

NEO New Oncology GmbH • Gottfried-Hagen-Str. 20 • 51105 Köln

Firma

Kontaktperson

Straße

PLZ, Ort

07.02.2019

NEOonsite- NEOselect, Data Analysis and NEOdb may provide inaccurate MSI analysis results

Dear customer,

according to our documents, you are using the following product(s):

- **NEOselect**

in combination with

- **NEOonsite – Data Analysis 1.4.1 & NEOdb 2.2.1**

Reason for the Correction and when does this issue occur?

Determining the MSI (microsatellite instability) status in samples at the boundary between MSI-low and MSI-high, one or two out of five loci are instable respectively, can lead to inaccurate results (false positives and false negative) especially in samples with low tumor cell content.

What are the possible risks to health?

Currently MSI status only has a predictive value and no targetable therapy associated with it in the EU. Therefore, there is no direct patient risk of death or serious deterioration in the state of health associated with current MSI calling. As the affected feature of the products solely involves software components, there is no risk for the user of the product.

What steps can the user take to avoid the possible risks associated with this issue?

- Cease further use of the MSI functionality in NEOselect, additionally NEO New Oncology GmbH will remove the functionality from all affected products and software applications.
- review of patient's previous results or patient follow up, if applicable.

How will the issue finally be resolved?

NEO New Oncology GmbH is working towards an optimized MSI calling algorithm which will be made available for future analysis as well as retrospective analysis of samples. We strive for the highest level of safety and quality. Therefore, availability of the optimized algorithm is yet to be determined.

Dissemination of the content of this notice

Please ensure that all users of the affected products within your organization, and others, who may need to be informed receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

Acknowledge Receipt of this Safety Advisory Notice

Please fill out the attached Acknowledgment of receipt and follow the instructions for sending it back to NEO New Oncology GmbH via fax (+49 (0) 221 / 888238-22), e-mail (info@newoncology.de) or hand it to one of our NEO New Oncology field team members.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) is informed about this notice.

Sincerely Yours,

CEO

Head of Quality / Safety Officer

Acknowledgement of receipt

Customer address:

I hereby confirm as the owner / responsible operator of NEOselect, Data Analysis and NEOdb that I have read and understood this notice and accept the implementation of the recommended measures.

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Place, Date: _____

Name: _____

Signature: _____