

Atellica® Solution

Atellica IM Active-B12 - Duplicate Reagent Pack Error

Our records indicate that your facility may have received the following product:

Table 1. Atellica® IM Affected Product(s)

Assay	Catalog Number / Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	Manufacturing Date (YYYY-MM-DD)
Active-B12 (AB12)	10733001	35437023	2020-02-04	2019-03-04

Reason for Recall

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed customers may experience a “Duplicate Reagent Pack” error with Atellica IM Active-B12 kit lot 35437023. This error message occurs when a second ReadyPack from this kit lot is added onto an Atellica IM 1300 or Atellica IM 1600 analyzer.

The error message is a result of a barcode labeling error which causes the analyzer to believe that it has already depleted the tests in the ReadyPack and prevents testing.

As this is a barcode labeling issue that does not impact assay performance, results obtained with the first ReadyPack introduced to an analyzer are acceptable for use. No other kit lots are affected by this issue.

Risk to Health

There is negligible risk to health associated with an apparent delay in testing of patient samples for active B12. There is no impact to the accuracy of patient results that are generated with the first ReadyPack. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- The options below will allow the continued processing of Active-B12.
 - If you experience the “Duplicate Reagent Pack” error, discontinue use of and discard the remaining inventory of the kit lot listed in Table 1.
 - You may continue to use the first ReadyPack introduced to any Atellica IM analyzer since the “Duplicate Reagent Pack” error will not be generated.

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- Review your inventory of this product 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 30 days.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice AIMC 19-03.A.OUS dated October 2019 regarding Atellica IM Active-B12 - Duplicate Reagent Pack Error. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

- 1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No
- 2. If you are experiencing the "Duplicate Reagent Pack" error, discontinue use of and discard the remaining inventory of the kit lot listed in Table 1. Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
Atellica IM Active-B12 SMN 10733001 / Lot 35437023	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX.

Or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens Healthineers technical support representative.