



GenetiSure Dx Hybridization Kit

K1201-64200



Intended Use The GenetiSure Dx Hybridization Kit is intended for use in the hybridization of labeled samples 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 reagents used in the microarray hybridizations.

Materials Provided & Storage

Component	Part Number	Quantity	Storage Temperature
10X Oligo aCGH Blocking Agent, Lyophilized	5190-7319	1 tube	15° to 30°C, lyophilized –25° to –15°C, reconstituted
2X CGH Hybridization Buffer	5190-7320	5 × 1.4 mL	15° to 30°C

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

To reconstitute the 10X Oligo aCGH Blocking Agent, add 1.35 mL of nuclease-free water to each tube. Store at –25° to –15°C. The reconstituted stock is 10X.

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 10X Oligo aCGH Blocking Agent has been shown to be unaffected for up to 16 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

Inspect packages upon arrival. If the tamper-evident label is opened at the perforations, 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.













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

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

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