatory guidelines

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The withdrawal of FDA approved drugs from the market beginning in the late 1990s due to Torsade de pointes (TdP) in patients shocked the global regulators and the pharmaceutical industry and led to the issuing of ICH S7B and E14 guidelines in May 2005. For the past decade, *in vitro* hERG channel assays and *in vivo* QT measurements have been conducted as surrogates for proarrhythmic risk propensity according to these guidelines. This paradigm, although effective, suffered from lack of specificity and led to unnecessary compound attrition during drug development. The Comprehensive *in vitro* Proarrhythmia Assay (CiPA) is a new cardiac safety testing paradigm sponsored by the Cardiac Safety Research Consortium (CSRC), Health and Environmental Sciences Institute (HESI), and Food and Drug Administration (FDA) intended to address this limitation with improved prediction of a drug's proarrhythimic liability.

This new CiPA paradigm includes a panel of *in vitro* assays that integrates effects of the test compounds on several cardiac ion channels for safety margin calculations and in silico modelling, which relies on automated patch clamp platforms (APC) to efficiently provide reliable and reproducible estimates of the potency of a drug block of multiple currents that modulate repolarisation and affect proarrhythmic risk. Eurofins Discovery is a member and key contributor of the CiPA initiative and has recently published a research article on Scientific Reports jointly with 17 major pharmaceutical companies, CROs, instrument providers, and academic labs, presenting results from a pilot study to determine variability of APC data from multiple sites. This multi-platform/multi-site study provides the largest comparison of results and provide estimates of the variability associated with IC50 values characterising the blocking potency of 12 blinded drugs on four prominent human cardiac currents using suggested experimental protocols across five automated patch platforms and 17 sites.

This study will guide the industry on the development of best practices using APC technologies for early screening to avoid cardiac safety liabilities and subsequent characterisation of the risk of delayed repolarisation and proarrhythmia to guide clinical studies and regulatory submissions of CiPA initiative. For information, visit: *www.eurofinsdiscoveryservices.com*

Eurofins PHAST creates new B2B online shop for over 7,000 global Reference Standards

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Eurofins PHAST offers customers with a need for Reference Standards a new easy-to-use online shop for the purchase of USP, EP, and BP Standards. In pharmaceutical quality control, the measurement results in the release analysis of active substances/API, and finished drugs containing the active substance must be traceable to an officially recognised primary standard. In addition to creating complete transparency in the method, this also includes the calibration of the measuring system. Reference Standards are used for this purpose.

Eurofins' online shop exclusively offers over 7,000 original pharmacopoeia standards from USP (United States Pharmacopoeia), EDQM (Ph.Eur.) and MHRA (BP/British Pharmacopoeia) to professionals such as the pharmaceutical industry, laboratories, and pharmacies. The webshop offers its services in three languages: English, French, and German. As "Authorized Distributor", Eurofins PHAST is the official distributor in Europe for more than 3,700 USP Reference Standards.

Why use USP standards? Pascal Van De Veire, Managing Director at Eurofins PHAST, comments: "The USP sets the standard for quality control and assurance in pharmaceutical development and manufacturing. USP Reference Standards are officially recognised, e.g. by the FDA (U.S. Food and Drug Administration). In addition, the official standards help to ensure that the product tests are GMP-compliant. Official USP Reference Standards support laboratory staff in saving time and resources in quality control and in meeting compliance requirements. For customers of the online shop, Eurofins PHAST handles the EU import from the US with its complex and time-consuming customs clearance." For all your Reference Standards needs, visit the new B2B online shop: *www.reference-standards.com*

Microbial contamination : Eurofins BPT Bactup delivers expertise in crisis management and preventive consulting

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Eurofins BioPharma Product Testing Bactup (France) intervenes in crisis management when microbial contamination is proven. The impact for customers is direct and immediate in terms of business, if there is a production delay or if the lots cannot be released. It is crucial to act as quickly as possible (often at Day + 1) in order to unlock the situation. Although the consulting approach is customised, it consists of three steps that allow Eurofins to test hypotheses and identify the source of contamination and its treatment.

Step 1: Technical visit to the customer's site. This investigation lasts on average between 1 and 3 days and allows an accurate view of all the steps at risk in the process in order to identify possible sources.

Step 2: Eurofins Bactup consultants interview multiple stakeholders directly or indirectly related to the process (cleaning operators, line managers, quality assistants, etc.) in order to obtain as much relevant information as possible. This allows Eurofins to fully understand all the steps, cross-check the information, and develop hypotheses, which will be confirmed or refuted by analyses.

Step 3: Analysis in Eurofins BPT laboratories: incubation, identification (Maldi-Tof or sequencing) and strain typing to identify the source of contamination.

Eurofins Bactup not only intervenes in case of urgency, but also in preventive consulting, to make sure that this type of event does not recur in the future. Eurofins' experts formalise & implement an optimal control strategy, meaning: rational, structured, and reasonable. The goal is not to implement a huge labyrinthine system, but rather to be pragmatic and make the process financially acceptable to customers.

Additional services offered by Eurofins Bactup:

- Data review models: identification of KPIs and models for interpretation
- Strain storage bank service (-80 °C or -150 °C in nitrogen)
- Technical audits (in France or abroad)
- Custom Training

For more information, visit: *www.bactup.com/en/accueil_en/*

Two-dimensional Powder X-ray Diffraction: fast and effective PXRD technique for material characterisation

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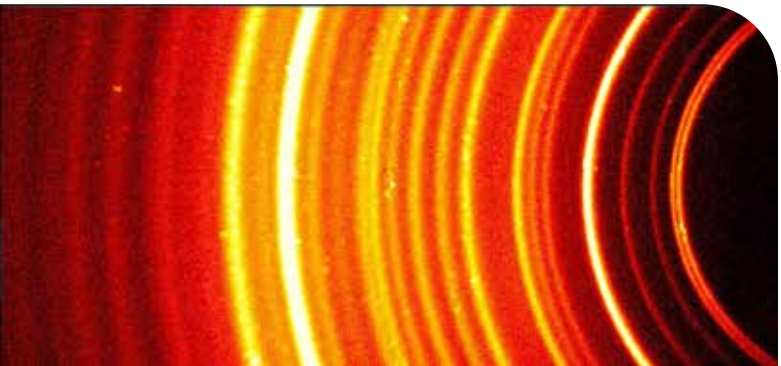
Physicochemical characterisation of the API is a regulatory requirement and a vital step in drug development. Powder X-ray diffraction (PXRD) is an accepted technique in the pharmaceutical industry as a non-destructive test method to analyse the structure of a crystalline material, determine the amorphous content, or detect residual crystallinity in amorphous samples. While conventional PXRD instruments collect diffraction patterns using 1D detectors, area (2D) detectors have been utilised recently in more modern diffractometers providing many advantages over the 1D technique. A two-dimensional diffraction frame contains far more information than a diffraction pattern measured with a conventional diffraction system with a point detector or a linear position-sensitive detector. The speed of two-dimensional diffraction is typically several orders of magnitude higher than conventional diffraction, making it suitable for high-throughput and fast PXRD measurements. In addition, very small quantity of material is needed to perform 2D-PXRD analysis using modern instruments.



The Solid State Research & Development (SSRD) team at Eurofins CDMO utilises a D8 Discover diffractometer equipped with a 2D detector and a microfocus X-ray source, specialised for high-throughput PXRD studies, which is capable of collecting PXRD data on samples as low as 1 mg. In addition to high-throughput screening, Eurofins CDMO's solid state experts take advantage of this instrument for fast PXRD method developments based on the additional knowledge gained about the nature of the sample, preferred orientation, and crystallite size from the 2D detector. This knowledge-based approach to method development adds value to Eurofins' GMP method validation and data collection when performed on a D2 Phaser PXRD diffractometer with optimised sample preparation for each specific compound. In summary, with the help of this new 2D X-ray diffraction technology, the Eurofins CDMO SSRD team collects PXRD data on small sample amounts with speed, accuracy, and optimised sample preparation based on the knowledge obtained from a 2D detector. For more information: *www.eurofins.com/cdmo*

Eurofins BPT Ireland has expanded and now affords global biopharmaceutical companies increased opportunities for Large Molecule and Gene Therapy Testing

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Large molecule therapies, biologics and especially biosimilars, are important and increasingly affordable sources of remedies around the world. Since more and more companies have been started up to develop biosimilars, there has been an equally intensified demand for testing of the safety, potency, efficacy, and identity of these therapies.

Gene therapies have exploded onto the scene, producing exciting customised treatments for specific disease states and even specific people. Customised therapies show promise and are on the rise. More and more pharmaceutical companies are racing towards clinical testing at an ever-increasing pace. Testing of gene therapeutics also for safety, potency, efficacy and identity are increasingly critical as the rapidity of development surges.

Eurofins BioPharma Product Testing Ireland, determined to meet the rising demand for testing, made significant investments in laboratory additions totalling 47,360 square feet (4,400 square meters). The Molecular Cell Biology (MCB) laboratory suites currently have multiple new Biosafety Cabinets, RT-qPCR systems, plate readers, plate washers, and much more – occupying about two-thirds of the new expansion space. And cold storage capacity is currently comprised of +5°C, -20°C, -80°C, and cryogenic storage.

As the demand for testing has increased, the last one-third, approximately 8,000 square feet, of this laboratory space expansion is being outfitted with additional new equipment and state-of-the-art instrumentation designed specifically for testing biologics and gene therapies, including ddPCR and Sanger sequencing capabilities. Continually looking ahead, new technologies, such as analytical ultracentrifugation, are also being evaluated for inclusion at the Dungarvan site.

Successfully operational for testing large molecule and gene therapeutics, the new MCB suites offer state-of-the-art laboratories specific for cell based assays (potency, efficacy), ELISA assays (potency, identity), and qPCR assays (safety, identity). Moreover, a fully trained team of skilled scientists and team leaders continually strive to ensure that the highest level of quality is maintained and provide accurate results in a timely manner. To that, the Dungarvan site has uniquely and accurately positioned itself as a Center of Excellence.

Eurofins BPT in Dungarvan, Ireland, is proud to be proficiently testing therapeutics for multiple clients and has the capacity and expertise to launch testing for any new or established therapeutic destined for the European or worldwide marketplace. Eurofins is resolute in delivering complete GMP compliant support for every client, every time. For more information, please visit: *www.eurofinsus.com/bpt*

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