Certificate of Analysis

MaxiSeq™ Human FFPE TCR+BCR (with UMIs)

Catalog Nos.	Amount	Lot Number
634386	24 Rxns	Specified on product label.
634387	96 Rxns	Specified on product label.

Description

MaxiSeq Human FFPE TCR+BCR (with UMIs) is used to generate T-cell receptor and/or B-cell receptor diversity information from low-quality RNA isolated from FFPE samples. The full kit is designed to work with a range of RNA input amounts and has been shown to generate high-quality libraries from as little as 200 ng–1 µg of total RNA obtained from FFPE tissues. The kit can be used to generate data for α-, β-, γ-, and δ-chain of TCR, and/or data for BCR heavy-chain and light-chain isotypes, either in the same experiment or separately, by capturing the complementarity-determining region 3 (CDR3) sequences of TCR and/or BCR transcripts.

The workflow incorporates unique molecular identifiers (UMIs), providing greater accuracy for clonotype identification and counting. Using the unique dual index (UDI) plate contained within the kit, the protocol can generate up to 96 multiplexed libraries that are ready for sequencing on Illumina® NextSeq® 500/550, NextSeq 2000, and NovaSeq™ platforms.

Package Contents

Package 1:

634386 (24 Rxns)	634387 (96 Rxns)	
5 µl	5 µl	Human PBMC RNA (50 ng/µl)

Package 2:

634386 (24 Rxns)	634387 (96 Rxns)	
24 µl	120 µl	TCR RT-Oligos (20X)
24 µl	120 µl	BCR RT-Oligos (20X)
50 µl	200 µl	hTCR Forward Primer PCR1 (20X)
50 µl	200 µl	hBCR Forward Primer PCR1 (20X)
200 µl	800 µl	Binding Buffer (4X)
2.75 ml	11 ml	Nuclease-Free Water
90 µl	360 µl	dNTPs (10 mM)
220 µl	880 µl	RT Buffer (5X)
30 µl	120 µl	Reverse Transcriptase (20X)
30 µl	120 µl	RT Extension Oligos (20X)
600 µl	2 x 1.2 ml	PCR Buffer (5X)
40 µl	150 µl	DNA Polymerase (100X)
250 µl	1 ml	PCR1 Extension Primer (10X)

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634386 (24 Rxns)	634387 (96 Rxns)	
80 µl	300 µl	Exonuclease
24 µl	84 µl	Forward Sequencing Primer (100 µM)
24 µl	84 µl	Reverse Sequencing Primer (100 µM)
24 µl	84 µl	Forward Indexing Primer (100 µM)
24 µl	84 µl	Reverse Indexing Primer (100 µM)

Package 3:

634386 (24 Rxns)	634387 (96 Rxns)	
1	1	MaxiSeq Human FFPE TCR+BCR (with UMIs) Unique Dual Index Plate

Storage Conditions

- Store Package 1 at –70°C.
- Store Packages 2 & 3 at –20°C.

Expiration Date

- Specified on product label.

Shipping Conditions

- Dry ice

Product Documents

Documents for our products are available for download at **takarabio.com/manuals**
The following documents apply to this product:

- MaxiSeq Human FFPE TCR+BCR (with UMIs) User Manual

Quality Control Data

A sample kit from each lot was tested as follows: 50 ng of control RNA and 150 ng of degraded RNA (human PBMC RNA) was subjected to cDNA synthesis using gene-specific primers as described in the MaxiSeq Human FFPE TCR+BCR (with UMIs) User Manual. cDNA was then extended with forward gene-specific primers, followed by PCR amplification of TCR and BCR sequences and final amplification with UDI primers. The final sequencing libraries were purified with Agencourt AMPure XP magnetic beads (Beckman-Coulter, Product No. A63881) and resuspended in 20 µl of Nuclease-Free Water. The final library concentration was measured by Qubit and diluted to 10 nM (1.6 ng/µl) for next-generation sequencing using NextSeq500. Library quality was measured with electrophoresis using a 3% gel and the Agilent Fragment Analyzer System using the High Sensitivity DNA kit (Cat. # 5067-4626). The resultant analysis indicated that the TCR library size range was approximately 320 bp (+/– 60 bp) and BCR library size range was approximately 350 bp (+/– 60 bp). The area containing the peaks was manually integrated from 200–450 bp.

The sample UDI plate for each lot was validated as follows: 150 ng of control degraded RNA was subjected to cDNA synthesis using gene-specific primers as described in the MaxiSeq Human FFPE TCR+BCR (with UMIs) User Manual. cDNA was then extended with forward gene-specific primers followed by PCR amplification of TCR and BCR sequences. The amplified product was diluted in PCR2 master mix and aliquoted in 96 well UDI plate for final amplification with UDI primers. The 96 libraries were quantified by fragment analyzer followed by equal volume pooling and NGS analysis. The amplification efficiency between UDI wells varied no more than +/– 50%.

cDNA libraries generated using reagent kit and UDI plate showed uniform yield across all UDI primers (CV ≤ 20%), with no individual primer generating a library yield more than +/– 40% of the overall average. The libraries were sequenced on an Illumina platform and confirmed uniform representation of all the barcodes (CV ≤ 25%).

It is certified that this product meets the above specifications, as reviewed and approved by the Quality Department.

Notice to Purchaser

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CATALOG NOS.

634386, 634387

NOTICE TO PURCHASER:

Our products are to be used for **Research Use Only**. They may not be used for any other purpose, including, but not limited to, use in humans, therapeutic or diagnostic use, or commercial use of any kind. Our products may not be transferred to third parties, resold, modified for resale, or used to manufacture commercial products or to provide a service to third parties without our prior written approval.

Your use of this product is also subject to compliance with the licensing requirements, listed below if applicable, and described on the product´s web page at http://www.takarabio.com. It is your responsibility to review, understand and adhere to any restrictions imposed by these statements.

STATEMENT 455

This product is sold under license from Becton Dickinson and Co., and may be the subject of U.S. Patent Nos.: 8,835,358; 9,290,809; 9,315,857; 9,708,659; 9,845,502; 10,047,394; 10,059,991; 10,202,646; 10,392,661; 10,619,203; 11,970,737; 12,060,607; and its foreign counterparts.

TRADEMARKS:

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