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**FINAL**

## **virco<sup>®</sup>TYPE HIV-1 resistance test achieves CE-Marking approval**

***Only bioinformatic diagnostic to provide CE-Marking quality assurance in HIV market***

*Beerse, Belgium, 3<sup>rd</sup> November 2010:* Virco BVBA has today announced that their HIV resistance testing product, virco<sup>®</sup>TYPE HIV-1, has achieved CE-Marking approval. virco<sup>®</sup>TYPE HIV-1 is the only bioinformatic diagnostic device of its kind to carry CE-Marking in the HIV market.

The CE-Marking indicates that virco<sup>®</sup>TYPE HIV-1 is a medical device that complies with all applicable quality and safety standards for devices of this kind. This CE-Marking demonstrates that Virco has obtained regulatory approval from the authorities for virco<sup>®</sup>TYPE HIV-1 in the European Union (EU), European Economic Area (EEA) and Switzerland.

Dr Anton Pozniak from the Chelsea and Westminster Hospital in London, UK, commented: "virco<sup>®</sup>TYPE HIV-1 is a state-of-the-art device that guides physicians through the extremely complex HIV treatment decision process and can help to facilitate effective disease management, particularly for treatment-experienced patients. This CE-Marking means that clinicians can rest assured about the safety and proper performance of virco<sup>®</sup>TYPE HIV-1, also helping laboratories to reduce their existing burden of validating resistance test results."

virco<sup>®</sup>TYPE HIV-1 is used by clinical laboratories to predict how susceptible a patient's virus will be to currently licensed reverse transcriptase and protease inhibitor HIV-1 drugs. Virus from the patient is genetically sequenced by the referring laboratory and the sequence is sent securely to Virco. The mutations are evaluated and then the virco<sup>®</sup>TYPE HIV-1 software conducts complex mathematical modeling to predict how the virus will respond to a given drug.

The product does this by drawing on information contained in Virco's extensive database, which includes 61,000 matching genotype/phenotype pairs, derived from 445,000 genotypes and 98,000 phenotypes.<sup>1</sup> This is supported by a database of over 16,000 patient clinical outcomes to link resistance to response to therapy in treated patients.<sup>1</sup> Studies have demonstrated this system to be a highly reliable predictor of treatment response.<sup>2,3</sup>



Werner Verbiest, General Manager Worldwide, Virco BVBA, noted: "This is a significant milestone for Virco and our product. CE-Marking extends the value of virco<sup>®</sup>TYPE HIV-1 to our customers as a unique, bioinformatic, software-based diagnostic that provides service in a regulated manner to support complex clinical decision making for this chronic disease in the EU."

A new service that will evaluate response to integrase inhibitors is due to be launched in the near future and will be known as virco<sup>®</sup>TYPE HIV-1 *IN*.

### **About Virco BVBA**

Virco's goal is to facilitate personalised clinical decision-making via advanced diagnostic and bioinformatic tools to improve patient outcomes. A pioneer and leader in this specialised field, in addition to providing resistance interpretation, education and facilitating access to this technology worldwide, Virco actively collaborates with hospitals and academic institutions in researching topics of virological and clinical relevance in HIV, hepatitis C virus and other infectious diseases.

It is also actively engaged in the use of new diagnostic technologies and in developing bioinformatic tools, health information technologies (such as electronic medical records and registries), and data interpretation with these new technologies to realise potential new products for managing antiviral resistance and complex disease states.

### **About virco<sup>®</sup>TYPE HIV-1**

Information about virco<sup>®</sup>TYPE HIV-1 can be found at:

<http://www.vircolab.com/hiv-resistance-products/vircotype-hiv-1>

### **About CE-Marking**

Additional information can be obtained via:

[http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/legislation/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/legislation/index_en.htm)

### **References:**

1. Data on File (August 2010). Accessed at: <http://www.vircolab.com/hiv-resistance-products/vircotype-hiv-1/how-does-vircotype-work> (26th August 2010)
2. Winters, B, *et al.* Clinical cut-offs for HIV-1 phenotypic resistance estimates: Update based on recent pivotal clinical trial data and a revised approach to viral mixtures. *Journal of Virological Methods*. 2009;162: p101-108.
3. Van Houtte, M, *et al.* A Comparison of HIV-1 Drug Susceptibility as Provided by Conventional Phenotyping and by a Phenotype Prediction Tool Based on Viral Genotype. *Journal of Medical Virology*. 2009; 81: p1702-1709.

Dr Pozniak is a paid consultant to Virco BVBA and Tibotec Virology BVBA.

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