MEDICOVER
GENETICS

# UltraVerse
# Index Oligos

## Instructions For Use

CE IVD

For Diagnostic Procedure Only
Proprietary Document: WI-03-102-TT-ENG
Version 3.0

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# Revision History

| Date (YYYY-MM-DD) | 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 | 2.0 | Removal of CE Mark and Rebranding |
| 2024-03-01 | 3.0 | Compliance with IVDR |

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# Symbols


Keep dry


Consult instructions for use


Temperature



Lot number


Expiration date



Contains sufficient for N tests



Item



In-Vitro diagnostic medical device


Manufacturer


Telephone number


Email address



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


96-well plate


Keep away from sunlight

# Trademarks and Disclaimers

Use of the UltraVerse Index Oligos (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) UltraVerse Index Oligos 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).

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# Abbreviations

| | |
|---|---|
| °C | Degree Celsius |
| GLP | Good Laboratory Practice |
| 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

## UltraVerse Index Oligos Kit Contents 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 Kit** | ET2XX-00-2016 | Reagents for library preparation and targeted capture enrichment for Next Generation Sequencing applications |
| **TarCET PGT** | ET202-00-2016 | Screening pre-implantation embryos for genetic alterations |
| **TarCET PGT** *incl. WGA* | ET302-00-2016 | Screening pre-implantation embryos for genetic alterations |
| **VERACITY Advanced** | EV101-00-2096 | NIPT screening test |
| **VERACITY Premium** | EV102-00-2096 | NIPT screening test |

Table 3 Products used with UltraVerse Index Oligos

| | | | | Combined in sequencing run | |
|---|---|---|---|---|---|
| Product Name | P/N | VERACITY Advanced/ VERACITY Premium | TarCET Kits | VERACITY Advanced/ VERACITY Premium | TarCET Kits |
| **UltraVerse Index Oligos Type A** | EU100-00-100A | ✓ | ✓ | ✓ | |
| **UltraVerse Index Oligos Type B** | EU100-00-100B | ✓ | ✓ | ✓ | |
| **UltraVerse Index Oligos Type C** | EU100-00-100C | | ✓ | | ✓ |
| **UltraVerse Index Oligos Type D** | EU100-00-100D | | ✓ | | ✓ |

Table 4 UltraVerse Index Oligos used per product

# 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

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