



TITLE: CERTIFICATE OF ANALYSIS – OMIXON HLA TWIN RUO 3.1.1 - HOLOTYPE

3.0

DOCUMENT NO. COA-02

STATUS: CURRENT

ISSUED: 2018-04-12

VERSION: 1

Certificate of Analysis

Product name	Omixon HLA Twin RUO
Version number	3.1.1
Build ID	527911537bff7857ee376c96e33c5ea8da07db9c
Release date	22 nd Oct 2018
IMGT/HLA version	3.30.0_5
Assay version	Holotype HLA v3.0

Test, acceptance criteria, result

Test	Acceptance criteria	Result
Accuracy	PASS: Accuracy is at least 95% for all loci with no known limitations, for loci with known limitations (namely, HLA-DRB4), at least 80% is achieved. FAIL: Accuracy is less than 95% for one or more loci or less than 80% for loci with known limitations (namely, HLA-DRB4).	PASSED
Precision	PASS: Precision is at least 95% for all loci with no known limitations, for loci with known limitations (namely, HLA-DRB4), at least 80% is achieved. FAIL: Precision is less than 95% for one or more loci or less than 80% for loci with known limitations (namely, HLA-DRB4).	PASSED
Analytical sensitivity	PASS: Sensitivity is at least 95% for all loci with no known limitations, for loci with known limitations (namely, HLA-DRB4), at least 80% is achieved. FAIL: Sensitivity is less than 95% for one or more loci or less than 80% for loci with known limitations (namely, HLA-DRB4).	PASSED
Analytical specificity	PASS: Specificity is at least 95% for all loci with no known limitations, for loci with known limitations (namely, HLA-DRB4), at least 80% is achieved. FAIL: Specificity is less than 95% for one or more loci or less than 80% for loci with known limitations (namely, HLA-DRB4).	PASSED
Negative Predictive Value	PASS: NPV is at least 95% for all loci with no known limitations, for loci with known limitations (namely, HLA-DRB4), at least 80% is achieved. FAIL: NPV is less than 95% for one or more loci or less than 80% for loci with known limitations (namely, HLA-DRB4).	PASSED



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