Omixon Holotype HLA™

Make the switch to NGS for HLA

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NGS

SBT

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Omixon Holotype HLA

- Believe the Data
  - 2000+ routine clinical samples at CHOP
  - 253 samples for ASHI validation study
  - 2500+ samples in worldwide EAP
  - 200 samples in CE-IVD Performance Evaluation Study

- Technician friendly protocol
  - All loci pooled together
  - Only 1 bead cleanup
  - 4 hours hands on time and 3.5 day TAT
  - Automation

- Scalability
  - 8 - 192 samples per run
  - 1, 5, 7 or 11 loci

- Entire team focused on NGS for HLA

Omixon Manufacture & Supply

- US-based contracted manufacturing

- ISO-13485 and GMP

- Operating Statistics
  - 83,000 active customers
  - 2,800 orders shipped per day
  - 20,000 SKUs under management
  - 100+ OEM product lines
  - 4,500+ finished goods produced per month

- Worldwide distribution

Omixon Support and Services

- Presales
  - Comprehensive NGS Cost Analysis
  - Protocol viewing at an Omixon Reference Lab
  - Hands on workshop at an Omixon Reference Lab
  - Site Visit Consult/Presentation

- Site Preparation
  - Full equipment, reagent and consumable check

- Evaluation and Training
  - 1 week onsite training
  - Data analysis walkthrough
  - Ongoing remote and onsite support

- Validation
  - 200 samples and 50 blind
  - Complex case dataset

- Clinical Production
  - Parallel testing

EAP Results

- 24 labs, 2530 samples, 26286 alleles

- 8788 alleles with known typings

- 1.7% background FTA (failure to amplify) rate

Locus	Total alleles (with known types)*	Unique alleles
HLA-A	1490	56
HLA-B	1468	84
HLA-C	1481	47
HLA-DQB1	1491	23
HLA-DRB1	1530	53

- * = some known types were missing

Concordance

Category	Count	Percent
Alleles with known typings	8878	100%
Total discordances	333	3.8%
Incorrect known typing	147	1.7%
Discordant with QC failure	85	1%
Discordance due to novelty	63	0.7%
Still under investigation	35	0.4%

- Concordance = 2 field concordance

Result Statistics

Locus	HLA-A	HLA-B	HLA-C	HLA-DQB1	HLA-DRB1
Typed alleles	1490	1468	1481	1491	1530
Sensitivity	98.65%	97.48%	98.18%	95.71%	96.41%
Specificity	99.98%	99.97%	99.97%	99.88%	99.96%
PPV	98.66%	97.57%	98.18%	95.71%	97.04%
NPV	99.98%	99.97%	99.97%	99.88%	99.95%
TCC (Accuracy)	99.96%	99.95%	99.94%	99.76%	99.91%

- PPV = Positive Predictive Value

- NPV = Negative Predictive Value

- TCC = Type Correctly Classified (TP + TN / N) = Accuracy

Questions?

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