Key to Symbols Used

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<th>Description</th>
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<tr>
<td>REF</td>
<td>List Number</td>
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<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
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<td>In Vitro Test</td>
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<td>CONTROL -</td>
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<td>CONTROL +</td>
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<td>Temperature Limit</td>
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<td>Warning</td>
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ABBOTT REALTIME IDH2 CONTROL KIT

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 IDH2 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)

1. CONTROL - Abbott RealTime IDH2 Negative Control
(List No. 08N82Z) (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.

2. CONTROL + Abbott RealTime IDH2 Positive Control
(List No. 08N82W) (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

Abbott RealTime IDH2 Negative Control
Abbott RealTime IDH2 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.
P322+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 IDH2 Control Kit must be stored at -15°C to -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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