Quality Notification

MY-QN-RDS-PathologyLab-2026-103

RDS/histology
Post-Market Quality
Version 1
Tang Kea Yin
11-Aug-2026

Potential Lack of Prime in Manually Filled Dispensers

Product	GMMI
Instrument / System	BenchMark GX (05894662001) BenchMark ULTRA (05342716001) BenchMark ULTRA PLUS (09576797001)
Components	Reagent
Target Group	Application
Details	Customer information Customer Action
Feedback Due Date	21-Oct-2026

Executive Summary

Roche is issuing this notification following an internal investigation that identified an increased incidence of 'no prime,' 'loss of prime,' or 'failure to dispense' errors associated with a specific, manually filled subset of reagents manufactured between 25-JUL-2025 and 03-OCT-2025.

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Root Cause

An internal investigation has determined that the defect was due to a single operator's failure to adhere to the proper manual fill manufacturing process used in the production of small batches. Because operations personnel routinely rotate tasks within a shift to mitigate ergonomic risks, manual fill jobs are shared across multiple operators. **Therefore, the defect distribution is sporadic rather than systematic, resulting in variable impact within and between affected lots; some lots produced within this window may not be affected. Please note that any mechanical or material defects within the dispenser hardware components have been ruled out.** A CAPA has been initiated for further investigation, corrective, and preventive actions.

Units Concerned

Only reagents using our manual fill process, between 25-JUL-2025 and 03-OCT-2025, are in scope. However, definitive identification of specific kits is not possible due to the manufacturing process. Production of reagents filled on the automated fill lines are not in scope. Refer to Table A at the end of this letter for a full list of products that may be affected.

Detectability

This failure is highly detectable. If the dispenser fails to release the reagent, the control tissue will show a complete lack of staining. Because this failure is easily recognized by a trained pathologist, an incorrect patient result is prevented from being reported out, making it unlikely that this defect will lead to adverse health consequences.

The detectability of this issue relies on two primary mechanisms: pre-analytical visual inspection of the dispenser and post-analytical evaluation of the assay controls. Users who deviate from recommended procedures must accept responsibility for the interpretation of patient results. **Please note that users assume responsibility for interpretation of patient results when deviating from recommended protocols.**

<u>Pre-Analytical Visual Inspection</u>

The failure mode is partially detectable prior to testing by inspecting the dispenser according to the instructions outlined in the Inline Dispenser Method Sheet ("Inspect Prime and Nozzle Tip Before Each Use"). Specifically, visual inspection of the priming chamber and nozzle tip of the dispenser can be performed to verify the presence of fluid. A properly primed dispenser features a fluid chamber filled with liquid, though small bubbles may occasionally be present. An improperly primed device will present a visibly empty or only partially filled priming chamber, alerting the user to a failure state before the run begins. Additionally, dispenser recommendations are to ensure a reagent meniscus is visible between the base and tip of the nozzle prior to use.

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- Natural (Clear) Dispensers: For natural dispensers, the issue is highly detectable through direct visual inspection of the priming chamber.
- Amber-Colored Dispensers: For amber-colored dispensers, visual detectability is significantly lower due to the opacity of the plastic, which obscures a clear view of the internal fluid levels. Holding the dispenser up to a light source may aid in determining the presence of fluid in the priming chamber and nozzle tip.

If a user suspects a priming issue during inspection, the Inline Dispenser Method Sheet troubleshooting section includes guidance to re-prime the dispenser:

- Aim the dispenser tip at a waste container, remove the nozzle cap, and depress the barrel to manually actuate a drop.
- If a drop is ejected, the user re-inspects the priming chamber.
- If no drop is dispensed after repeating the manual actuation several times, or if the dispenser repeatedly fails visual inspection, the user is instructed to reject the dispenser and contact a local support representative.

Post-Analytical Control Evaluation

If an unprimed dispenser bypasses pre-analytical visual inspection and is loaded onto the instrument, the resulting malfunction (complete non-dispensation of the reagent) becomes detectable post-run through the mandatory or recommended use of appropriate tissue controls. Clinical guidelines (including CLIA, CAP, and ASCO) and Roche product labeling mandate the use of positive tissue controls. The use of these controls is defined across the various Ventana product package inserts associated with the assays (e.g., the OptiView DAB IHC and ultraView Universal DAB Detection Kits), which state “A tissue control must be included with each staining run.” This helps identify any failures applying reagents to the slide.

Severity

The Final Safety Assessment has determined that overall, with established clinical mitigations in place, including but not limited to established controls, this failure mode of omission of a mandatory manual priming step is unlikely to cause serious or medically reversible adverse health consequences. If this failure goes unrecognized by the user, it could lead to the primary hazard of a false-negative diagnostic result. For critical companion diagnostic assays, such as HER2, these diagnostic errors could lead to inappropriate treatments or delays in diagnosis and treatment.

Despite the severity of a potential false-negative result, the **risk to patients is heavily mitigated by standard pre- and post-analytical laboratory practices.**

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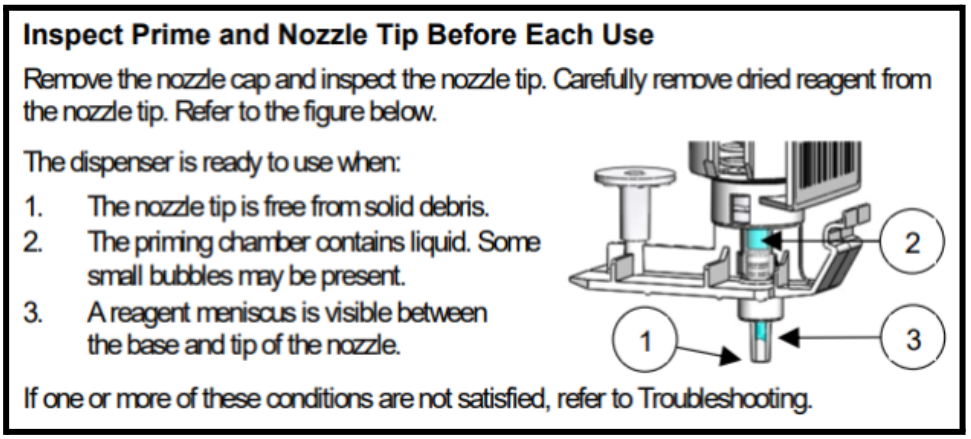
Important Information & Customer Instructions

Given that the failure mode is detectable and manageable through established pre- and post-analytical laboratory practices, our strategy ensures continued access to these products to ensure testing remains uninterrupted, while providing clear guidance for the visual verification of dispenser functionality.

Recommended Customer Actions:

Retrospective Review of previously used products or previously reported results is not required. The primary failure mode associated with this issue—a complete non-dispense of reagent—is inherently detectable post-run through the use of appropriate controls. If an unprimed dispenser were used in a previous run, the resulting control tissue failure would have been immediately apparent to laboratory personnel, effectively preventing the reporting of inaccurate patient results. Consequently, previously reported results remain reliable and do not require further re-evaluation.

- Inspect the Priming Chamber and Nozzle Tip (see image below). A properly primed dispenser features a chamber filled with liquid, though small bubbles may be present and a reagent meniscus which is visible between the base and tip of the nozzle.



Note: For amber-colored dispensers, holding the unit up to a light source may aid visibility.

- If an issue is suspected, attempt to re-prime the dispenser.
    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 manual actuation several times until a drop is ejected.
    3. If a drop is ejected, re-inspect the priming chamber.

If no drop is dispensed after repeating the manual actuation several times, or if the dispenser repeatedly fails visual inspection, reject the dispenser and contact a local support representative. Note: This action should not adversely affect the number of available tests as dispensers have a sufficient amount of reagent to account for the occasional need to re-prime.

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TABLE A. Potentially affected lots. Note: Red highlights indicate the product has already expired.

PN	Product Description	Lot Number	Date of Expiration	HHE Evaluation
05278783001	CONFIRM Anti-ALK-1 (ALK-01) Primary Antibody	N15079	2028-01-23	YES
		N20457	2028-03-04	YES
05913594001	Confirm anti-CD99 MOUSE Mono	N16217	2027-08-07	*NO
05267005001	CONFIRM ANTI-DESMIN (DE-R-11) PAb	N12249	2027-06-24	*NO
05267013001	CONFIRM anti-Kappa Rabbit Polyclonal	N13386	2027-07-06	YES
05878900001	CONFIRM EMA (E29) Mouse mAb	N13396	2027-07-06	YES
06478450001	ERG (EPR3864) PAB	N16218	2027-07-24	*NO
05267994001	FITC ANTI-C1Q PRIMARY ANTIBODY	N16567	2027-08-13	*NO
05267978001	FITC ANTI-C3 PRIMARY ANTIBODY	N14040	2027-08-05	*NO
05267960001	FITC ANTI-FIBRINOGEN PRIMARY ANTIBODY	N17393	2027-08-21	*NO
05267927001	FITC ANTI-IGA	N14039	2027-07-08	*NO
05267919001	FITC ANTI-IGG PRIMARY ANTIBODY	N18266	2027-08-21	*NO
05267935001	FITC ANTI-IGM PRIMARY ANTIBODY	N17390	2027-08-20	*NO
05278686001	INFORM CP LAMBDA MRNA PROBE-US EXPORT	N17014	2027-08-03	YES
05278678001	INFORM KAPPA PROBE-US EXPORT	N19437	2027-09-04	YES
05273323001	ISH PROTEASE 2	N18102	2027-02-19	*NO
09607137001	MSH2 (G219-1129) MM PAB W US EXPORT	N20443	2027-09-14	*NO
09606769001	MSH6 (SP93) RM PAB W US EXPORT	N19145	2027-09-03	*NO
06316514001	MUC1 (H23) PAB	N19137	2026-06-03	YES
		N20568	2026-06-21	YES
09607161001	PMS2 (A16-4) MM PAB W US EXPORT	N17396	2026-08-20	*NO
06683380001	Rabbit Monoclonal Negative Control Ig	N16569	2027-08-07	YES
08314373001	VENTANA HER2 DISH DNA PRB CKT-US EXPORT	N14931	2027-01-28	YES
		N13404	2027-01-28	YES
08494665001	VENTANA PAN-TRK (EPR17341) ASSAY	N14577	2027-07-10	YES

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09484515001	VENTANA PD-L1 (SP263) ASSAY IVD W	N18549	2027-08-26	YES
08318832001	VENTANA RED ISH DIG DETECTION KIT	N16553	2027-02-18	YES
08318883001	VENTANA SILVER ISH DNP DETECTION KIT	N16552	2027-02-26	YES

* Products evaluated as having acceptable residual risk per the existing risk files did not require further Health Hazard Evaluation (HHE).

Important Information/ Action

This notice must be passed on to all those who need to be aware within your organization where the reagents have been distributed/supplied.

By responding to the feedback, you will acknowledge that you have received the notification on <MY-QN-RDS-PathologyLab-2026-103-01 Potential Lack of Prime in Manually Filled Dispensers>; and will proceed to perform the instructions as listed.

Contact

Please do not hesitate to contact us in case of questions regarding the information provided.

Thank you.

Best regards,
ROCHE DIAGNOSTICS (M) SDN. BHD.

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