



TITLE: CERTIFICATE OF ANALYSIS – OMIXON HLA TWIN RUO 3.0.0 - HOLOTYPE v1
STATUS: CURRENT

DOCUMENT NO. COA-02

ISSUED: 2018-04-12

VERSION: 1

Certificate of Analysis

Product name	Omixon HLA Twin RUO
Version number	3.0.0
Build ID	dd652303e1992e54cb64cb496d66c7154e852c67
Release date	9 th July, 2018
IMGT/HLA version	3.30.0_5
Assay version	Holotype HLA v1

Test, acceptance criteria, result

Test	Test description	Acceptance criteria	Result
Analytical performance	Test for Accuracy, Precision, Analytical sensitivity, Analytical specificity and Negative Predictive Value.	All performance metrics should be equal to or over 95%.	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
Equivalency test	Comparison with previous release of Omixon HLA Twin.	Results are equal to or better than results generated with the previous version of the software (Omixon HLA Twin RUO 2.5.1).	PASSED

Verified by			
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