Additional Information Supplied for Reagents

Inline Dispenser
Preparing, Handling and Storage Instructions

IVD

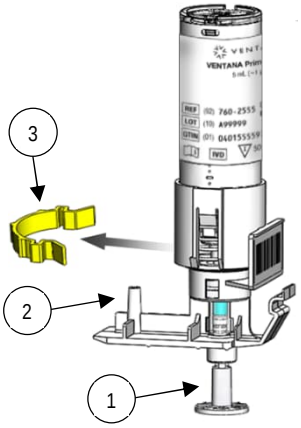
The inline dispenser is intended to carry and deliver test reagents and solutions for IVD assays performed on the BenchMark IHC/ISH instruments. Refer to the appropriate assay method sheets for more information.

For in vitro diagnostic (IVD) use.

INSTRUCTIONS FOR USE

Nozzle Cap and Shipping Key Removal

1. Remove the nozzle cap.
2. Place the nozzle cap on the nozzle cap holder. Fluid may be present inside the nozzle cap.
3. Hold the dispenser upright and pull the shipping key to disengage it at each end. Discard the shipping key.



WARNING: DO NOT touch or cover the dispenser tip while dispensing reagent or priming the dispenser as it could permanently damage the dispenser. DO NOT depress the top of the dispenser barrel while removing the shipping key as it could waste reagent.

For Ventana System Software (VSS) and for NexES software version 8.0 or higher

When initiating each staining run, the instrument software will recognize if a new dispenser is on the reagent carousel and prime it automatically by depressing the top of the barrel to move reagent into the priming chamber.

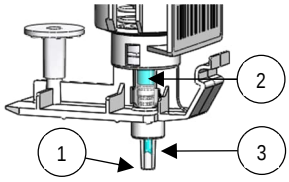
Manually priming the dispenser is not necessary and should not be done as it could waste reagent and decrease the number of available dispenses.

For all software versions before NexES software version 8.0

After removing the nozzle cap, remove the shipping key and PRIME THE DISPENSER BY RAPIDLY PUMPING 3 to 4 TIMES, keeping the dispenser in an upright position. Priming is only necessary prior to first time use. Refer to Inspect Prime and Nozzle Tip Before Each Use.

Inspect Prime and Nozzle Tip Before Each Use

Remove the nozzle cap and inspect the nozzle tip. Carefully remove dried reagent from the nozzle tip. Refer to the figure below.



The dispenser is ready to use when:

1. The nozzle tip is free from solid debris.
2. The priming chamber contains liquid. Some small bubbles may be present.
3. A reagent meniscus is visible between the base and tip of the nozzle.

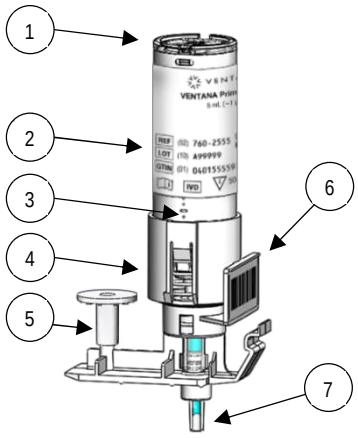
If one or more of these conditions are not satisfied, refer to Troubleshooting.

Storage and Handling

Refer to the assay method sheets and dispenser labels for storage handling instructions and expiration date.

To ensure proper reagent delivery and stability of each reagent, replace the nozzle cap onto the nozzle tip after every use and store the dispenser upright and in the environment specified in the assay method sheets.

Dispenser Features



1. Top of dispenser barrel.
   NOTE: Depressing the top of the barrel manually dispenses a drop of reagent. Refer to Warnings and Precautions and Troubleshooting sections.
2. Lot number on label.
3. Barrel is scaled in milliliter graduations.
4. Coupler.
5. Nozzle Cap on Nozzle Cap Holder.
6. Bar Code Label and Dispenser Serial Number.
7. Nozzle tip.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. Check priming chamber and meniscus before each use. Refer to Inspect Prime and Nozzle Tip Before Each Use.
4. When mounting the dispenser on the dispenser tray, grasp the coupler to avoid accidental manual dispensing.
5. Replace the nozzle cap on the nozzle tip after every use and store the dispenser in an upright position.
6. Do not manually dispense when inverted (upside down). Prime will be lost and may be impossible to restore.
7. Do not manually dispense with the nozzle cap in place. This can permanently damage the dispenser.
8. Do not manually dispense or prime prior to each use. This is not necessary and wastes reagent.
9. Do not hold the barrel in the compressed position. Fluid can leak from the dispenser when the barrel is compressed.
10. Do not stack carousels with dispensers installed. This can cause dispensers to leak.

TROUBLESHOOTING

VENTANA pre-filled dispensers have been filled to allow a sufficient number of tests. Manually dispensing or priming the dispenser can cause insufficient tests remaining in the dispenser and may cause undesirable staining results.

Issue	Solution
The dispenser is not primed properly (partially-filled priming chamber or empty priming chamber)	Re-Prime the Dispenser The dispenser should not lose prime if it is handled correctly. If re-priming is necessary, do the following: 1. Aim the dispenser tip at a waste container. Remove the nozzle cap and depress the barrel (top of the dispenser). This should dispense a drop. 2. If no drop is dispensed, repeat Step 1 several times until a drop is ejected. 3. If a drop is ejected, refer to the Inspect Prime and Nozzle Tip Before Each Use section. If no drop is ejected or inspection for prime fails (Step 3), or if repeated priming of the dispenser is required, contact your local support representative.
Reagent meniscus absent from base and tip of the nozzle.	Partial Dispense to Restore Meniscus 1. If no reagent is visible in the nozzle area, slowly press down on the barrel to push reagent into the base and tip of the nozzle. When the meniscus is visible, release the barrel.

Issue	Solution
	2. If this does not resolve the condition, re-prime the dispenser by following the steps in the Re-Prime the Dispenser section above. If condition recurs, contact your local support representative.
Debris in nozzle tip.	Inspect nozzle tip for dried reagent and remove carefully. If meniscus is absent, follow the steps in Partial Dispense to Restore Meniscus.
Leaking dispenser.	Contact your local support representative.
Blocked dispenser, or no drop is ejected, or inspection for prime fails.	The normal performance characteristics of the dispenser are such that particulates (i.e., fibers, precipitation) could cause a dispenser blockage. A sign of blockage could include higher reagent volume than expected remaining within the dispenser after a period of use. Blockage is also evidenced by the failure of the dispenser to yield fluid upon manual prime, which can be tested by following the steps in the Re-Prime the Dispenser section above. If blockage is suspected (or if foreign material is observed in the dispenser barrel, priming chamber, or nozzle), contact your local support representative.

CONTACTING YOUR LOCAL SUPPORT REPRESENTATIVE

If your dispenser does not look or perform as expected, please contact your local support representative for advice or return information. Please have the dispenser Lot Number (from the reagent label) available when you call.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see elabdoc.roche.com/symbols for more information).

GTIN Global Trade Item Number

REVISION HISTORY

Rev	Updates
J	Updated to current template.

INTELLECTUAL PROPERTY

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