

Quality Notification

MY-QN-RDS-PathologyLab-2022-017

RDS / Histology
 Jasmine Michael
 Version 1
 19-August-2022

Change in Expiration Date of PAS Staining Kit for BenchMark Special Stains Instruments

Product	Quant. GMMI
PAS Staining Kit	N/A 05279291001
Instrument/System	BenchMark Special Stains (06468373001)
Component	Reagent
Feedback Due Date	30 August 2022

Dear Valued Customer,

Roche Diagnostics Solutions (RDS) – Pathology Lab is requesting to stop using and discard any inventory of PAS Staining Kit (860-014 / 05279291001) that are older than 12 months past the date of manufacture. Going forward, the expiration date for PAS Staining Kit will be changed from 24 months to 12 months for all new kits manufactured starting with Lot J10418.

Internal Stability and Surveillance testing is carried out to ensure that a product maintains and performs within an established acceptance criteria throughout its stability-dating period after the product is released. Weak staining was observed in the surveillance lots that suggest that the products is not supporting a 24-month product dating.

When the PAS Staining Kit is used with kidney tissue, the basement membrane staining pattern is assessed, and weak staining would be recognized.

When the PAS staining Kit is used to demonstrate the presence of fungus or glycogen, weak or absent staining would not always be easily recognized without the use of tissue controls. staining), making this defect highly detectable by a trained pathologist.

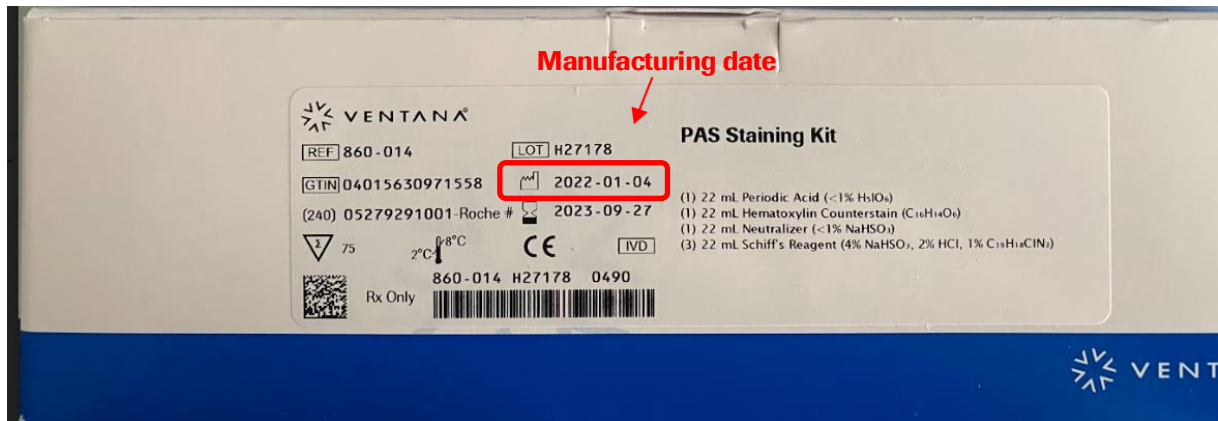
According to the product method sheet, appropriate controls must be run with every staining procedure performed. If the controls fail to demonstrate appropriate staining, any results with the test specimens should be considered invalid.



Additionally, given the mitigations of tissue controls and use of other clinical tests, it is not likely that weak PAS staining due to stability issues would lead to inappropriate patient therapy.

Action item: please stop using and discard all lots in your inventory, manufactured before Lot J10418 that are 12 months past the date of manufacture. The table below is detailing the PAS Staining Kit (860-014 / 05279291001) lots manufacture date to allow you to determine the corrected expiration date.

Change in Expiration Date of PAS Staining Kit for BenchMark Special Stains Instruments



PAS Staining Kit GMMI 05279291001 Lots	Date of Manufacturing on packaging (MM/DD/YYYY)	Expiry Date on packaging (MM/DD/YYYY)
G20612	10/6/2020	8/3/2022
G23749	10/23/2020	8/4/2022
G24963	11/17/2020	8/16/2022
G28056	12/11/2020	8/18/2022
G29854	1/4/2021	10/19/2022
G31213	1/20/2021	10/27/2022
G32060	2/4/2021	11/1/2022
H00383	3/16/2021	2/2/2023
H03072	4/14/2021	2/2/2023
H06307	5/12/2021	2/2/2023
H08993	6/2/2021	3/9/2023
H11542	6/22/2021	2/15/2023
H13305	7/9/2021	3/14/2023
H15070	7/30/2021	5/3/2023
H17503	8/13/2021	6/15/2023
H18226	9/27/2021	7/9/2023
H19912	9/14/2021	6/20/2023
H21099	10/15/2021	7/20/2023
H22287	10/22/2021	8/8/2023
H25256	11/18/2021	9/6/2023
H26156	12/17/2021	8/20/2023
H27178	1/4/2022	9/27/2023
H31102	2/10/2022	10/11/2023
H33651	2/24/2022	10/24/2023
H36852	3/14/2022	10/24/2023
J01404	4/12/2022	12/8/2023
J05602	4/22/2022	2/23/2024
J07794	5/09/2022	2/23/2024

Please kindly complete and return the Customer Acknowledgement Receipt within 2 business days to acknowledge your reading and understanding of this notice.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Should you have any additional questions or concerns regarding this notification, please do not hesitate to contact your sales representative or our Customer Call Centre: **1800 88 8881**

Thank you.

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

A handwritten signature in black ink, appearing to read "Jasmine Michael".

Jasmine Michael
MS Marketing Partner
Email: jasmine.michael@roche.com
Tel. +603-7967 2388

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

Ong Yean Ting
Head, Regulatory Affairs & Quality
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Customer Acknowledgement Receipt

Roche Diagnostics Malaysia
Fax Back: +603 7967 2399
Email: malaysia.diagnostics@roche.com

Attention: Customer Partner Team

I acknowledge I have received notification on **“Change in Expiration Date of PAS Staining Kit for BenchMark Special Stains Instruments”** and will proceed to take the action suggested i.e. take note of the corrected expiration date and stop using and discard all lots in inventory, manufactured before Lot J10418 that are 12 months past the date of manufacture.

No. of kits disposed: _____

Thank you.

Name:

Organization:

Stamp:

Date: