# Abbott RealTime IDH2 Control Kit

# en **REF** 08N82-080 51-608431/R1

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Key to Symbols Used	
REF	List Number
IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
In Vitro Test	In Vitro Test
For In Vitro Diagnostic Use	For In Vitro Diagnostic Use
PRODUCT OF USA	Product of USA
	Prescription Use Only
$\Sigma$	Use by
CONTROL -	Negative Control
CONTROL +	Positive Control
X	Temperature Limit
i	Consult instructions for use
	Warning
	Manufacturer

# CUSTOMER SERVICE: 1-800-553-7042

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 IDH2 Control Kit

# INTENDED USE

The Abbott RealTime IDH2 Controls are used to establish run validity of Abbott RealTime IDH2 when used for the qualitative detection of single nucleotide variants (SNVs) coding nine DR2 mutations (R140Q, R140L, R140G, R140W, R172K, R172M, R172G, R172S, and R172W) in DNA extracted from human blood (EDTA) or bone marrow (EDTA).

#### REAGENTS

Abbott RealTime IDH2 Control Kit

(List No. 08N82-080)

- CONTROL Abbott RealTime IDH2 Negative Control (List No. 8N82Z) (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<sup>®</sup> 950.
- CONTROL + Abbott RealTime IDH2 Positive Control (List No. 8N82W) (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 IDH2 Control Kit must only be used with the Abbott RealTime IDH2 Amplification Reagent Kit (List No. 08N82-090).

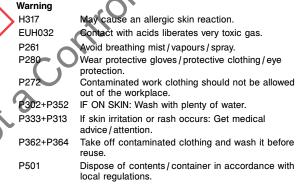
#### WARNINGS AND PRECAUTIONS

**IVD** In Vitro Diagnostic Medical Device For In Vitro Diagnostic Use

- Consult Abbott RealTime IDH2 package insert instructions for use.
- Do not use beyond expiration date.
- The CONTROL and CONTROL + 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 IDH2 Negative Control Abbott RealTime IDH2 Positive Control The following warnings apply:



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

<sup>--15℃</sup> The Abbott RealTime IDH2 Control Kit must be stored at -25 to -15°C. -25°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 Molecular Technical Services at 1-800-553-7042 or visit the Abbott Molecular website at http://www.abbottmolecular.com.

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