GenDx has registered NGSgo®-MX11-3 as CE marked IVD.

A new multiplexed amplification approach for HLA genotyping by NGS

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Genome Diagnostics B.V., also known as GenDx, received approval this week to CE mark its multiplexed amplification product NGSgo®-MX11-3, which can now be used for accurate HLA typing of donors and patients in need of organ or stem cell transplantation.

This approval of NGSgo-MX11-3 completes the series of GenDx' CE-marked IVD amplification products, including a singleplex (NGSgo®-AmpX v2) and a six-gene multiplex (NGSgo®-MX6-1) strategy for HLA typing by Next-Generation Sequencing (NGS). All amplification products can be used in combination with the recently CE-marked IVD Library Full Kit for indexing, library preparation, and cleanup.

NGSgo-MX11-3 consists of amplification primers for eleven HLA genes (HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1, DRB3/4/5, DQA1, and DPA1). The three-tube design results in low noise levels and well-balanced alleles, providing similar high-quality data with the 11-loci multiplex compared to the GenDx singleplex strategy.

Dr. Wietse Mulder, CEO of GenDx, commented: *"We are proud to now offer the NGSgo-MX11-3 multiplex amplification for diagnostic use, and we are convinced this innovative product will accelerate the demand for high-quality multiplex data for stem cell transplantation"*

NGSgo-MX11-3 has a whole-gene coverage approach, resulting in low-ambiguity genotyping and also resolution of nearly all null alleles. The NGSgo workflow is very efficient with minimal cleanups and quantifications, so results can be obtained quickly. NGSgo-MX11-3 provides highly reliable HLA typing results in a very short time. Starting the amplification on day 1 will result in a typing report on day 2 before noon.

Similar to other NGSgo products, GenDx strives to make the amplification of NGSgo-MX11-3 compatible with multiple NGS platform providers such as Illumina, IonTorrent, and PacBio, for which studies are currently ongoing.

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About High-Resolution HLA Typing

The Human Leukocyte Antigen (HLA) system consists of a large family of highly variable genes and allelic variants which form the basis of the human immunological defence system. In stem cell transplantations, HLA matching of patient and donor is vital as small differences between HLA alleles may have serious effects on transplantation outcome. High-resolution typing is a technology which enables determination of even the smallest variations in HLA genes, making it ideal for stem cell transplantation purposes*.

Until recently, Sanger sequencing-based HLA typing was considered the main reference for high-resolution typing. Nowadays, NGS is being adapted by HLA laboratories worldwide and is rapidly becoming the new gold standard for HLA typing, as this technique offers a higher resolution and is more suitable for high throughput. The easiness of amplifying whole genes in a single run also strengthens the trend towards multiplexed amplification.

As one of the pioneering companies in the HLA field, GenDx started offering NGS strategies in 2013, consisting of NGSgo reagents and the software package NGSengine® for various NGS platforms. NGSgo-AmpX was CE marked in 2014, and the NGSgo full workflow compatible with the Illumina NGS platform received the CE mark in 2016. The products NGSgo-AmpX v2, NGSgo-MX6-1 and NGSengine are also IVD marked by Health Canada.

About GenDx
Genome Diagnostics B.V., also known as GenDx, is a Dutch company, specialized in molecular diagnostics, focused on development, production and sales of innovative assays and analysis software for transplantation and companion diagnostics.
GenDx specializes in HLA sequencing-based typing strategies and offers reagents and software for both Sanger and NGS approaches. Additionally, GenDx offers post transplantation products for chimerism monitoring by qPCR and NGS. Thanks to its extensive in-house expertise, GenDx also offers custom laboratory services for basic and clinical research organizations. GenDx Education organizes dedicated HLA sequence based typing and chimerism monitoring training courses worldwide on a regular basis for anyone working in tissue typing or research laboratories, blood banks, and donor registries.

GenDx is based at the Utrecht Science Park, the Netherlands and was founded in 2005 by Erik Rozemuller PhD, Wietse Mulder PhD and UMC Utrecht Holdings B.V. represented by Oscar Schoots PhD and Raoul Linschoten LLM. GenDx also has a USA-based office near O'Hare airport, Chicago, IL. In 2019, Ampersand Capital Partners completed a minority growth equity investment in the company and David Parker joined the GenDx Board of directors. Recently Bob van Gemen has taken the position of independent board director. For further information about GenDx go to www.GenDx.com. GenDx has also an office in USA.

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