

## Embgenix™ PGT-A Kit (CE-IVD)

**Catalog No.**  
634758

**Amount**  
96 rxns

**Lot Number**  
Specified on product label.

### Description

Embgenix PGT-A Kit (CE-IVD) has been developed to analyze DNA obtained from biopsies of single or multiple embryonic cells for Preimplantation Genetic Testing for Aneuploidies (PGT-A). All 24 chromosomes are accurately screened for whole chromosome aneuploidy and sub-chromosomal abnormalities utilizing Whole Genome Amplification (WGA) and Next Generation Sequencing (NGS) technologies.

### Package Contents

#### Box 1:

- 1,040 µl Cell Extraction Buffer
- 75 µl Cell Extraction Enzyme
- 2 x 1.8 ml WGA Buffer
- 115 µl WGA Enzyme
- 3 x 1.8 ml WGA Nuclease-Free Water

#### Box 2:

- 25 ml WGA Dilution Solution
- 60 µl 10X FE
- 1 ml FE Dilution Buffer
- 480 µl Lib Prep Buffer
- 280 µl Lib Prep Enzyme
- 400 µl Rxn Enhancer
- 480 µl Stem-Loop Adapters
- 2 x 1.2 ml Amplification Buffer
- 120 µl PrimeSTAR® HS DNA Polymerase (5 U/µl)
- 4 x 1 ml Nuclease-Free Water
- 1 plate Unique Dual Index Kit (1–96) (5 µl x 96 wells)

### Storage Conditions

- Store at –20°C.

### Expiration Date

- Specified on product label.

### Shipping Conditions

- Dry ice

---

#### Takara Bio USA, Inc.

2560 Orchard Parkway, San Jose, CA 95131, USA

U.S. Technical Support: [technical\\_support@takarabio.com](mailto:technical_support@takarabio.com)

United States/Canada  
800.662.2566  
(080422)

Asia Pacific  
+1.650.919.7300

Europe  
+33.(0)1.3904.6880

Japan  
+81.(0)77.565.6999

## Product Documents

Documents for our products are available for download at [takarabio.com/manuals](http://takarabio.com/manuals)

The following documents apply to this product:

- Embgenix PGT-A Kit (CE-IVD) for Illumina MiSeq® System Instructions for Use
- Embgenix PGT-A Kit (CE-IVD) Library Pooling Calculator for Illumina MiSeq System
- Embgenix PGT-A Kit (CE-IVD) for Illumina NextSeq® System Instructions for Use
- Embgenix PGT-A Illumina MiSeq96 SampleSheet LocalRunManager
- Embgenix PGT-A Illumina MiSeq96 SampleSheet
- Embgenix PGT-A Illumina NextSeq96 SampleSheet
- Embgenix Analysis Software (CE-IVD) Instructions for Use
- Embgenix PGT-A Kit (CE-IVD) Protocol-at-a-Glance

## Quality Control Data

The Embgenix PGT-A Kit (CE-IVD) was functionally validated using 30 pg of gDNA and 5 sorted cells each of NA008331 and GM08331 (Coriell Institutes), using the protocol described in the Embgenix PGT-A Kit (CE-IVD) for MiSeq System User Manual. The resulting WGA products were quantified using an Agilent 4200 TapeStation System with average yields of at least 2.5 µg and average negative control (NTC) yields below 1 µg.

The Illumina®-compatible libraries were then purified according to the protocol with NucleoMag NGS Clean-Up and Size Select (Takara Bio, Cat. No. 744970.5) and resuspended in 25 µl of Nuclease-Free Water. Library quantification was performed with the Qubit dsDNA HS Assay Kit (Beckman Coulter, Part No. Q32851 or Q32854); the resulting library yield of samples was determined to be >100 ng and <25 ng from the NTC.

Libraries were successfully sequenced on an Illumina MiSeq System using the MiSeq Reagent Micro Kit v3 (150-cycles) (Illumina Cat No. MS-102-3001) and passing the below QC criteria.

| QC Metric                              | Passing Value<br>(for at least 10 of 11 replicates) |
|--|---|
| Total Reads per sample                 | >1,500,000  |
| <b>Downsample to 1.5M reads/sample</b> |   |
| Informative Reads %                    | >50 %   |
| MAPD                                   | <0.22   |
| DLRS                                   | <0.14   |
| Gender Karyotype                       | XY  |

## Unique Dual Index Kit (1–96)

All primers were verified by ESI analysis to have a major peak with a measured molecular weight within 10 Da of the predicted molecular weight.

All primers were functionally tested with first-strand cDNA generated with reagents obtained from the SMARTer® Stranded Total RNA-Seq Kit v2 - Pico Input Mammalian. The libraries were purified, quantified, and verified to generate a uniform yield across all the primers (CV ≤ 20%) with no primers generating a library yield 40% above or below the average yield of all libraries. Following quality assessment by quantification, libraries were pooled and then sequenced on an Illumina sequencing platform, generating 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.

## Embgenix™ PGT-A Kit (CE-IVD)

### CATALOG NO.

634758

### NOTICE TO PURCHASER:

This product is CE-IVD marked and intended for **In Vitro Diagnostic use in Europe**. This product is considered a medical device subject to the requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices and to the requirements of the United States Code of Federal Regulations Title 21, Part 820: Quality Systems Regulation. The IVD claim is indicated by the IVD symbol on the label. Products are region specific and may not be approved in some countries/regions and are intended for research use only. It is the end user's responsibility to obtain the appropriate product information for your country of residence. Resale or transfer of this product, any component thereof, or any substance produced through use of this product, or any component thereof, to any third party is expressly forbidden. For assistance with additional product information or to obtain additional rights, please contact your local office or go to our website.

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 M54

This product is covered by the claims of U.S. Patent Nos. 7,704,713 and its foreign counterparts.

### STATEMENT 326

This product is protected by U.S. Patents 7,803,550; 8,399,199; 8,728,737, 9,598,727, 10,196,686, 10,208,337, 11,072,823 and corresponding foreign patents. Additional patents are pending. For further license information, please contact a Takara Bio USA licensing representative by email at [licensing@takarabio.com](mailto:licensing@takarabio.com).

### STATEMENT 328

This product is protected by U.S. Patents 8,206,913 and corresponding foreign patents. Additional patents are pending. For further license information, please contact a Takara Bio USA licensing representative by email at [licensing@takarabio.com](mailto:licensing@takarabio.com).

### TRADEMARKS:

#### ©2022 Takara Bio Inc. All Rights Reserved.

All trademarks are the property of Takara Bio Inc. or its affiliate(s) in the U.S. and/or other countries or their respective owners. Certain trademarks may not be registered in all jurisdictions.

---

#### Takara Bio USA, Inc.

2560 Orchard Parkway, San Jose, CA 95131, USA

U.S. Technical Support: [technical\\_support@takarabio.com](mailto:technical_support@takarabio.com)

**United States/Canada**

**Asia Pacific**

**Europe**

**Japan**

8/4/2022

800.662.2566

+1.650.919.7300

+33.(0)1.3904.6880

+81.(0)77.565.6999