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Urgent Field Safety Notice:

IMMULITE 2000

IMMULITE 2000 XPi

Incorrect Scanning Order of Tubes within the Allergen Holder Wedge

To whom it may concern,

Our records indicate that you have received:

Product	Siemens Material Number/ Catalog Number/ Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date	Kit Component
3gAllergy Specific IgE Universal Kit	10380875 / L2KUN6 / 00630414962269	169 170 171 172	22-Jul-2025 23-Jul-2025 24-Jul-2025 25-Jul-2025	22-Jul-2026 22-Jul-2026 22-Jul-2026 22-Jul-2026	3gAllergy Specific IgE Adjustor Antibody (L2UNS1), 3gAllergy Specific IgE Control Antibody (L2UNS2)
Allergen-Specific IgG	10380877 / L2KGG2 / 00630414997377	323	04-Jun-2025	04-Jun-2026	Allergen-Specific IgG Adjustor Antibody (L2GGS1), Allergen-Specific IgG Control Antibody (L2GGS2)
Allergen-Specific IgG ₄	10380879 / L2KG46 / 00630414966793	330	11-Apr-2025	11-Apr-2026	Allergen-Specific IgG ₄ Adjustor Antibody (L2G4S1), Allergen-Specific IgG ₄ Control Antibody (L2G4S2)
Insulin, Human Specific Allergen	10385627 / C73L2 / 00630414959634	625	13-Aug-2025	31-Aug-2027	N/A
Mint Specific Allergen	10385820 / F405L2 / 00630414960128	631	29-May-2025	31-May-2027	N/A
Common Millet Specific Allergen	10385837 / F55L2 / 00630414978635	627	12-Aug-2025	31-Aug-2027	N/A
Food Panel 3 Specific Allergen	10385891 / FP3L4 / 00630414960418	629	28-Aug-2025	31-Aug-2027	N/A

Oak Mix Specific Allergen	10386105 / T77L2 / 00630414965970	627	19-Aug-2025	31-Aug-2027	N/A
rAra h 2 Specific Allergen	11643681 / F423L2 / 00630414636351	201	30-Jul-2025	31-Jul-2026	N/A
Tri a 19 Specific Allergen	11643682 / F416L2 / 00630414636368	201	31-Jul-2025	31-Jul-2026	N/A
nAra h 1 Specific Allergen	11643846 / F422L2 / 00630414636375	201	30-Jul-2025	31-Jul-2026	N/A
rAra h 8 Specific Allergen	11643849 / F352L2 / 00630414636504	201	30-Jul-2025	31-Jul-2026	N/A

- Siemens Healthineers has confirmed through the internal investigation of customer complaints that barcode orientation on the products listed above causes incorrect scanning order of tubes within the allergen holder wedge. When using an IMMULITE 2000 / IMMULITE 2000 XPI instrument in combination with a Zebra barcode scanner (See Appendix for image), the instrument will not correctly recognize the position of tubes within the allergen holder wedge.

When any one (or more) of the products listed above are loaded into an allergen holder wedge and scanned by a Zebra barcode scanner, positions of tubes within the wedge will be incorrectly assigned. This includes the products listed above in addition to any tubes that are included within the same allergen holder wedge.

This issue has only been observed when using a Zebra barcode scanner AND the lot numbers listed above.

Siemens Healthineers is currently investigating the root cause of this issue.

Impact to Results

There is the potential for:

- Patient sample results to be inaccurate for any allergen loaded in the same allergen holder wedge.
- Quality Control (QC) results to fail or to be inaccurate.
- Adjustment to fail.

Customer Actions

This issue has only been observed when using a Zebra barcode scanner AND the lot numbers listed above.

If you are a Zebra barcode scanner user and have received the lot numbers listed above, perform the instructions provided below:

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Discontinue use of and discard the kit lots listed in the table above (Products Section).
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 7 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

*If your system **does not use the Zebra barcode scanner**, you can continue to use all the products listed above as intended.*

Resolution

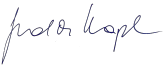
The issue is resolved with the next available lots. It is anticipated that replacement lots will start to become available mid-October 2025.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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*Electronically signed by: Gudrun Kapl
Reason: I have reviewed this document
Date: Oct 14, 2025 17:02:21 GMT+2*

i.V. Dipl.-Ing. Gudrun Kapl



*Electronically signed by: Michael
Edetsberger
Reason: I have reviewed this document
Date: Oct 14, 2025 10:53:56 GMT+2*

i.V. Dr. Michael Edetsberger

Appendix

Zebra barcode scanner image



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