NANOTYPE™

omixon
WE IMPROVE TRANSPLANT OUTCOMES

OMIXON'S
VISION

Nanopore-based long-read sequencing technologies have the potential to fundamentally change the clinical routine of HLA genotyping. This technology may represent a paradigm shift similar to Luminex technology for antibody assessment in the early/mid 2000's. Nanopore sequencing is the first technology that is able to generate 2-3 field allelic resolution within 6 hours for deceased donors. The same technology is also convenient for routine typing providing results in less than 24h for 12 to 24 samples. This technology will enable better allocation for solid organ patients using epitope matching and rapid typing for all urgent situations (e.g. cardiac patient enlistment, confirmatory typing, and reflexive testing).

ABOUT
NANOPORE-BASED TYPING

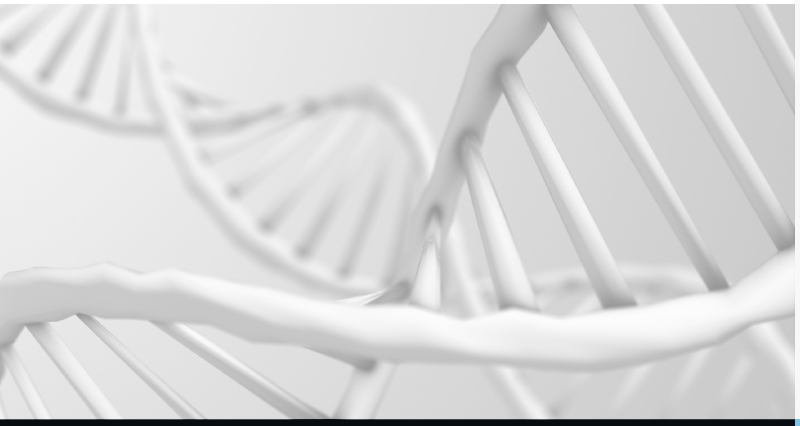
Nanopore has developed a new generation of sensing technology that uses nanopores embedded in high tech electronics to perform precise molecular analysis. When a DNA fragment is entering a nanopore, each DNA base is disrupting the electrical field with a specific signature and can be used as a single molecule detector. The deconvolution of the electrical signal is done using a basecaller converting the electric signal into a DNA sequence with a FASTQ output format, similar to Illumina based sequencing. This FASTQ file is then imported into HLA Twin 5.0 for genotyping. One major advantage of Nanopore sequencing is the long reads facilitating the phasing of even long-distant SNPs resulting in fewer ambiguities.

> "This technology may represent a paradigm shift similar to Luminex Technology for Antibody assessment in the early / mid 2000's"

BENEFITS TO

BETA TESTING PARTICIPANTS

- Early exposure to product
- Future Key Account status
- Ability to influence assay and software product development
- RUO validation reagents from Omixon at 50% discount



BENEFITS OF

NANOPORE-BASED HLA TYPING

- The fastest sequencing-based HLA genotyping method
- Minimal capital cost
- Simplified workflow compared to classical NGS
- Higher resolution compared to SSO/ SBT/ Real Time PCR
- Turn around Time from DNA to results:
  - *For deceased donor-like workflow: < 6 hours*
  - *For routine typing for 12 samples: < 24 hours*
- Flexible and scalable based on laboratory requirements

ABOUT THE ALPHA PROGRAM

The Alpha program was the initial testing phase and allowed some laboratories to proceed with our assay workflow using the MinION™ device and flowcells.
The laboratory agreed to proceed with an experimental plan and the results were transferred and analyzed at Omixon.
This initial feedback was used to position the product and understand how laboratories would use it in routine.

ABOUT THE BETA PROGRAM

Our Beta program will allow participants to test the prototype version of HLA Twin 5.0 with long reads genotyping and the improved version of our NanoTYPE™ assay. We will provide the software installer together with FASTQ files and we are looking for feedback on stability, usability, ergonomic and missing features.
During the 6 months of the Beta program, we will also provide you with the latest version of our amplification reagents in order to test the whole workflow. Similarly, we would value your feedback.

PARTICIPATING TO THE BETA PROGRAM

Laboratories interested in enrolling to the program will be under Non-Disclosure Agreement and Omixon will provide the amplification reagents and HLA Twin 5.0, the software supporting long read analysis. An overview of the specific equipment (not provided) is listed below, and a Site Preparation Guide is also provided.

JOIN NOW!

EQUIPMENT & REAGENTS

SPECIFIC EQUIPMENT PROVIDED BY OMIXON

- NanoTYPE™ amplification reagents for 11 loci (HLA-A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1, DPB1)
- HLA Twin 5.0 including NanoTYPE™ typing module (Beta program trial license)
- On-site and/or remote protocol training

SPECIFIC EQUIPMENT NOT PROVIDED BY OMIXON

ESTIMATED INVESTMENT < 10K USD / EUR

- MinION™ sequencer, MinION™ flow cell, Library preparation Kit
- Computer: OS Linux Ubuntu 18.04 (64 bit), RAM 32 GB, CPU I7 with 8 cores or I9 / Xeon with at least 4 cores/8 threads, specific NVIDIA graphics card, at least 1 Tb of disk capacity, additional storage for data

THE DETAILED LIST OF ALL EQUIPMENT AND MATERIAL CAN BE FOUND IN THE NANOTYPE™ SITE PREPARATION GUIDE.

EXPERIMENTAL PLAN

Our Field Application Scientists will set up a call with the participants and help them prepare the laboratory for testing. Once the laboratory is equipped, the NDA signed and the resources available, Omixon and the laboratory agrees on a starting date to run the evaluation with the support of the local Field Application Scientist.

PHASE I

SOFTWARE TESTING

Participants of alpha testing program will be provided first with the HLA Twin 5.0 installer and will analyze their samples to provide the feedback on the functionality and new feature requests for the software.

PHASE II

FULL WORKFLOW TESTING

We would like the participants to run at minimum 2 × 12 samples in total, including 2 Omixon's reference DNA samples in each run according to the protocol and participant can run 2 different protocols.

- One for short turn around time typing with 1 or 2 samples e.g deceased donor-like workflow
- One for routine typing with up to 12 samples

RESPONSIBILITIES OF BETA TESTING PARTICIPANTS

- Purchase all necessary material not provided by Omixon, as specified in the Site Preparation Guide
- Report in the 'Beta Testing Lab Book' all instruments, reagents and consumables used
- Execute the protocol identically to Omixon R&D with no deviation
- Complete Beta testing of a 2x10(+2) samples for 11 HLA loci
- Feedback on assay performance
- Feedback on software analysis

SAMPLE REQUIREMENTS:

Various DNA sample sources (including but not limited to whole blood, glands and other tissue)

All samples should have known reference typing, 2nd field/G group resolution minimum for all loci (any technology that achieves this resolution)

Reference Typings are to be provided to Omixon in Omixon's Template

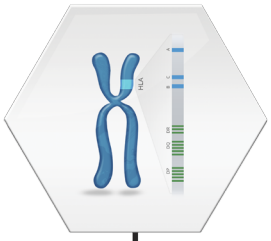
Provide all Beta Testing data to Omixon, including raw sequencing data, reference data, and Lab Book for meta-analysis

Provide the aliquot (at least 500 ng of DNA) of the tested samples for further QC in Omixon lab

WORKFLOW OVERVIEW

NANOTYPE™
STAT TYPING

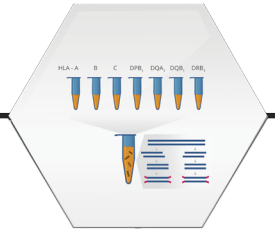
Long Range-PCR



5min
HANDS-ON TIME

2h 05min
TOTAL TIME

Transposase based
Library Preparation



15min
HANDS-ON TIME

30min
TOTAL TIME

MinION™
Flow Cell Priming
Flow Cell Loading

5min
HANDS-ON TIME

2h
TOTAL TIME

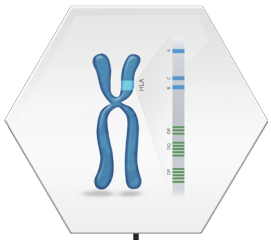
Data Analysis

1min
HANDS-ON TIME

5min
TOTAL TIME

NANOTYPE™
ROUTINE TYPING

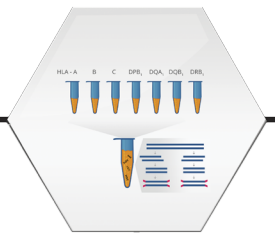
Long Range-PCR



15min
HANDS-ON TIME

2h 15min
TOTAL TIME

Transposase based
Library Preparation



15min
HANDS-ON TIME

50min
TOTAL TIME

MinION™
Flow Cell Priming
Flow Cell Loading

5min
HANDS-ON TIME

12h 10min
TOTAL TIME

Data Analysis

5min
HANDS-ON TIME

<1h
TOTAL TIME

*MinION™ is a registered trademark of Oxford Nanopore Technologies Ltd in various countries

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