Date: July 5, 2024

Urgent safety advice EndoPredict QS Kit

FSCA_2024-01

Type of safety instruction:	Field Safety Corrective Action
Addressed to:	Clinical laboratory specialists, trained users
Affected products:	EndoPredict® QS Kit UNO (SVQ350) or EndoPredict® QS Kit DUO (SVQ360), especially: EndoPredict® QS Kit Part 2 of 5: Optical Sealing Foil (SV33F)
Sender:	Myriad International GmbH Nattermannallee 1 50829 Cologne, Germany

Dear customer,

According to our records, you have received one or more of the following components of our EndoPredict® QS Kit UNO (SVQ350) or EndoPredict® QS Kit DUO (SVQ360):

Product name	REF	Lot	Expiry date
EndoPredict® QS Kit Part 2 of 5: Optical Sealing Foil	SV33F	0F10022	31.05.2025
EndoPredict® QS Kit Part 2 of 5: Optical Sealing Foil	SV33F	0F10024	31.10.2025

Description of the problem:

Based on customer feedback, internal investigations showed that individual Optical Sealing Foils of the two batches mentioned above may have a kink in the middle. This damage can very likely be caused by processing during internal quality control. The cause has now been eliminated so that no similar damage can occur in the future.

Internal investigations showed that this kink can affect the RT-qPCR measurement and usually leads to an invalid result. However, it cannot be excluded that an incorrect EndoPredict test result is obtained when using a damaged Optical Sealing Foil as described above.

Potential risk to the patient:

In the worst case, an incorrect test result can lead to a patient being offered chemotherapy where none would be necessary, or endocrine therapy without chemotherapy where chemotherapy would be the more promising option. However, the following must be considered: EndoPredict® is neither intended for diagnosis of breast cancer, nor to detect response to a specific therapy. The physician should only use the results obtained from this test in conjunction with other risk assessment tools when determining a therapy protocol.

Measures taken by the manufacturer:

1) Blocking the affected batches in the internal warehouse so that further delivery of potentially defective Optical Sealing Foils is prevented.
2) Adaptation of the internal quality control process to prevent recurrence.
3) Replacement of defective Optical Sealing Foils on the customer side.

Measures to be taken by the user:

1) Check not yet used Optical Sealing Foils for kinks. Damaged Optical Sealing Foils must not be used for a measurement and should be disposed of according to local regulations. You can request replacement for damaged Optical Sealing Foils through the appropriate customer support via e-mail to epsupport@myriadgenetics.eu.
2) In case there is any doubt that patient samples were analyzed with damaged Optical Sealing Foils, we recommend repeating the analysis with existing FFPE samples. For any replacement deliveries, please contact epsupport@myriadgenetics.eu by e-mail.
3) Return the completed customer form for the Field Safety Notice (Annex 1).

Disclosure of the information described here:

Please ensure in your organization that all users of the products and other persons to be informed are aware of this Field Safety Notice. If you have provided the products to third parties, please forward a copy of this information or inform the contact person specified below.

Please keep this information at least until the measure has been completed.

The competent authorities have been informed of this Field Safety Notice.

Contact information

For further information, please contact Myriad International GmbH directly by e-mail to: epsupport@myriadgenetics.eu or the local sales partner.

Manufacturer information:

Name:	Myriad International GmbH
Email:	epsupport@myriadgenetics.eu
Telephone:	+49 221 66956100
Address:	Nattermannallee 1, 50829 Köln, Germany

Contact details of the local sales partner:

Name:	Myriad GmbH
Email:	info@myriadgenetics.eu
Telephone:	+49 221 66956100
Address:	Staffelseestrasse 6, 81477 Munich

We appreciate the trust you place in our products and sincerely apologize for the inconvenience caused by this situation.

Yours sincerely

[redacted]

Dr. Martin Lempert, PRRC

Annex 1

Field Safety Notice Customer Response Form

FSCA _ 2024-01 | EndoPredict QS Kit

Please complete this form and return it to regulatory_cologne@myriad.com within 10 calendar days of receipt of this letter.

Name of institution:	
Address of the institution:	
Name of contact person:	
E-mail of the contact person:	Tel. No. the contact person:
I confirm with my signature that this field safety notice has been read and understood and that the recommended measures have been followed.	
Completed by (name in document):	
Signature:	Date: