MEDICOVER GENETICS

UltraVerse®

index oligos

INSTRUCTIONS FOR USE

IVD

For Diagnostic Procedure Only
Proprietary Document: WI-03-102-TT-ENG
Version 2

Medicover Genetics Ltd.
31 Neas Engomis Str, 2409 Engomi,
Nicosia - Cyprus

www.medicover-genetics.com

Revision History

Date	Version	Description of Change (Initial Version/Revision)
2021-10-07	0.1	Initial Document Issue
2022-07-07	1.0	Update Version Number for Release
2022-09-12	1.1	Edits for Release
2022-11-01	1.2	Changes to Reflect Acquisition by Medicover
2023-05-05	2	Removal of CE Mark and Rebranding

Table of Contents

Symbols


Reagents/Samples


Manufacturer


Keep dry


Telephone number


Consult instructions for use


Email address


Temperature

Material consists of polypropylene and can be recycled with plastic (PMD)

Lot number


Box number


Expiration date


96-well plate

Contains sufficient for N tests


GHS07 Health hazard

Item


Keep away from sunlight

Trademarks and Disclaimers

Use of the TarCET UltraVerse Kit (the **Product)** signifies the agreement of any user of the Product with the following terms:

1. The Product may be used solely in accordance with the instructions for use (the IFU) TarCET UltraVerse workflow and only with components described in the **IFU**.

2. Medicover Genetics Ltd with registration number HE **418406** (ex NIPD Genetics Molecular Laboratories Ltd) (the **Manufacturer**) grants no license to use or incorporate the enclosed component of the Product with any component not included within the kit except as described in the IFU.

3. The Product and its components are licensed for one-time use and may not be reused, refurbished, or resold.

4. The sale and the use of this Product is conditioned on not using this product outside such prescribed fields of use or any other purpose not expressly authorized by the Manufacturer.

5. This Product may include limited, non-transferable, licenses under the relevant legislation of patents owned by Medicover Biotech Ltd with registration number HE 418372 (ex NIPD Genetics Biotech Ltd) or Medicover Public Co Ltd with registration number HE 275644 (ex NIPD Genetics Public Company Ltd).

Medicover name and logo are registered trademarks in the name of Medicover Holding (Cyprus) Limited with registration number HE 171748. All other names of third-party products or companies cited in this document are property of their respective owners and may also be trademarks. Inclusion of the product or company names in this document does not imply endorsement by Medicover Genetics Ltd.

Abbreviations

°C	Degree Celsius
GLP	Good Laboratory Practice
IVD	In-Vitro Diagnostic
NGS	Next Generation Sequencing
P/N	Product Number
Qty	Quantity

Intended Use

These UltraVerse Index Oligos Type A, B, C and D are dual index oligos intended to be used in conjunction with Medicover Genetics medical device products in order to create target-enriched libraries for Next Generation Sequencing (NGS). The UltraVerse Index Oligos Type A, B, C and D are intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained.

Purpose, Scope and Users

The purpose of the document is to provide details regarding the methodology, execution, and validation of the UltraVerse Index Oligos Type A, B, C and D. UltraVerse Index Oligos Type A, B, C and D assays utilize dual-index barcoding to distinguish between samples.

High-throughput and high-resolution advanced technologies such as NGS have helped to make great advances in unraveling the underlying mechanisms of genetic disorders as they are able to interrogate thousands of genomic loci for the identification of potentially deleterious genomic alterations. In order to efficiently use the high-throughput capabilities of NGS, multiple samples should be sequenced simultaneously. Samples can be identified through a unique nucleotide sequence that is attached to the nucleic acid molecule in a given sample during library construction and subsequently read during the sequencing process. The unique nucleotide sequence is often termed an “index”. UltraVerse Index Oligos Type A, B, C and D provide pre-mixed unique index pairs.

Quality Control and Validity of Results

Medicover Genetics UltraVerse Index Oligos Type A, B, C and D should be used with care as any mixing will result in inability to distinguish sequenced samples.

General Guidelines

Transport and Storage Conditions

The reagents are shipped and stored at -20°C until the expiration date, as stated on the label. All components must be kept away from sunlight and should be protected from humidity.

Training Requirements

Testing for identifying genetic mutations should be performed in an equipped laboratory with staff trained to carry out the relevant technical procedures according to the Occupational Safety and Health Administration (OSHA) Laboratory standards. Refer to the World Health Organization Interim guidance on laboratory biosafety and the Centers for Disease Control and Prevention (CDC) guidelines for Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with genetic testing.

Precautions and Recommendations

- The procedures in this handbook must be followed as described. Any deviations may result in assay failure or cause erroneous results and interpretation.
- Good Laboratory Practice (GLP) is required to ensure the performance of the kit, with care required to prevent contamination of the kit components.
- Use routine laboratory precautions. Do not pipette by mouth. Do not eat, drink, or smoke in designated work areas. Wear disposable gloves and laboratory coats when handling specimens and assay reagents. Wash hands thoroughly after handling specimens and assay reagents.
- Proper laboratory practices and good laboratory hygiene is required to prevent PCR products from contaminating reagents, instrumentation, and genomic DNA samples. PCR contamination may cause inaccurate and unreliable results.
- To prevent contamination, ensure that pre-amplification and post-amplification areas have dedicated equipment (e.g., pipettes, pipette tips, vortex, and centrifuge).
- Avoid cross contamination by changing pipette tips between samples and between dispensing reagents. Do not vortex the plates. Using aerosol-resistant tips reduces the risk of amplicon carry-over and sample-to-sample cross-contamination. Thaw reagents on ice prior to use and keep them on ice at all times.
- Do not use reagents past the expiration date. After the expiration date, the quality guarantee is no longer valid.
- Do not mix reagents from different kits and/or lots and/or another supplier.
- Handle all specimens as if infectious using GLP and the OSHA Laboratory standard (29 CFR 1910.1450).
- Dispose of waste in compliance with local, state, and federal regulations.

- Regular decontamination of commonly used equipment is recommended, especially micropipettes and work surfaces with at least 70% (v/v) ethanol.
- Please consult the Safety Data Sheet (SDS) before using this kit, which is available upon request.
- Consult each instrument's reference manual for additional warnings, precautions, procedures, and data analysis.

Material Provided

Ordering Information

Name	Number of Tests	P/N
UltraVerse Index Oligos Type A	96	EU100-00-100A
UltraVerse Index Oligos Type B	96	EU100-00-100B
UltraVerse Index Oligos Type C	96	EU100-00-100C
UltraVerse Index Oligos Type D	96	EU100-00-100D

Table 1 Index Oligos Product Information

Kit Contents

Name	ID in Box	Container	Volume	Qty	Storage	P/N
UltraVerse Index Oligos Type A	100A	96-well Plate	5 µL/well	1	-20°C	EU100-00-100A
UltraVerse Index Oligos Type B	100B	96-well Plate	5 µL/well	1	-20°C	EU100-00-100B
UltraVerse Index Oligos Type C	100C	96-well Plate	5 µL/well	1	-20°C	EU100-00-100C
UltraVerse Index Oligos Type D	100D	96-well Plate	5 µL/well	1	-20°C	EU100-00-100D

Table 2 Index Oligos Reagent information

If the box is damaged upon receipt, contact Medicover Genetics Ltd. directly. If the box has been opened before arrival, contact Medicover Genetics Ltd. directly. The product should be stored at the temperatures indicated on the box labels. You can contact Medicover Genetics Ltd. directly at customersupport.genetics@medicover.com

Test Procedure

Instructions For Use

UltraVerse Index Oligos Type A, B, C and D are intended for use in conjunction with the Medicover Genetics medical device products. Please refer to the Indexing step of the respective medical device IFU.

When preparing to use oligos please follow the instructions below:

1. Thaw plate for ten minutes at room temperature prior to use.
2. After thawing, spin down the plate to ensure all liquid is at bottom of the well.
3. Wipe foil seal with 70% ethanol and allow it to dry.
4. Avoid repeated freezing and thawing of the plate.

Associated Products

Product Name	P/N	Product Description
TarCET IVD Kits	ET10X-00-2016	Screening of genetic variants associated with disorders
TarCET PGT IVD Kit	ET102-00-2016	Screening pre-implantation embryos for genetic alterations
VERACITY IVD Kit	EV10X-00-2096	NIPT screening test

Support Contact Info

For Technical Support inquiries: ivdsupport.genetics@medicover.com

For Customer Support inquiries: customersupport.genetics@medicover.com

For more information visit our website: www.medicover-genetics.com

Medicover Genetics Ltd.
31 Neas Engomis Str, 2409 Engomi,
Nicosia - Cyprus