

REF 08N90-080
51-608284/R4

NOTE: Changes Highlighted

Key to Symbols Used	
	List Number
	In Vitro Diagnostic Medical Device
	Lot Number
	Authorized Representative in the European Community
	In Vitro Test
	For In Vitro Diagnostic Use
	Prescription Use Only
	CE Mark
	Use by
	Negative Control
	Positive Control
	Temperature Limit
	Consult instructions for use
	Warning
	Manufacturer

NOTICE TO USER

If a serious incident occurs in relation to this device, the incident should be reported to the manufacturer and to the appropriate competent authority of the member state in which the user and/or the patient is established. To report to the manufacturer, see the contact information provided in the Customer service section or Technical assistance section of these instructions.

CUSTOMER SERVICE: 1-800-553-7044

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

Abbott RealTime IDH1 Control Kit

INTENDED USE

The Abbott RealTime IDH1 Controls are used to establish run validity of Abbott RealTime IDH1 when used for the qualitative detection of single nucleotide variants (SNVs) coding five IDH1 R132 mutations (R132C, R132H, R132G, R132S, and R132L) in DNA extracted from human blood (EDTA) or bone marrow (EDTA).

INTENDED USER

The intended users for the Abbott RealTime IDH1 Control Kit are laboratory and healthcare professionals.

REAGENTS

Abbott RealTime IDH1 Control Kit
(List No. 08N90-080)

- Abbott RealTime IDH1 Negative Control (List No. 8N90Z) (5 vials, 0.210 mL per vial). <0.01% noninfectious plasmid DNA in a buffered solution with carrier DNA. Preservatives: sodium azide and 0.15% ProClin® 950.
- Abbott RealTime IDH1 Positive Control (List No. 8N90W) (5 vials, 0.210 mL per vial). >0.01% noninfectious plasmid DNA in a buffered solution with carrier DNA. Preservatives: sodium azide and 0.15% ProClin 950.

The Abbott RealTime IDH1 Control Kit must only be used with the Abbott RealTime IDH1 Amplification Reagent Kit (List No. 08N90-090 or 08N90-075).

WARNINGS AND PRECAUTIONS

In Vitro Diagnostic Medical Device

For In Vitro Diagnostic Use

- Consult Abbott RealTime IDH1 package insert instructions for use.
- Do not use beyond expiration date.
- The and vials are intended for single use only; remaining reagents after first use should be discarded.

The controls contain sodium azide and 2-methyl-2H-isothiazol-3-one, which is a component of ProClin 950.

Abbott RealTime IDH1 Negative Control

Abbott RealTime IDH1 Positive Control

The following warnings apply:

	Warning	
	H317	May cause an allergic skin reaction.
	EUH032	Contact with acids liberates very toxic gas.
	P261	Avoid breathing mist / vapours / spray.
	P280	Wear protective gloves / protective clothing / eye protection.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P302+P352	IF ON SKIN: Wash with plenty of water.
	P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
	P362+P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheet Statement: Important information regarding the safe handling, transport, and disposal of this product is contained in the Safety Data Sheet.

STORAGE INSTRUCTIONS

The Abbott RealTime IDH1 Control Kit must be stored at -25 to -15 °C.

SHIPPING CONDITIONS

The product is shipped on dry ice.

If assay reagents are received in a condition contrary to the label recommendation, or are damaged, contact Abbott Technical Services.

TECHNICAL ASSISTANCE

For technical assistance, call Abbott Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott website at www.molecular.abbott.

Abbott RealTime is a trademark of Abbott.

All other trademarks are property of their respective owners.

The Abbott RealTime IDH1 Control Kit is imported into the European Union by Abbott Diagnostics GmbH, located at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.



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