

# Urgent Field Safety Notice

## *SBN-RDS-Pathology Lab-2022-006*

RDS / Pathology Lab / VENTANA PD-L1 (SP142) Assay  
Version 1

### Unacceptable Light Staining & review of negative results - VENTANA PD-L1 (SP142) Assay Specific Lots

|                                                              |                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product Name</b>                                          | VENTANA PD-L1 (SP142) Assay (Class III, US IVD)<br>VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)<br>VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical)                                                                                                                                              |
| <b>GMMI / Part No</b><br><b>Device Identifier</b>            | VENTANA PD-L1 (SP142) Assay (Class III, US IVD)<br>GMMI: 07709374001,<br>UDI: 04015630967155<br><br>VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)<br>GMMI: 08008540001<br>UDI: 07613336106709<br><br>VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical)<br>GMMI: 07011571001<br>UDI: 04015630976591 |
| <b>Production Identifier</b><br><b>(Lot No. /Serial No.)</b> | Please refer to Table A and Table B.                                                                                                                                                                                                                                                                   |
| <b>SW Version</b>                                            | Not applicable                                                                                                                                                                                                                                                                                         |
| <b>Type of Action</b>                                        | Field Safety Corrective Action (FSCA)                                                                                                                                                                                                                                                                  |

Dear Valued Customer,

#### Description of Situation

VENTANA Medical Systems, Inc. (Roche) observed unacceptable, light staining with some VENTANA PD-L1 (SP142) on-market lots, during internal comparison studies. Light staining affects the borderline of positive versus negative test results. It can cause a reduction in both staining intensity and the percent positivity, which could potentially lead to a false-negative PD-L1 result. In addition, where the assay is used as a companion diagnostic, a patient may not be identified as eligible for treatment with the associated therapy TECENTRIQ® (atezolizumab).

Considering the hazard involved, there is a remote probability that use of the affected lots is likely to lead to adverse events in populations at greatest risk such as patients undergoing testing with Ventana PD-L1 SP142

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assay for treatment with TECENTRIQ® (atezolizumab). Adverse health consequences are otherwise not likely.

VENTANA Medical Systems, Inc. (Roche) is requesting that customers identify, discontinue the use of and discard any remaining inventory of the lots listed below in Table A. Additionally; the lots listed in Table B are being short dated to ensure optimum product performance.

Please refer to Table A and Table B below for specific information and additional details.

## Actions taken by Roche Diagnostics

The on-going investigation has determined the root cause is related to variability in the selection of antibody concentration in raw materials, affecting specific VENTANA PD-L1 (SP142) Assay lots made with the impacted raw materials. A CAPA investigation is still ongoing to further identify and address the root cause.

## Actions to be taken by the customer/user

Customers should immediately discontinue the use of and discard any remaining inventory of the VENTANA PD-L1 (SP142) Assay specific lots listed in Table A below.

Additionally, other specific lots are being short dated to ensure optimum product performance in the field; refer to Table B below. These short dated lots can be used until the updated Date of Expiration.

Furthermore, all negative results generated using specific, affected lots are to be reviewed.

Customers should follow their standard laboratory operating procedures to investigate any suspected false negative results generated with the affected lots.

Please find the list of VENTANA PD-L1 (SP142) Assay lots and related information in Table A and Table B.

## Table A

The usage of the following affected VENTANA PD-L1 (SP142) Assay lots must be immediately discontinued and the dispensers must be discarded.

| Description                                         | Material Number | Affected Lots | Date of Expiration (MM-DD-YYYY) | Reached Expiration | Negative results review needed |
|-----------------------------------------------------|-----------------|---------------|---------------------------------|--------------------|--------------------------------|
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | F30596        | 01/01/2022                      | Yes                | Yes                            |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | G31438        | 12/09/2022                      | No                 | Yes                            |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | H03958        | 02/23/2023                      | No                 | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | F31427        | 01/02/2022                      | Yes                | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | G06715        | 03/29/2022                      | Yes                | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | G16831        | 06/17/2022                      | Yes                | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | G24564        | 09/13/2022                      | Yes                | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | H00001        | 01/10/2023                      | No                 | Yes                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | H07164        | 03/22/2023                      | No                 | Yes                            |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | H08373        | 04/12/2023                      | No                 | Yes                            |

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**Table B**

The following affected VENTANA PD-L1 (SP142) Assay lots are being short dated. Please refer to the Current and Updated Dates of Expiration and the column indicating whether previously generated negative results should be reviewed. If the "Updated Dates of Expiration" is in the past, these lots should no longer be distributed nor should they be used by customers.

| Description                                         | Material Number | Affected Lots | Current Date of Expiration (MM-DD-YYYY) | Updated Date of Expiration (MM-DD-YYYY) | Negative results review needed                |
|-----------------------------------------------------|-----------------|---------------|-----------------------------------------|-----------------------------------------|-----------------------------------------------|
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | G27114        | 11/01/2022                              | 03/01/2022                              | Yes - Only results generated after 03/01/2022 |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | H13049        | 05/09/2023                              | 09/09/2022                              | Yes - Only results generated after 09/09/2022 |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | H35110        | 01/06/2024                              | 05/06/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | J25361        | 09/29/2024                              | 01/29/2024                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | J12769        | 05/03/2024                              | 09/03/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (Class III, US IVD)     | 07709374001     | J18775        | 07/25/2024                              | 11/25/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | H15132        | 05/27/2023                              | 09/27/2022                              | Yes - Only results generated after 09/27/2022 |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | H18578        | 07/18/2023                              | 11/18/2022                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | H23050        | 08/29/2023                              | 12/29/2022                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | J00572        | 01/06/2024                              | 05/06/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | J01568        | 02/03/2024                              | 06/03/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | J14244        | 05/30/2024                              | 09/30/2023                              | No                                            |
| VENTANA PD-L1 (SP142) Assay (CE IVD Predictive)     | 08008540001     | J20989        | 08/07/2024                              | 12/07/2023                              | No                                            |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | H17865        | 07/08/2023                              | 11/08/2022                              | Yes - Only results generated after 11/08/2022 |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | H30521        | 11/04/2023                              | 03/04/2023                              | No                                            |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | H35111        | 01/09/2024                              | 05/09/2023                              | No                                            |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | J11932        | 05/01/2024                              | 09/01/2023                              | No                                            |
| VENTANA PD-L1 (SP142) IHC Assay (CE IVD Analytical) | 07011571001     | J20132        | 08/07/2024                              | 12/07/2023                              | No                                            |

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## Communication of this Field Safety Notice (if appropriate)

*<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:*

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

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

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action. (If appropriate).

**The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:**

*Include if applicable:* The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

<closing salutations>,

## Contact Details

*To be completed locally:*

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com