



NGS on Target

The Holotype HLA™ EAP Guide

Omixon is gearing up to launch Holotype HLA - a combination Assay and Software product that leverages the power of Next Generation Sequencing (NGS), for use on the Illumina® sequencing platform. The Assay has been developed by Professor Dimitri Monos, Director of the Immunogenetics Laboratory in the Department of Pathology and Laboratory Medicine at CHOP and his group.

The Assay provides targeted amplification by long range PCR and library preparation reagents for whole gene coverage of HLA-A, B, C and DQB1, and partial coverage for HLA-DRB1. Sequencing on the Illumina MiSeq will generate 2x 250 bp of paired end reads. The long range PCR and the paired end sequencing allows for complete genetic characterization and gene-level phasing for the 5 loci.

The Software was co-developed with the Assay in-house by Omixon and includes a number of features that give scientists the highest possible confidence in the results as demonstrated by 100% accuracy with known samples through a double-blind Alpha Study coordinated by Dr. Monos at CHOP to be presented at ASHI 2014.

All participants will need to sign the Early Access Program (EAP) Agreement and agree to those terms.

EAP Timeline

INVITATION

- » Review this guide
- » Review Terms and Conditions
- » Review requirements (IT, lab equipment, staffing, budget)

REGISTRATION AND PAYMENT

- » Agree the Terms and Conditions, including:
 - Non-disclosure
 - Publicity, e.g. PR, quotes and testimonials
 - Data sharing (anonymous) for peer-reviewed publication
 - Reporting and feedback
- » Send Omixon a purchase order for Holotype HLA (the amount will include a minimum of 40% participation discount on list price).

TRAINING

- » Omixon will provide training and support to become familiar with the appropriate use of Holotype HLA.

PERFORMANCE EVALUATION OF HOLOTYPE HLA

- » You will complete a technical performance evaluation on a set of at least 16 of your own samples (64 is recommended to guarantee inclusion in the EAP) including ones with known HLA types over 5-10 weeks.



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- » You will assess assay performance in terms of:
 - Determining concordance/accuracy of genotyping if using known samples
 - Demonstrating evenness of coverage depth, whole gene coverage
 - Demonstrating that there are no allele drop-outs.
 - Demonstrating allele balance
 - Estimating failed sample rate
- » You will assess the software for ease-of-use, computational performance, accurate genotyping, comprehensive quality metrics and detailed visualization.
- » Reporting and Successful Completion
 - Continuous feedback through the process
 - Completing questionnaires and other feedback forms
 - Complete performance evaluation and quality assessment report on the Assay and the Software
 - Provide anonymized Raw Data and Results to Omixon for meta-analysis, re-analysis and use in peer-reviewed publication

Benefits to EAP Participant

- » Early access to Holotype HLA, first mover advantage for adopting NGS for HLA
- » Complementary training on use of our products for evaluation and research purposes
- » Ability to influence software product development roadmap
- » 40% discount for up to six months after the conclusion of the EAP
- » Expert technical advice on IT, equipment, laboratory process and automation requirements for routine HLA genotyping by NGS at any volume

Technical and Equipment Requirements

- » Owning or having access to a MiSeq
- » 64-bit computer with a minimum of 8 GB RAM
- » DNA Size Selection: SAGE Science Pippin Prep
- » Thermal Cycler: any brand
- » qPCR instrument: any brand
- » Plate reader: any brand

What's Next?

To register your interest in joining the Holotype Early Access Program, email our CEO, Tim Hague directly on tim.hague@omixon.com