

**Field Safety Notice (FSN) – Customer Communication****15 October 2025****Purpose of this Notice**

Sysmex (Thailand) Co., Ltd., on behalf of Japan Lyophilization Laboratory. This Field Safety Notice informs you of a Field Safety Corrective Action (FSCA) concerning the product identified below. Please read this notice carefully and follow the required actions immediately.

**Product Identification**

Product Name	Model/Catalogue No.
HISCL Anti-TP Assay Kit	CN-364-470

**Description of the Issue and Potential Risk**

On 15 August 2025, a potential false-negative HISCL Anti-TPAb result was identified. This may result from early stages of disease, or other interfering clinical conditions or treatments, resulting in reactive results close to COI. If inadequate testing algorithms are in place, confusion may occur, affecting clinical management decisions for diagnosis or treatment.

**Actions to be Taken by the Customer/User**

No.	Description
1.	Distribute this notice to all hospitals and facilities that received the HISCL Anti-TPAb Kit.
2.	If this issue is suspected, repeat testing and perform confirmatory testing in accordance with applicable clinical practice guidelines. Issue the final report only after considering confirmatory results together with clinical findings.

**Contact Information in Thailand**

Yossathorn Jongsirikul (Too)  
Marketing Executive (Immunology)  
Office : (+66) 2032 253  
Email: yossathorn@sysmex.co.th

**International:** Sysmex Asia Pacific Pte Ltd

Kelvin Fan  
Quality Management Manager  
Office: (+65) 6221 3629  
Fan.Kelvin@Sysmex-AP.com

Or contact your local Sysmex representative.

Sincerely,



(Ms. Amonrat Inkhao)  
Managing Director



**Acknowledgement & Effectiveness Form (Return to Sender)**

<b>Contact Person / Email / Phone</b>	
<b>We have received and understood this FSN</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Signature / Stamp</b>	