



JAPAN LYOPHILIZATION LABORATORY

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1 Dec 2025

Field Safety Notice

Replacement with Improved Version of HISCL Anti-HBc Assay Kit

Dear Distributors, Business partner and Customers

cc: Chairman of the Medical Board relevant Heads of Departments

In July of last year, Japan Lyophilization Laboratory (JLL) informed you of an issue concerning the HISCL Anti-HBc Assay Kit. Specifically, the light intensity of the calibrator NC (NC count) was found to increase over time, and when it exceeded 20,000 counts, measurement could not be performed. Initially, we mitigated this issue through pre-testing of raw materials. Since July of this year, we have been able to provide a permanently improved version of the product.

We are pleased to inform you that we will now proceed with replacing your current product (initial countermeasure version) with the newly improved version.

Products Subject to Exchange and Lot Numbers

Product code as per label	Product name	Lot number
AQ-094-429	HISCL Anti-HBc Assay Kit	CB0157
		CB0158
		CB0159

Status of Issue Occurrence

To date, there have been no reported cases in which measurement became impossible due to increased NC counts for the HISCL Anti-HBc Assay Kits with the lot numbers listed above.

However, since the possibility cannot be completely ruled out, JLL will replace these kits with improved products.

Diagnostic or Patient Impact

When the NC count exceeds 20,000, a calibration curve error alert is triggered, and measurement becomes unavailable. This may cause a slight delay in diagnosis. However, it does not lead to misdiagnosis or worsening of the patient's condition.

Even when the NC count is very high, as long as it remains below 20,000, the HISCL analyzer can perform both calibration and measurement. In such cases, the values for both NC and samples may be higher than usual, but the COI* remains unaffected, ensuring accurate results.

* COI : Cut Off Index



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Regarding Product Improvement

We would like to inform you that countermeasures addressing the recent issue have been implemented in products with lot numbers from CB0160 onward. Through JLL's investigation, a correlation between the issue and certain raw materials was identified. Until now, we have mitigated the increase in NC counts to a certain extent by selectively using those raw materials based on prior evaluations. Currently, we have adopted a more proactive approach that almost completely and reliably prevents the occurrence of this issue. Furthermore, JLL has already evaluated and confirmed that these countermeasures do not pose any concerns regarding product performance or safety.

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We kindly ask for your understanding and cooperation in proceeding with the replacement from the initial countermeasure product to the improved version.

When carrying out the replacement, please complete the attached acknowledgment form with the required information, sign it, and return it to us as a document certifying that you have received this notice and communicated it to all relevant customers. Kindly return the form by fax or as a scanned copy by 16 Dec 2025.

We appreciate your support and cooperation.

Sincerely yours,

Yukie Mori

Safety Management Officer

JAPAN LYOPHILIZATION LABORATORY