



TITLE: CERTIFICATE OF ANALYSIS – OMIXON HLA TWIN CE 3.1.1 – HOLOTYPE V2.1
 STATUS: CURRENT

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VERSION: 2

Certificate of Analysis

Product name	Omixon HLA Twin CE
Version number	3.1.1
Build ID	527911537bff7857ee376c96e33c5ea8da07db9c
Release date	22nd Oct, 2018
IMGT/HLA version	3.31.0_5
Assay version	Holotype HLA v2.1

Test, acceptance criteria, result

Test	Test description	Acceptance criteria	Result
Performance test	Test for Accuracy, Precision, Analytical sensitivity, Analytical specificity and Negative Predictive Value.	Accuracy is at least 95% for all loci with no known limitations, for loci with known limitations, at least 80% is achieved.	PASSED
Reproducibility	Comparison of results generated with different manufacturing lots of the Holotype HLA assay.	The same genotype is identified in all three lots with a total variability less than 1% between and with less than 2 % variability per individual HLA locus between all three LOTs involved in the studies.	PASSED
Repeatability	Comparison of results generated for technical repeats within the same sequencing run.	Repeatability is equal to or more than 98% within repeats in a sequencing run for all loci.	PASSED
Clinical comparison study	Comparison of results generated with a commercially available NGS-based pipeline.	For loci with no known limitations, correctness % is equal to or over 95%. For loci with known limitations, correctness % is equal to or over 90%.	PASSED
Equivalency test	Comparison with previous CE release of Omixon HLA Twin.	Results are equal to or better than results generated with the previous version of the software (Omixon HLA Twin CE 2.5.1).	PASSED

Verified by

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