CareDx Pty Ltd

AlloSeq Tx

Product name:	AlloSeq Tx 17	
Product code:	ASTX17.1(24)	
Lot number:	23-1700	
Expiry date:	2024-12-07	
Number of tests:	24	
Storage:		
	Box 1, 3 and 4:	-15°C to -25°C
	Box 2:	Room temperature
	Box 5:	2°C to 8°C
	Product Insert: Room temperature	
Kit contents:	This product contains DNA sequencing tests designed to detect variants of the tissue typing genes for research use only.	
Warnings and Precautions	It is strongly recommended that these kits are validated by the user prior to implementation in the laboratory using samples whose genotype has been determined by other molecular based procedures. It is strongly recommended that the user follows all instructions provided via product labelling. Deviations from the described procedure are not recommended, may not be supported and could lead to typing errors. It is recommended that a positive control (human DNA) and negative/no template control (using sterile water in place of DNA) be included on every library preparation run. The positive control must produce a quantifiable library and the resultant sequence must be concordant with the sample's expected genotype. There must be no quantifiable library (measured by QuBit) in the negative template control for each experiment. If a quantifiable library is produced for the no template control the run must be repeated.	

Changes compared to the previous IFU:
IFU083 updated: Addition of Hazard H373 for Hybridisation Buffer in section 1.10. Buccal swabs were added as sample source in section 1.6. Note about barrier tips use was added to section 1.9. Instructions for PCR primers handling in section 3.3 and 5.5 were edited for clarity. 5mL tube added as an option in Library Preparation Section 4.2. Corrected editing errors in the table of contents. TEC478 updated: Corrected typographical error on cover page for Stop buffer Hazard category and Section 2 Hazard Identification of Stop Buffer

The following documents, and their translations, may be downloaded from https://www.caredx.com/lab-products/ or upon request from Manufacturer.

- IFU083_AlloSeq Tx Instructions for Use (Version 9.0, issued Feb 2024)
- IFU083-1_AlloSeq Tx Library Preparation Workbook RUO (Version 7.0, issued Sep 2023)
- IFU083-2_AlloSeq Tx Hybrid Capture Workbook RUO (Version 7.0, issued Sep 2023)
- IFU083-3_AlloSeq Tx Sequencing Workbook RUO (Version 5.0, issued Sep 2023)
- IFU083-5_AlloSeq Tx Early Pooling Workbook RUO (Version 9.1, issued Sep 2023)
- TEC478_ AlloSeq Tx Safety Data Sheets (Version 4.4, issued Feb 2024)

ADDRESSES:

Manufacturer:

CareDx Pty Ltd,
20 Collie Street, Fremantle, WA, Australia, 6160.
Tel: +61-8-9336-4212
Email: orders-aus@caredx.com
Website: http://www.caredx.com

Distributed by:

CareDx AB,
Franzéngatan 5, SE-112 51 Stockholm, Sweden.
Tel: +46-8-508 939 00
Fax: +46-8-717 88 18
E-mail: orders-se@caredx.com
Website: http://www.caredx.com/

CareDx Lab Solutions Inc.,
901 S. Bolmar St., Suite R, West Chester, PA 19382
Tel: 1-877-OLERUP1
Fax: 610-344-7989
Email: orders-us@caredx.com
Website: http://www.caredx.com

CareDx Pty Ltd
20 Collie Street
Fremantle WA 6160
AUSTRALIA

CareDx Pty Ltd

CERTIFICATE OF ANALYSIS

CERTIFICATE NUMBER: 24-0014

MANUFACTURER AND TESTING LABORATORY:

CareDx Pty Ltd
20 Collie Street
Fremantle WA 6160
AUSTRALIA

PRODUCT INFORMATION

Product Name:	AlloSeq Tx 17	Kit size:	24
Batch number:	23-1700	Expiry date:	2024-12-07

TESTING PROCEDURE

A panel of DNA samples (whose genotype was known) was used to assess the library preparation, enrichment and sequencing performance on a single kit from this batch against defined acceptance criteria

TEST RESULTS

TEST	ACCEPTANCE CRITERIA	RESULT
Pre Hybridisation		
Yield	≥ 41.36 ng/uL	PASS
Fragment Size	≥703 bp	PASS
Enrichment		
Enrichment Yield	≥ 3 ng/uL	PASS
Fragment Size	≥ 675 bp	PASS
Sequencing Analysis		
Genotype	Correct genotypes obtained for all	PASS
Q30	≥ 95% of loci tested with ≥ 87% reads with quality score of Q30 or higher	PASS
Allele balance	≥ 95% of loci tested with ≥ 38% average	PASS
Coverage	≥ 95% of loci tested with ≥ 150x average	PASS

CONCLUSION

Compliance with acceptance criteria? **YES** ~~NO~~

CERTIFICATION

I hereby certify that the testing was performed according to the company's standard operating procedures. I also certify that the results obtained were reviewed and released by myself prior to the issue of this certificate.

Signed: Lhang

Name: Lorie Langley

Position: QA Associate

Date of Issue: 05Mar24