



## GenDx' HLA typing products IVD registered at Health Canada

Utrecht, the Netherlands - February 22, 2021

GenDx has completed IVD registration in Canada for two NGSgo products.

- 1) **NGSgo®-AmpX v2** for individual HLA gene amplification
- 2) **NGSgo®-MX6-1** for multiplexed amplification of six HLA genes in one tube

The amplification products can be used to obtain high-resolution HLA genotyping information by means of downstream sequencing applications, and genotype analysis with IVD-registered NGS-engine® software.

The completion of the registration makes NGSgo the first IVD product line in Canada that is suitable for diagnostic NGS-based HLA typing of donors and patients in need of a stem cell transplantation.

**NGSgo-AmpX v2** is the successor of the original NGSgo-AmpX, which is successfully being sold globally. This v2 product uses the same primer design, but has been optimized by a faster cycling protocol, colored primers for easier handling, and a convenient enzyme mastermix that requires fewer pipetting steps.

**NGSgo-MX6-1** is a more recently released multiplex amplification strategy, that combines amplification primers of six HLA genes (HLA-A, B, C, DRB1, DQB1 and DPB1) in a single tube. The primer design is similar to the robust NGSgo-AmpX approach, resulting in a product that delivers high quality data, while the number of pipetting steps and hands-on time are greatly reduced.

Wietse Mulder PhD, CEO of GenDx, commented: *"We have worked intensely to validate and document these NGSgo products according to the Health Canada IVD regulation. It took a great deal of work to complete, and we are proud to be the first supplier that can offer this IVD product for the transplant community in Canada. We believe the products will truly support better typing of the HLA genes."*

### About High-Resolution HLA Typing

The Human Leukocyte Antigen (HLA) system consists of a large family of highly variable genes and many allelic variants which form the basis of the human immunological defense 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 genotyping 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 gold standard for high-resolution typing. Nowadays, Next Generation Sequencing (NGS) is being adapted by the vast majority of HLA laboratories worldwide to become the new gold standard for HLA typing. This NGS approach offers higher resolution and is more suitable for high throughput.

As one of the pioneering companies in the HLA field, GenDx started offering NGS strategies already 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 Illumina MiSeq received the CE mark in 2016. Since 2017, NGSengine is also registered as IVD at 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 also has a USA-based office near O'Hare airport, Chicago, IL.

GenDx specializes in HLA sequencing-based typing strategies and offers reagents and software for both Sanger and NGS approaches. Additionally, GenDx offers products for chimerism monitoring by qPCR and is developing products for chimerism monitoring by 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. In 2019, Ampersand Capital Partners completed a minority growth equity investment in the company and David Parker joined the GenDx Board of directors. For further information about GenDx visit [www.GenDx.com](http://www.GenDx.com).

### **GenDx Netherlands**

Yalelaan 48  
3584 CM Utrecht  
Office: +31 30 252 3799  
E-mail: [info@gendx.com](mailto:info@gendx.com)

### **Contact GenDx**

Wietse Mulder PhD  
CEO  
Email: [w.mulder@gendx.com](mailto:w.mulder@gendx.com)  
Phone: +31 30 252 3799

*NGSgo® and NGSengine® are registered trademarks of GenDx. GenDx is a registered trade name of Genome Diagnostics B.V. MiSeq® is a registered trademark of Illumina*