

**IVD** GenetiSure Dx Cot-1 Human DNA

K1201-64400

1 For In Vitro Diagnostic Use

**Intended Use** The GenetiSure Dx Cot-1 Human DNA is intended for use in the prevention of non- specific hybridization in laboratory defined, microarray-based, diagnostic assay workflows. The Cot-1 Human DNA is intended for use as part of molecular diagnostic test systems.

**Rx Only** 

**Summary** The kit contains a solution of fractionated human DNA that has been enriched for repetitive sequences.

## Materials Provided & Storage

Component	Part Number	Quantity	Storage Temperature	
GenetiSure Dx Cot-1 Human DNA	5190-7321	625 μL	–25° to –15°C	

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

## Warnings and Precautions

- 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 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<br/>Instability or<br/>DeteriorationInspect packages upon arrival. If the tamper-evident label is opened at the perforations, or if the dry ice used<br/>for shipping has evaporated, do not use the contents of the package. For customer service or technical<br/>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
ĺ	Consult Instructions for Use	$\sum$	Use-by date
$\sum_{i=1}^{n}$	Contains sufficient for <n> tests</n>	$\triangle$	Caution
UDI	Unique Device Identifier	LOT	Batch code
(	Do not reuse	<i>%</i>	Humidity limitation
CE	European Conformity	RCNS	Reconstitute with
EC REP	Authorized representative in the European Community		



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