



TITLE: CERTIFICATE OF ANALYSIS – OMIXON HLA TWIN RUO 3.0.0 –HOLOTYPE V2.1
STATUS: CURRENT

DOCUMENT No. COA-02

ISSUED: 2018-04-12

VERSION: 1

Certificate of Analysis

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| 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 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 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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|-----------|--------------------|-----------|---------------------------|
| Name | Krisztina Rigó | Function | Head of Software Research |
| Signature | | Sign date | 13/07/2018 |
| Name | Gabriella Adlovits | Function | RAQS Manager |
| Signature | | Sign date | 13/07/2018 |