



201 Great Valley Parkway
Malvern, PA 19355
610.240.3800
610.240.3803 fax
www.fdi.com

FIELD SAFETY NOTIFICATION

MESOMARK® Kits, Lot Number 57K04409 and 57K04510

Item Number 801-900

July 7, 2010

Dear Customer,

Fujirebio Diagnostics, Inc. recently became aware of an issue regarding Lots 57K04409 and 57K04510 of MESOMARK kits (Item number 801-900). An internal investigation has determined that MESOMARK kit Lots 57K04409 and 57K04510 may generate inaccurate MESOMARK values.

As a result of this issue, you must immediately discontinue using MESOMARK kit Lot 57K04510. MESOMARK Kit lot 57K04409 is expired.

There is a residue present on the underside of some microtiter wells that can be detected visually. An inaccurate absorbance value may result from the presence of this residue on the microtiter wells.

Intended Use: The Fujirebio Diagnostics, Inc. (FDI) MESOMARK is an Enzyme-Linked Immunosorbent Assay (ELISA) for the quantitative measurement of Soluble Mesothelin Related Peptides (SMRP) in human serum.

Our records indicate that you were previously sent Lots 57K04409 and/or 57K04510.

Attachment A2

The following actions are required:

- Immediately discontinue using MESOMARK kit, Lot 57K04510 and discard any remaining inventory.
- Complete and return the attached Confirmation of Receipt form upon receipt of this notification.
- Please return this form as soon as possible but no later than **July 30, 2010**.
- Notify your ordering physician or health care provider as appropriate.

Once we receive the completed Confirmation of Receipt form, Fujirebio Diagnostics, Inc. will contact you or your distributor regarding a credit for the MESOMARK kit Lot 57K04510 you discarded.

We regret that we are unable to supply you with replacement product at this time. We are actively investigating the root cause of this issue and are working diligently to have a replacement lot of MESOMARK available as soon as possible.

We sincerely apologize for any inconvenience this may cause your laboratory and appreciate your continued support of Fujirebio Diagnostics, Inc. products. We have anticipated some questions you may have in the following Question and Answer section. If you have any additional questions, please contact Customer Service at 877.861.7246 or 610.240.3800.

Sincerely,



Director, Quality and Regulatory Compliance

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CNL0710 801-900
Fujirebio Diagnostics, Inc.

FIELD SAFETY NOTIFICATION
MESOMARK® Lots 57K04409 and 57K04510

Questions and Answers

1. What impact does the presence of residue on the underside of some microtiter wells have on MESOMARK results?

We have confirmed that MESOMARK kit Lots 57K04409 and 57K04510, may generate inaccurate absorbance values due to the presence of a residue on the underside of some microtiter wells that can be detected visually. The residue on the underside of some microtiter wells may or may not cause an elevated percent Coefficient of Variation (%CV) within replicates. The inaccurate absorbance values and/or elevated %CV may affect the calibration curve, controls and/or test results. MESOMARK kit Lot 57K04409 is expired but expected to be similar in performance to 57K04510 due to observed residue.

The Fujirebio Diagnostics, Inc. (FDI) MESOMARK is an Enzyme-Linked Immunosorbent Assay (ELISA) for the quantitative measurement of Soluble Mesothelin Related Peptides (SMRP) in human serum.

Please refer to the MESOMARK® Product Insert for additional information.

The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture. We recommend that you discuss this information with your Laboratory Medical Director or with the ordering physician to determine the appropriate course of action.

2. Will quality control and test samples be affected by this issue?

You may obtain inaccurate test results when using MESOMARK kit Lots 57K04409 and 57K04510 due to the presence of a residue on the underside of some microtiter wells that can be detected visually. Inaccurate absorbance values and/or elevated %CV may affect the calibration curve, controls and/or test results.

Due to the potential for inaccurate MESOMARK results, we are requesting that you immediately discontinue using MESOMARK kit Lot 57K04510 and discard any remaining inventory. MESOMARK kit Lot 57K04409 has expired.

3. Is there an alternative method for performing MESOMARK testing?

Currently there is no alternative method for performing the MESOMARK test. We are actively investigating the root cause of this issue and are working diligently to have a replacement lot of MESOMARK available as soon as possible.

4. When will replacement product be available?

We regret that we are unable to supply you with replacement product at this time. We are working diligently to resolve this situation as soon as possible. Fujirebio Diagnostics, Inc. will notify you or your distributor when replacement product is available.

Please complete the Confirmation of Receipt form and return to Fujirebio Diagnostics, Inc. Upon receipt of the Confirmation of Receipt form, Fujirebio Diagnostics, Inc. will contact you or your distributor regarding a credit for the MESOMARK kit Lot 57K04510 you discarded.

Attachment A2

Confirmation of Receipt

FIELD SAFETY NOTIFICATION

**MESOMARK® Kits, Lot Number 57K04409 and 57K04510
Item Number 801-900**

So that we can complete our records, please return this form to us as soon as possible but no later than **July 30, 2010**.

FAX TO: [REDACTED] Fujirebio Diagnostics, Inc.
FAX : 610-240-3949

Section I – Confirmation

I received the Field Safety Notification regarding MESOMARK kits (CNL0710 801-900). I have taken the actions recommended in the notification. I have discontinued using and discarded MESOMARK kit Lot 57K04510.

Please indicate the quantity of products that you discarded:

Quantity Discarded MESOMARK kit, Lot 57K04510
--

Your Name: _____ Job Title (optional): _____
Institution: _____ Date: _____
Fax Number: _____ Telephone Number: _____
Signature: _____

Your comments are always welcome:

Please complete this section if your name or mailing address has changed:

Institution Name: _____
Contact Name: _____
Address: _____
City: _____ State/Province: _____ Zip/Postal Code: _____
Telephone: _____ FAX: _____



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FIELD SAFETY NOTIFICATION

**MESOMARK® Kits, Lot Number 57K04409 and 57K04510
Item Number 801-900**

July 7, 2010

Dear Distributor,

Fujirebio Diagnostics, Inc. recently became aware of an issue regarding Lots 57K04409 and 57K04510 of MESOMARK kits (Item number 801-900). An internal investigation has determined that MESOMARK kit Lots 57K04409 and 57K04510 may generate inaccurate MESOMARK values.

As a result of this issue, you must immediately discontinue selling MESOMARK kit Lot 57K04510. MESOMARK Kit lot 57K04409 is expired.

There is a residue present on the underside of some microtiter wells that can be detected visually. An inaccurate absorbance value may result from the presence of this residue on the microtiter wells.

Intended Use: The Fujirebio Diagnostics, Inc. (FDI) MESOMARK is an Enzyme-Linked Immunosorbent Assay (ELISA) for the quantitative measurement of Soluble Mesothelin Related Peptides (SMRP) in human serum.

Our records indicate that you were previously sent Lots 57K04409 and/or 57K04510.

Please identify all customers that were shipped MESOMARK lots 57K04409 and 57K04510 and forward the enclosed notification (CNL0710 801-900)

Attachment B2

The following actions are required:

- Inspect your current inventory and discontinue selling MESOMARK, Lot 57K04510.
- Discard any of the affected product remaining in your inventory.
- Complete and return the attached Confirmation of Receipt form as soon as possible but no later than **July 30, 2010**.
- Send all customers that were shipped MESOMARK lots 57K04409 and 57K04510 the enclosed notification (CNL0710 801-900).

Once we receive the completed Confirmation of Receipt form, Fujirebio Diagnostics, Inc. will contact you regarding a credit for the MESOMARK kit Lot 57K04510 you discarded.

We regret that we are unable to supply you with replacement product at this time. We are actively investigating the root cause of this issue and are working diligently to have a replacement lot of MESOMARK available as soon as possible.

We sincerely apologize for any inconvenience this may cause and appreciate your continued support of Fujirebio Diagnostics, Inc. products. If you have any additional questions, please contact Customer Service at 877.861.7246 or 610.240.3800.

Sincerely,



Director, Quality and Regulatory Compliance

Attachment B2

Confirmation of Receipt

FIELD SAFETY NOTIFICATION

MESOMARK® Kits, Lot Number 57K04409 and 57K04510
Item Number 801-900

So that we can complete our records, please return this form to us as soon as possible but no later than **July 30, 2010**.

FAX TO: [REDACTED] Fujirebio Diagnostics, Inc.
FAX : 610-240-3949

Section I – Confirmation

I received the Field Safety Notification regarding MESOMARK kits (DNL0710 801-900). I have taken the actions recommended in the notification. I have discontinued selling and discarded any MESOMARK kit Lot 57K04510 that was on hand.

Please indicate the quantity of products that you discarded:

Quantity Discarded MESOMARK, Lot 57K04510
--

Your Name: _____ Job Title (optional): _____
Facility Name: _____ Date: _____
Fax Number: _____ Telephone Number: _____
Signature: _____

Your comments are always welcome:

Please complete this section if your name or mailing address has changed:

Facility Name: _____
Contact Name: _____
Address: _____
City: _____ State/Province: _____ Zip/Postal Code: _____
Telephone: _____ FAX: _____