



Product name:

AlloSeq HCT

Product code:

ASHCT.1(96)

Lot number: Expiry date: 24-200 2025-07-26

Number of tests:

96

Storage:

Box 1 and 2:

-15°C to -25°C

Box 3:

2°C to 8°C

Product Insert:

Room temperature

Kit contents:

This product contains tests that enables relative quantification of genetic chimerism in genomic DNA (gDNA)

samples for research use only.

Warnings and Precautions

Through the CareDx Pty Ltd risk management process, all risks have been mitigated to an acceptable limit. Instructions for Use must be followed to prevent hazardous use scenarios. Hazardous materials are present in this

kit. Please consult the Safety Data Sheets and take all required precautions in handling and disposal.

Changes compared to the previous product batch:

IFU088 & IFU092 - Instructions added to section 2.3, steps 4,8,12 & 20 to briefly spin down the tube content prior to placing on the magnet.

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

- IFU088_AlloSeq HCT IFU RUO (version 6.0, issued November 2023)
- IFU092_AlloSeq HCT 96 IFU RUO (version 4.0, issued November 2022)
- TEC513 AlloSeq HCT Safety Data Sheet (version 3.0, issued December 2021)

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

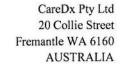
Email: orders-se@caredx.com Website: http://www.caredx.com/ CareDx Lab Solutions Inc.,

901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-653787 Fax: 610-344-7989

Email: orders-us@caredx.com Website: http://www.caredx.com

March 2024 Version No: 9.0 For Research Use Only 2024-016





CERTIFICATE OF ANALYSIS

CERTIFICATE NUMBER: 24-0016

MANUFACTURER AND TESTING LABORATORY:

CareDx Pty Ltd

20 Collie Street

Fremantle WA 6160

AUSTRALIA

PRODUCT INFORMATION

Product Name:

AlloSeq HCT

Product Code:

ASHCT.1(96)

Kit size:

96

Batch number:

24-200

Expiry date:

2025-07-26

TESTING PROCEDURE

A panel of DNA samples (of known genetic mixtures) was used to assess the performance on a single kit from this batch against defined acceptance criteria.

TEST RESULTS

TEST	ACCEPTANCE CRITERIA	RESULT
Locus Count	≥ 186	PASS
Uniformity	≥ 0.75	PASS
Mean Coverage	≥ 500	PASS
Recipient % DNA	Within limits	PASS
Donor 1 % DNA	Within limits	PASS
Donor 2 % DNA	Within limits	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: Lang

Position: QA Associate

Date of Issue: 06 mar 24