IVD

GenetiSure Dx DNA Labeling Kit

K1201-64100

Intended Use

The GenetiSure Dx DNA Labeling Kit is for use in the labeling of samples to be hybridized to oligonucleotide microarrays in laboratory defined, microarray-based, diagnostic assay workflows. The kit is intended for use as part of molecular diagnostic test systems.

Rx Only

Summary

The kit contains Random Primers and the Exo (-) Klenow fragment to differentially label genomic DNA (gDNA) samples with fluorescently labeled nucleotides for the purpose of labeling samples prior to microarray hybridization.

Materials Provided & Storage

Component	Part Number	Quantity	Storage Temperature
Exo (-) Klenow	5190-7306	55 µL	–25° to –15°C
5X gDNA Reaction Buffer	5190-7310	550 µL	–25° to –15°C
Nuclease Free Water	5190-7311	1.5 mL	–25° to –15°C
Alu I Restriction Enzyme	5190-7312	28 µL	–25° to –15°C
Rsa I Restriction Enzyme	5190-7313	28 µL	–25° to –15°C
10X Restriction Enzyme Buffer	5190-7314	142 µL	–25° to –15°C
BSA	5190-7315	15 µL	–25° to –15°C
10X dNTP Mix	5190-7316	265 µL	–25° to –15°C
Cyanine 3-dUTP	5190-7308	78 µL	–25° to –15°C
Cyanine 5-dUTP	5190-7309	78 µL	–25° to –15°C
Random Primers	5190-7307	265 µL	–25° to –15°C
Human Reference DNA Female	5190-7317	125 µL; 0.2 µg/µL	2° to 8°C
Human Reference DNA Male	5190-7318	125 µL; 0.2 µg/µL	2° to 8°C
Purification Columns	—	50	15° to 30°C

Store the kit components at the recommended storage temperature until the expiration date.

Cyanine 3-dUTP and Cyanine 5-dUTP are light sensitive and are subject to degradation by multiple freeze-thaw cycles. To avoid prolonged exposure to light, keep the tubes of Cyanine 3-dUTP and Cyanine 5-dUTP covered with foil or a darkened lid.

Warnings and Precautions

1. For In Vitro Diagnostic Use
2. Avoid microbial contamination, which may cause erroneous results.
3. All biological specimens and materials with which they come into contact should be handled as if capable of transmitting infection and disposed of with proper precautions in accordance with federal, state and local regulations. Refer to the appropriate blood borne pathogen precautions indicated by your facility or local regulations. Never pipet by mouth. Avoid specimen contact with skin and mucous membranes.
4. Exercise standard precautions when obtaining, handling and disposing of potentially carcinogenic reagents.
5. Exercise care to avoid cross-contamination of samples during all steps of this procedure, as this may lead to erroneous results.
6. Use powder-free gloves whenever possible to minimize introduction of powder particles into sample or kit materials.
7. This product is stable until the expiration date when stored at the recommended storage temperature.
8. Performance of the kit has been shown to be unaffected for up to 8 freeze-thaw cycles.
9. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results by qualified personnel.

10 Don't use products past their expiration dates.

11 Proper storage and handling of reagents and samples are essential for the performance. All laboratory equipment used to prepare the target during this procedure should be calibrated and maintained to ensure accuracy. Incorrect measurement of reagents may affect the outcome of the procedure.

Indications of Instability or Deterioration

This product contains components that ship at different temperature conditions (room temperature and dry ice). Product may arrive as separate packages or in a single box that contains different shipping areas. Inspect packages upon arrival. If the tamper-evident label is opened at the perforations, or if the dry ice used for shipping has evaporated, do not use the contents of the package. For customer service or technical support, please contact Agilent Technical Support.

Safety Information

A Material Safety Data Sheet(s) (MSDS) is available at www.agilent.com.

Procedure

Refer to the GenetiSure Dx Postnatal Assay for instructions for use of this product and limitations of the procedure.

Limitations of the Procedure

Proper storage and handling of reagents and samples are essential for the performance. All laboratory equipment used to prepare the target during this procedure should be calibrated and maintained to ensure accuracy. Incorrect measurement of reagents may affect the outcome of the procedure.

Technical Support

Visit www.agilent.com/en/contact-us/page to find country-specific phone numbers, or send an email to one of the email addresses below.

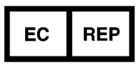
United States: clinical.support@agilent.com

Europe: genomics_dx_tech_europe@agilent.com

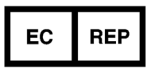
Japan: email_japan@agilent.com

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.

Symbol Table

	Catalog / code number		In Vitro Diagnostic Medical Device
	Temperature limit		Manufacturer
	Consult Instructions for Use		Use-by date
	Contains sufficient for <n> tests		Caution
	Unique Device Identifier		Batch code
	Do not reuse		Humidity limitation
	European Conformity		Reconstitute with
	Authorized representative in Switzerland		Importer
	Authorized representative in the European Community		

Agilent Technologies, Inc.
5301 Stevens Creek Blvd, Santa Clara, CA 95051, USA
Manufactured at:
1834 State Hwy 71 W, Cedar Creek, TX 78612, USA
www.agilent.com



Agilent Technologies Denmark ApS
Produktionsvej 42
2600 Glostrup, Denmark

Agilent Technologies (Schweiz) AG,
Lautengartenstrasse 6
4052 Basel, Switzerland

Agilent Technologies Deutschland GmbH
Hewlett-Packard-Str. 8
76337 Waldbronn, Germany

Agilent Technologies (Schweiz) AG,
Lautengartenstrasse 6
4052 Basel, Switzerland

Revision D0, September 2024

K1201-90003