



TITLE: CERTIFICATE OF ANALYSIS - LIBRARY PREPARATION COMPONENT BOX 24

REF: R2

DOCUMENT NO. COA-01-R2

ISSUED: 2018-07-06

STATUS: CURRENT

VERSION: 1

Certificate of Analysis

Library Preparation Component Box 24

Product name	Library Preparation Component Box 24
Reference number	R2
LOT number	R2/016
Expiration date	2020-FEB-12

1 Library Preparation Reagent Component Box

The library preparation component box provides reagents for library preparation (fragmentation, blunt-end and adenylate the ends of the amplicons and ligate indexed adaptor sequences to them) from HLA amplicons.

Reagent	REF #	Rxns	Vol/tube	# Tubes	Color code
Fragmentation Enzyme (A)	R12	24	85 μ L	1	Yellow
Fragmentation Buffer (B)	R22	24	85 μ L	1	Red
End Repair Enzyme (C)	R32	24	50 μ L	1	Green
End Repair Buffer (D)	R42	24	95 μ L	1	Orange
Ligation Enzyme (E)	R52	24	81 μ L	1	Blue
Ligation Buffer (F)	R62	24	900 μ L	2	Black

2 Summary of Quality Control testing

Evaluation/Assessment	Pass/Fail
Assessment of fragmentation reagents	Pass
Assessment of end repair and ligation reagents	Pass



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2.1 Physical inspection

All contents of the kit are inspected for proper components, volumes and labeling. The condition of all reagents were inspected after packaging and shipping.

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 Library Preparation reagent quality control testing

2.2.1 Assessment of fragmentation

The 12 sample pools are inspected to assess that the fragmentation reagents were functioning properly, breaking the DNA into a wide range of sizes. Amplicons were pooled together prior to fragmentation and a small amount of each pool was used to assess the proper fragmentation through gel electrophoresis.

2.2.1.1 Results of fragmentation

Criteria for acceptability	Pass/Fail
All samples should produce a wide range of DNA fragments	Pass
Similar size profile as the previous LOT	Pass

2.2.2 Assessment of End Repair and Ligation Reagents

To assess the end repair reagents and the ligation reagents during library preparation, qPCR is performed to ensure that there is library present. This is performed after size selection to ensure that adapter dimers are removed and the concentration of the library is based upon fragments with DNA from the amplicons generated.

2.2.2.1 Results of fragmentation

Criteria for acceptability	Pass/Fail
qPCR value should exceed 1 nM (1,000 pM)	Pass



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Authorization for release

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