Certificate of Analysis of the ABO Primer Component Box 24

Product name	ABO Primer Component Box 24
Reference number	P13.1
LOT number	P/014
Expiration data	2020.06.25

1 Quality control application overview

1.1 ABO Primer Component Box

The primer component provides specific ready to use primer solutions.

Primer mix	REF #	Rxns	Vol/tube	# Tubes	Color code
ABO	*P163*	*24*	*60 µL*	*1*	*Red*

2 Summary of Quality Control testing

Evaluation/Assessment	Pass/Fail
Physical inspection	Pass
Qualitative assessment of amplification by gel electrophoresis	Pass
Quantitative assessment of amplification by picogreen	Pass
Assessment of mappability of sequences	Pass
Assessment of amplification bias	Pass
Performance specifications: accuracy, precision, sensitivity, specificity	Pass

2.1 Physical inspection

All contents of the primer box are inspected for proper components, volumes and labeling. The condition of all primers were inspected after packaging.

2.1.1 Results of physical inspection

Criteria for acceptability	Pass/Fail
Expected volumes in all tubes	Pass
Proper labeling	Pass
Proper shipping condition (on dry ice)	Pass
Reagents clear and not discolored	Pass

2.2 Amplification components quality control testing

2.2.1 Results of amplification

Criteria for acceptability	Pass/Fail
Quantitative assessment of amplification by picogreen : > 50 ng/µL for all amplicons (excluding FTA)	Pass
Qualitative assessment of amplification by gel electrophoresis	Pass

2.2.2 Primer sequence and location test

Samples were analyzed with disabled primer and consensus trimming. The sequence and location of primers were manually checked in the generated consensus sequences and allele sequences using the sequence search function of the Gene Browser of Omixon HLA Twin.

2.2.3 Amplification success and balance

Results generated using a default analysis were inspected: mapped read counts, coverage depth, and imbalanced metrics were collected. Zygosity of allele calls was inspected, for homozygous allele calls, the zygosity of the consensus sequence and the presence of systematic noise were assessed.

2.2.4 Amplification specificity

Mappability statistics (i.e., the number of reads mappable to any ABO allele, compared to all reads) were collected for all samples using the default analysis results.

2.2.5 Criteria of acceptability

Test	Acceptance criteria	Result
Primer sequnece and location test	PASSED: At least one of the forward primers (or its reverse complement) is observed at the consensus start, the reverse primer (or its reverse complement) is observed at the consensus end. FAILED: No forward and/or no reverse primers can be observed. The forward primers are not located at the 5' end of the consensus, or the reverse primer is not located at the 3' end of the consensus.	PASSED
Amplification success	PASSED: Mappable read count is equal to or higher than 10,000. FAILED: Mappable read count is less than 10,000 reads in one or more samples.	PASSED
Amplification balance	PASSED: Exon and non-exon imbalance is equal to or less than 0.8:0.2. FAILED: Exon or non-exon imbalance is higher than 0.8:0.2.	PASSED
Amplification specificity	PASSED: Mappability is equal to or over 60% for all samples. FAILED: Mappability is less than 60% for one or more samples.	PASSED

Authorization for release			
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Signature	Simon	**Sign date**	**2019.05.03**
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