



TITLE: CERTIFICATE OF ANALYSIS - LIBRARY PREPARATION COMPONENT BOX 96

REF: R1

DOCUMENT NO. COA-01-R1

ISSUED: 2018-10-30

STATUS: CURRENT

VERSION: 2

Certificate of Analysis

Library Preparation Component Box 96

Product name	Library Preparation Component Box 96
Reference number	R1
LOT number	R1/016
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)	R11	96	278 μ L	1	Yellow
Fragmentation Buffer (B)	R21	96	278 μ L	1	Red
End Repair Enzyme (C)	R31	96	162 μ L	1	Green
End Repair Buffer (D)	R41	96	324 μ L	1	Orange
Ligation Enzyme (E)	R51	96	324 μ L	1	Blue
Ligation Buffer (F)	R61	96	1800 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



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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