

Quality Notification MY-QN-RDS-PathologyLab-2025-112

RDS/histology Post-Market Quality

Version 1

Tang Kea Yin

10-September-2025

Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

Product	GMMI	Lot No.
CONFIRM ANTI-ER (SP1) PRIMARY ANTIBODY	05278414001	TABLE A
CONFIRM ANTI-ER (SP1)	05278406001	TABLE A

Instrument / System	BenchMark ULTRA (05342716001) BenchMark ULTRA PLUS (09576797001) BenchMark XT/LT (XT 05265231001)
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Components	Reagents
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Feedback Due Date	10-Oct-2025
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Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

Dear Valued Customer,

Reports of light staining with CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody (05278414001 / 05278406001) were escalated globally to the Pathology Lab Post Market Quality (PMQ) Global Complaint Handling Team.

A preliminary internal investigation revealed a reduction in tumor stain intensity and percent tumor cell staining in weak-staining breast carcinoma cases when testing specific batches of raw material. Current raw material batches utilized in the production of finished goods show no evidence of light staining. A review of the historical data did not identify any discernible patterns or consistent trends in titer values. The affected lots are included in TABLE A below:

Units Concerned

TABLE A. The light staining issue affects the following finished good lots.

Product Description	Test Size	Material Number	Affected Lot	Exp (mm/dd/yyyy)
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M10666	06/11/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	250	05278414001	M12369	06/25/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M14110	07/31/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M17063	08/26/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	250	05278414001	M18867	09/12/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	250	05278414001	M24839	05/11/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M22072	10/14/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M25411	11/14/2026
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	M27133	01/08/2027
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	50	05278406001	N03328	03/13/2027
CONFIRM Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody	250	05278414001	M29468	02/10/2027



Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

Roche is requesting that customers identify, discontinue the use of, and discard any remaining inventory of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody (05278414001 / 05278406001) listed in TABLE A.

No instances of false-negative reports associated with these lots have been escalated on a global scale.

An investigation is ongoing to determine the root cause and implement any additional corrective/preventive actions.

Detactability

A CONFIRM anti-ER (SP1) antibody negative result does not exclude the presence of ER. Negative reactions in breast carcinomas may be due to loss or marked decrease of expression of the antigen. It is recommended that this antibody be used in a panel of antibodies, including PR. The clinical interpretation of any positive staining, or its absence, must be evaluated/complemented within the context of clinical history, morphology, proper controls, diagnostic tests, and other histopathological criteria.

This issue is not expected to cause adverse health consequences when the external positive control tissues and staining procedures are used, as recommended in the product Method Sheet, which states that a positive tissue control “must” be included with each run, and CAP/CLIA guidelines are followed. The results are interpreted by a qualified pathologist in conjunction with histological examination and relevant clinical information to detect inappropriate cell staining on known control tissues and internal control cells, per the product Method Sheet.

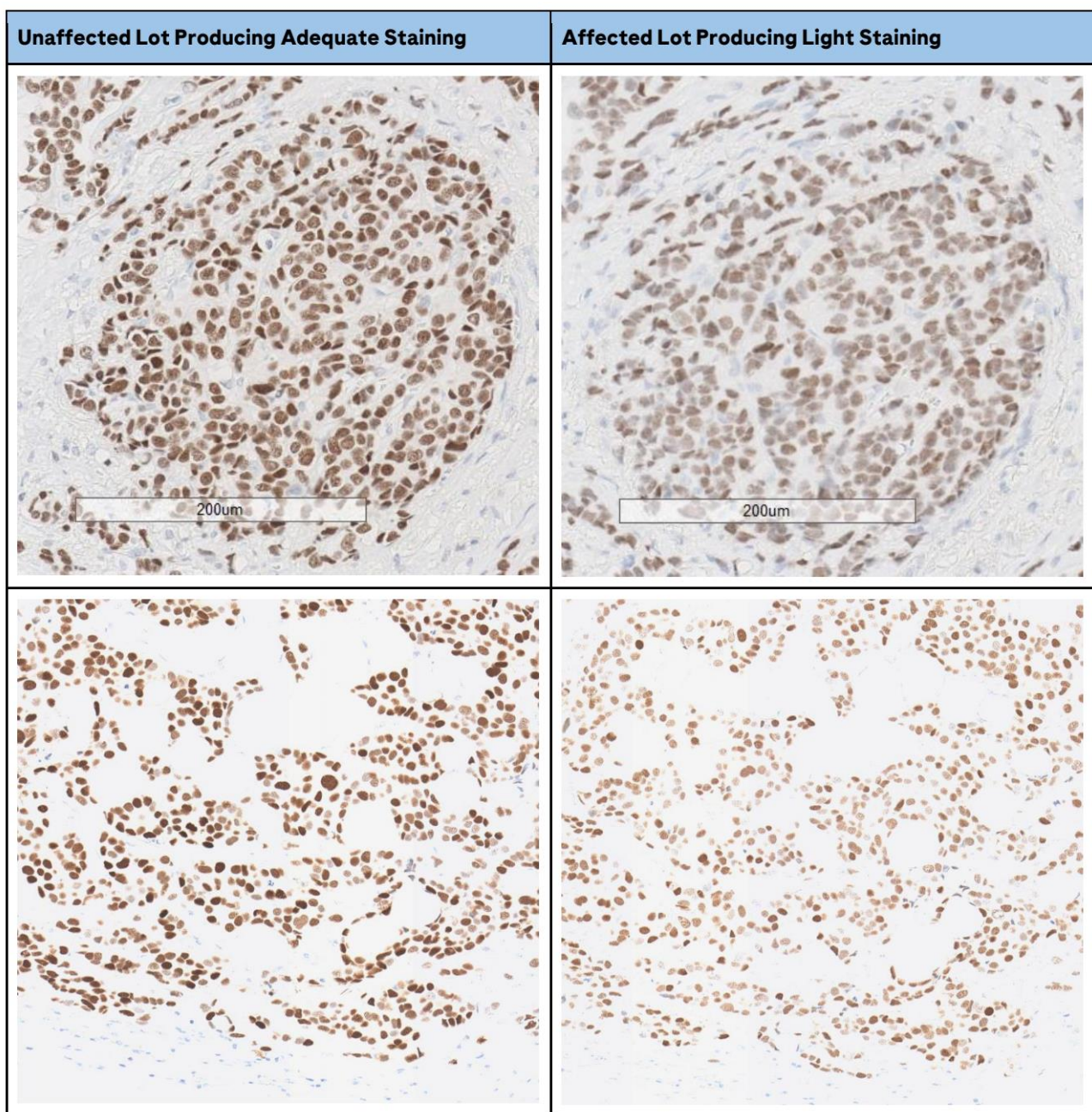
The College of American Pathologists (CAP) also recommends that a positive tissue control should be included on the patient slide. Further, it is stated in the Method Sheet that a tissue with weak positive staining, such as a weakly staining breast carcinoma, is more suitable as a positive control tissue than a strongly staining positive tissue. Using a stronger staining positive control (e.g., endometrial tissue or a strong staining breast case) may not stain weakly enough to detect small amounts of reagent degradation or problems with the IHC methodology.

The appropriate use of the product, as outlined in the Method Sheet, supports detectability of the issue by providing expected performance information, recommended staining protocol settings, and safety guidelines. The Method Sheet instructs users to verify the performance of new antibody lots by staining positive and negative tissues with known characteristics and to repeat these quality control procedures whenever there is a lot change in antibodies, reagents, or assay parameters.

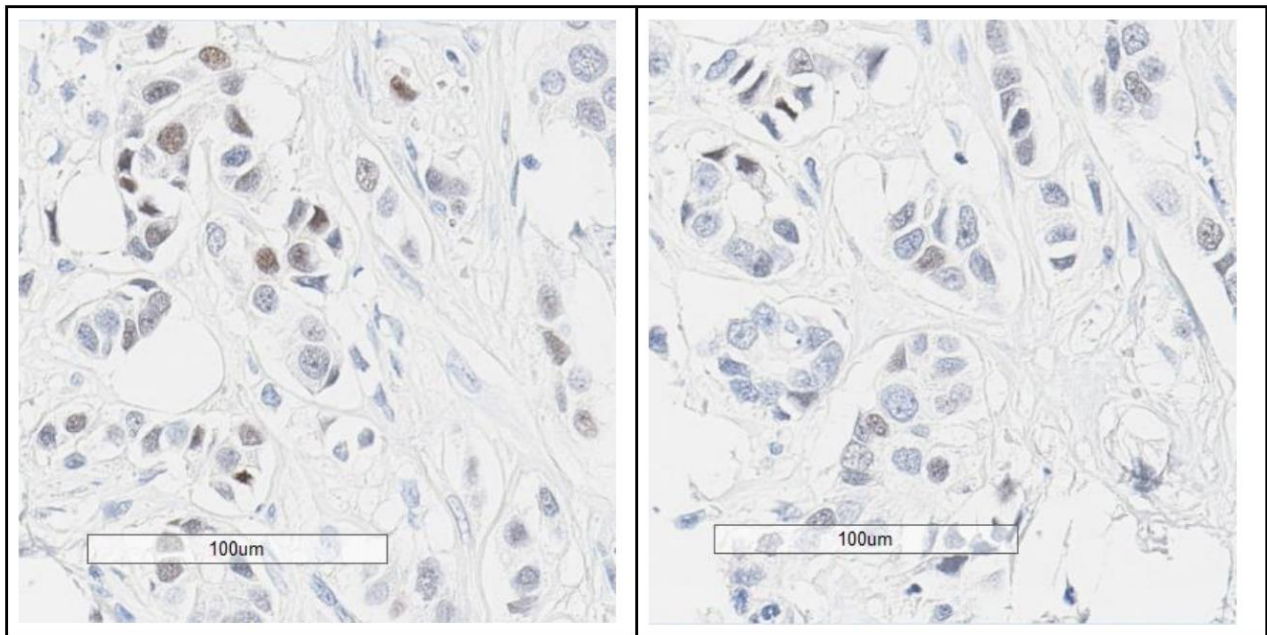
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Comparison images of Estrogen Receptor-positive breast carcinoma cases stained with affected and unaffected lots are provided in Figure 1 below:

Figure 1. Comparison of images from ER-positive breast carcinoma cases stained with affected and unaffected lots of the CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody.



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Actions

Roche is requesting that affected affiliates and customers immediately discontinue the use of and discard any remaining inventory of the impacted CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody lots listed in TABLE A. Please work with your local Roche sales team or distributor to arrange the replacement of discarded materials.

All current inventory of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody available in Roche distribution hubs shows no evidence of light staining.

This notice must be passed on to all those who need to be aware within your organization where the devices have been distributed/supplied (If appropriate).

Please transfer this notice to other organizations/individuals on which this action has an impact.

By responding to the feedback, you will acknowledge that you have received the notification on 'Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody' and will proceed to perform the instructions as listed in 'Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody'.



Unacceptable Light Staining with Specific Lots of CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody

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.

A handwritten signature in black ink, appearing to read "Kea Yin".

Tang Kea Yin
Marketing Partner
Email: kea_yin.tang@roche.com

A handwritten signature in black ink, appearing to read "Yean Ting".

Ong Yean Ting
Head of Quality Regulatory, Access and Policy
Email: yeen_ting.ong@roche.com