

Inline User-Fillable Kit **REF** 1637600
05250927001

Prep Kit **REF** 1637700
05250935001

Light Protective Prep Kit **REF** 1637701
07475144001

IVD

INTENDED USE

Inline User-Fillable Kit, Prep Kit, and Light Protective Prep Kit are used to deliver reagents and solutions on VENTANA BenchMark Series automated slide stainers (BenchMark, BenchMark GX, BenchMark XT, and BenchMark ULTRA) and may be used on DISCOVERY instrument platforms.

The dispenser is intended for single use only. Ventana has not validated the cleaning of these dispensers and re-use with a second reagent.

For in vitro diagnostic (IVD) use.

MATERIALS AND METHODS

Kit Contents

- One user-fillable dispenser
- Two dispenser labels
- One 30 mL transfer syringe
- One 5 mL priming syringe
- Three 0.8 µm filters
- One Nozzle Adapter

Material Required But Not Provided

Additional reagents including but not limited to VENTANA primary antibodies, probes, detection kits, and ancillary components, are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The barcode label with the touch memory button might not be included and can be ordered separately from Ventana.

Storage and Handling

To ensure proper reagent delivery and the stability of the product, replace the nozzle cap after every use and immediately place the dispenser in the appropriate storage environment in an upright position.

Do not register dispensers beyond the use-by date printed on the kit label. Dispenser may not perform correctly if registered past the use-by date. For more information about the dispenser use-by date, contact your local Roche support representative.

WARNINGS AND PRECAUTIONS

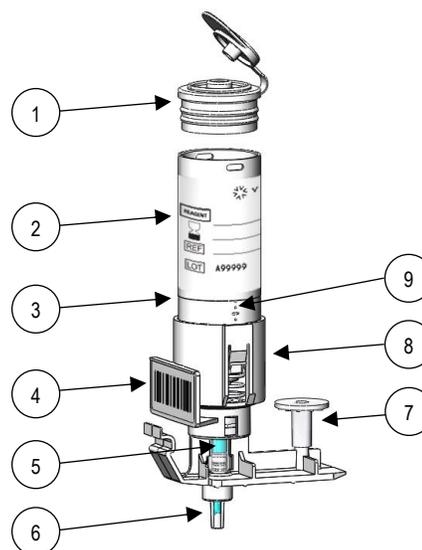
1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. Do not register dispensers beyond the use-by date printed on the kit label.
4. Do not manually dispense with the nozzle cap in place. This can permanently damage the dispenser.
5. Do not manually dispense or prime prior to each use.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

11. Do not manually dispense when inverted (upside down). Prime will be lost and may be impossible to restore.
12. Add reagent to the dispenser through the top of the barrel, not through the bottom nozzle tip. Do not refill the dispenser through the nozzle tip.
13. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.^{1,2}
14. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
15. Avoid microbial contamination of product as it may cause incorrect results.
16. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components.
17. Consult local and/or state authorities with regard to recommended method of disposal.
18. Product safety labeling primarily follows EU GHS guidance.
19. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

INSTRUCTIONS FOR USE

Dispenser Features

1. Flip top cap. Can be removed for ease of filling. When cap is installed, depressing barrel will manually dispense a drop of reagent. Refer to Warnings and Precautions and Troubleshooting.
2. Dispenser label. Blank lines to receive reagent information. Pre-printed dispenser lot number reflects the dispenser hardware build.
3. Label alignment line
4. Barcode label, and barcode label holder
5. Priming chamber
6. Nozzle tip
7. Nozzle cap, and nozzle cap holder
8. Coupler
9. Barrel is scaled in milliliter graduations



WARNING: DO NOT touch or cover the nozzle tip while dispensing or priming as it could permanently damage the dispenser.

Preparing the Dispenser for Use

Verify the Use-by Date

1. Ensure the use-by date printed on the kit label has not passed. Do not register the kit if it has expired.
2. If the kit is expired, dispose of kit components according to local regulations.

CAUTION: Do not register dispensers beyond the use-by date printed on the kit label. Dispensers may fail to operate properly after this date.

Affix the Labels

1. Do not use labels from another kit. The lot number on the kit label and the lot number on the dispenser label are a matched set.
2. Place the dispenser label on the dispenser. The bottom of the label must be above the label alignment line for proper operation (refer to Dispenser Features).
3. Place the barcode label squarely onto the barcode label holder on the empty reagent dispenser.
4. Run your thumb over the barcode label to secure it firmly in place.

Identify Reagent on Dispenser and Accessories

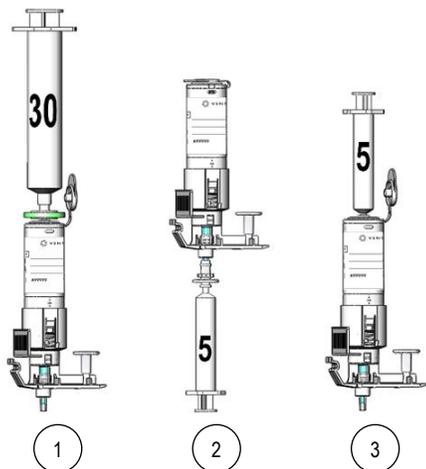
1. Use an indelible ink pen or permanent marking ink pen to write the reagent name, manufacturer, lot number, concentration and expiry date on the dispenser label.
2. Write the name of the reagent on the barrel of the priming syringe, and on the barrel of the transfer syringe.

Prepare Transfer Syringe and Filter

CAUTION: All reagents must be filtered using the filters included in the kit. Unfiltered reagents may contain particulate matter that could cause the dispenser to leak reagent through the nozzle onto slides, which may create undesirable results. Additional filters may be ordered directly from Ventana or you may contact your local support representative.

1. Remove the cap from the transfer syringe and draw the desired amount of reagent into the syringe.
2. Invert the transfer syringe and attach one 0.8 µm filter to the tip of the syringe.

Fill, Prime, and Return Reagent to the Dispenser



1. Fill the dispenser through the hole of the flip top cap. Always use a new filter when filling or refilling the dispenser.
 - a. Fill the dispenser by positioning the filter tip of the 30 mL transfer syringe into the hole of the flip top cap, and then slowly transfer the reagent into the dispenser.
 - b. Remove and discard the filter, and replace the cap on the 30 mL transfer syringe.
 - c. Close the dispenser flip top cap.
2. Prime the dispenser.

Once the dispenser has been filled, prime the dispenser so that it is ready for use.

- a. Place the nozzle adapter of the 5 mL priming syringe onto the dispenser nozzle tip.
 - b. With the dispenser barrel in the up position, slowly pull down on the piston of the priming syringe to approximately the 3 mL mark. While continuing to pull lightly on the priming syringe, rapidly pump the dispenser 3 to 4 times. Fluid should fill the priming chamber.
 - c. Release the dispenser barrel to its full up position and remove the 5 mL priming syringe.
3. Return reagent to the dispenser.
 - a. Place the 5 mL priming syringe into the hole of the flip top cap and express the reagent into the dispenser.
 - b. Remove the 5 mL priming syringe and close the flip top cap.

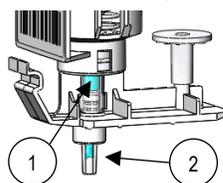
NOTE: Add reagent to the dispenser through the top of the barrel, not through the bottom nozzle tip. Do not refill the dispenser through the nozzle tip.

Check the Dispenser Before First Use

Manually depress the barrel once to ensure that a drop is dispensed. Check the meniscus and priming chamber (see Inspect Prime and Nozzle Tip Before Each Use). Do not use the dispenser before inspecting.

Inspect Prime and Nozzle Tip Before Each Use

Remove the nozzle cap and inspect the nozzle tip. Refer to the figure below.



The dispenser is ready to use when:

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

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

TROUBLESHOOTING

Issue	Solution
The dispenser is not primed properly (partially-filled priming chamber or empty priming chamber).	<p>Re-Prime the Dispenser</p> <p>The dispenser should not lose prime if it is handled correctly. If re-priming is necessary, do the following:</p> <ol style="list-style-type: none"> 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 until a drop is dispensed. 3. If a drop is dispensed, refer to the Inspect Prime and Nozzle Tip Before Each Use section. <p>If no drop is dispensed, follow the steps in the Prime the Dispenser section. If no drop is dispensed or inspection for prime fails (Step 3), or if repeated priming of the dispenser is required, contact your local support representative.</p>
Reagent meniscus absent from base and tip of the nozzle.	<p>Partial Dispense to Restore Meniscus</p> <ol style="list-style-type: none"> 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. 2. If this does not resolve the condition, re-prime the dispenser by following the steps in the Re-Prime the Dispenser section above. <p>If condition recurs, transfer the reagent into a new User-Fillable Kit or Prep Kit dispenser and follow the instructions in the Preparing the Dispenser for Use section.</p>

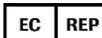
Issue	Solution
Debris in nozzle tip.	Inspect nozzle tip for dried reagent and remove carefully. If required, perform a partial dispense (as described in the previous section) in order to restore meniscus.
Leaking dispenser.	Transfer the reagent into a new User-Fillable Kit or Prep Kit dispenser and follow the instructions in the Preparing the Dispenser for Use section.
Blocked dispenser, or no drop is ejected, or inspection for prime fails.	<p>The normal performance characteristics of the dispenser are such that particulates (i.e., fibers, precipitation) could cause a dispenser blockage.</p> <p>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.</p> <p>If the dispenser barrel does not move freely, ensure that the dispenser label is positioned above the label alignment line.</p> <p>If blockage is suspected (or if foreign material is observed in the dispenser barrel, priming chamber, or nozzle), transfer the reagent into a new User-Fillable Kit or Prep Kit dispenser and follow the instructions in the Preparing the Dispenser for Use section.</p>

CONTACT INFORMATION



Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
USA
+1 520 887 2155
+1 800 227 2155 (USA)

www.ventana.com



Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany



REFERENCES

- Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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.

The summary of safety and performance can be found here: <https://ec.europa.eu>

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see www.ventana.com for definition of symbols used).

GTIN Global Trade Item Number

REAGENT Reagent icon, indicates the reagent contained in the dispenser

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