Dako Omnis Vial with Mixing Ball, 2 mL

**Code GC206**

**Intended use**

Dako Omnis Vial with Mixing Ball, 2 mL has been designed as an accessory for Dako Omnis and Dako Omnis Mixing Device and is intended for use in ISH procedures using user-provided FISH probes diluted in ethylene carbonate-based hybridization buffer (IQFISH). Dako Omnis Vial with Mixing Ball, 2 mL includes a gold-coated mixing ball that is used by Dako Omnis Mixing Device to mix the ethylene carbonate-based hybridization buffer (IQFISH) with the user-provided ISH probe.

**Summary and explanation**

The product is designed to follow the ISH workflow for the Dako Omnis instrument and Dako Omnis Mixing Device.

The label has a pre-defined 2D barcode attached that allows the Dako Omnis instrument to identify the vial, contents, volume and instructions for using the custom ISH reagent based on stored user input in the Dako Omnis software.

1. Wear nitrile gloves when handling the mixing ball and filling the vial. Ensure that the mixing ball, vial and pipette tip are clean from foreign matter
2. Insert the mixing ball into a cap-free vial and add a maximum of 2 mL reagent
3. Attach the cap to the vial
4. Follow the ISH workflow for the Dako Omnis Mixing Device and Dako Omnis instrument

**Materials provided**

Dako Omnis Vial with Mixing Ball, 2 mL. Each package contains 25 vials, 25 caps and 25 mixing balls.

**Storage**

Empty, unused vials and mixing balls should be stored at room temperature (15-30 °C). If the product is stored under any conditions other than those specified, the conditions must be verified by the user. There are no obvious signs to indicate instability of this product. If unexpected performance is observed which cannot be explained by variations in laboratory procedures and a problem with the product is suspected, contact Dako Technical Support.

Dako Omnis Vial with Mixing Ball, 2 mL containing custom ISH reagents should be stored upright with the cap closed under proper conditions established by the user. Proper storage of the Dako Omnis Vial with Mixing Ball, 2mL containing custom ISH reagents is the responsibility of the user.

**General limitations**

This product is designed for use with ISH reagents which have been selected and prepared by the user. The user must validate the appropriate dilution and staining conditions for the ISH reagent. When user-selected ISH reagents are added to the vial with mixing ball, the user must validate the appropriateness of the resulting stain. It is the responsibility of a qualified pathologist, familiar with the ISH probes, and methods used, to interpret the stain.

The vial is designed to be filled once and the vial and mixing ball should be regarded as single use only. Observe that the mixing ball, vial and pipette tip are clean from foreign matter before inserting the mixing ball into the vial. Follow the ISH workflow for the Dako Omnis instrument and Dako Omnis Mixing Device and follow the Instructions for Use for the ISH reagent and observe that the content is not frozen before mixing.

Once the reagent has been used up, the vial will be registered as empty by Dako Omnis and can no longer be used.

**Further information**

Refer to the proper Dako Omnis Basic and Advanced User Guides for instructions on registration custom ISH reagents in the Dako Omnis software and use of custom ISH reagents on Dako Omnis.

---

**Consult instructions for use**

**Use by**

**Authorized representative in the European Community**

**Manufacturer**

**LOT**

**Batch code**

**Catalogue number**

**Temperature limitation**

---

**Dako North America, Inc.**
6560 Via Real
Cupertino, California 95013 USA

Tel 855.556.6665
Fax 650.585.6668
Technical Support 855.424.02201
Customer Service 855.235.5763

**Dako Denmark A/S**
Produktionsvej 40
DK-2800 Glostrup, Denmark

Tel +45.4465.9500
Fax +45.4465.9690
www.dako.com

---

Edition 07/14

---

Edition 07/14