---

**Urgent safety information**

Incident

concerning

Micro-Dx™ CE IVD and MolYsis-SelectNA™*plus*

---

21.02.2023

**Sender:**

Molzym GmbH & Co. KG
Mary-Astell-Strasse 10
28359 Bremen, Germany

**Addressee:**

Users and distributors of Micro-Dx™ and MolYsis-SelectNA™*plus*

**Background**:

Recent field interventions reported similar technical problems occurring on the SelectNA™*plus* devices, used in conjunction with related kits – Micro-Dx™ CE IVD and MolYsis™-SelectNA™*plus* kits. This prompted our team to investigate the cause of these technical issues, and the root cause of the technical issue was successfully identified as being a consumable part of the kits mentioned in this letterhead.

Manufacturer awareness date: February 7th, 2023

Internal reference: ID 358

It was immediately decided to interrupt deliveries of kits, to establish a field corrective action to avoid any other technical issues at customer site, while defining a sustainable solution for our customers to be able to resume operations and usage of our kits in proper conditions.

A description of the situation, of proposed immediate actions and ongoing remedies being worked on by Molzym is presented herein.

**Identification of the affected medical devices:**

| **Product** | **Micro-Dx™ CE IVD** | **MolYsis-SelectNA™*plus*** |
|---|---|---|
| **Product number** | **U-200-024 and U-200-048** | **D-450-048** |
| **Affected Lot numbers** | X11hKU200.048 | X06hKD450.048 |
| | X12hKU200.048 | X07hKD450.048 |
| | X13hKU200.024 | Y01hKD450.048 |
| | X18hKU200.024 | Y04hKD450.048 |
| | X20hKU200.024 | Y09hKD450.048 |
| | X24hKU200.024 | Y17hKD450.048 |
| | Y01hKU200.048 | Y18hKD450.048 |
| | Y02hKU200.048 | Y28hKD450.048 |
| | Y03hKU200.048 | Z12hKD450.048 |
| | Y08hKU200.048 | Z13hKD450.048 |
| | Y09hKU200.048 | A03gKD450.048 |
| | Y10hKU200.024 and Y10hKU200.048 | A04gKD450.048 |
| | Y11hKU200.048 | A16gKD450.048 |
| | Y22hKU200.048 | A17gKD450.048 |
| | Y23hKU200.048 | A18gKD450.048 |
| | Y24hKU200.048 | A19gKD450.048 |
| | Y28hKU200.048 | A23gKD450.048 |
| | Y29hKU200.048 | A24gKD450.048 |
| | Y30hKU200.048 | A25gKD450.048 |
| | A02gKU200.024 and A02gKU200.048 | |
| | A05gKU200.048 | |
| | A09gKU200.048 | |
| | A10gKU200.048 | |
| | A11gKU200.048 | |
| | A17gKU200.048 | |
| | A18gKU200.048 | |
| | A23gKU200.048 | |
| | A25gKU200.048 | |
| | B01gKU200.048 | |
| | B02gKU200.048 | |
| | B06gKU200.048 | |

**Description of the problem including the determined cause:**

- Problem identified and disfunction of the device: In the above listed lot numbers of kits, it has been identified that foaming can occur in the extraction cartridges. If foam or humidity is transferred through the outlet filters of the cartridges by the vacuum pumps, a circular wet imprint is visible outside the outlet filter of the extraction cartridge.
  In course of time, the humidity can lead to a defect or failure of the vacuum pump which leads to missing eluates or to repeatedly rejected channels with uncritical specimens at the same channel.

  In the last resort, the humidity causes a defect of the vacuum pump that needs replacement.

- Risk evaluated: The risk for users and patients in the continued use of the device is the loss of the specimens and consequently no eluate available. There is no loss in the sensitivity of analysis of the PCR results based on the received eluate.

- Determined cause: deep investigations and advanced tests have been performed on our kits to allow for the replication of technical issues encountered by customers on their devices. These experiments led to identify the cause as being plastic consumable components of our kit, extraction columns, which performance did not fit with Molzym requirements in spite of proper quality control performed by supplier, upon goods receipt, assembly and final product quality control.

**What actions are taken by Molzym?**

Molzym Production Team is focusing on the production of new lots of Micro-Dx™ and MolYsis-SelectNA™*plus* and has reinforced its Quality Control procedures accordingly.

In parallel, our R&D Team is performing further experiments to propose an adapted protocol, as a short-term solution , for the minimization of foam formation using the kits already delivered by adding an additive into the extraction cartridges. As soon as the interim solution to minimize foam formation is available and validated, Molzym will inform users and distributors and will provide the adapted protocol; **no later than by March 8th , 2023.**

Through this communication, we want to ensure that all devices which have been used with the affected kit lots listed herein are subjected to thorough inspection and cleaning undertaken by qualified technicians. A Molzym's representative or the local distributor will contact you to coordinate this **before mid March**.

**After your device has been inspected and cleaned, please use the device only with the interim solution or new kits which will be provided asap.**

Our priority remains to provide you with the highest quality standard products and our team is doing its best to provide you an interim and long-term sustainable solution to avoid any disruption in your laboratory work.

We apologize for any inconvenience and thank you in advance for your understanding and cooperation.

**What measures are to be taken by the addressee?**

To preserve the system and avoid unnecessary damaging of the pumps, please follow the guidelines below:

- Please clean the vacuum suction cup below the vacuum unit with a paper towel soaked with disinfectant after each extraction run as described in the manual.

- Each position where the vacuum pump is defective shall not be used any further.

- The device can then be further used with empty extraction cartridges and buffer cartridges loaded at defective positions.

  - **For this purpose, please take an extraction cartridge out of the kit** which can be reused over and over. The cartridge will be filled with some water by the device, after the run is completed, please discard the water from the cartridge and reuse it for the next extraction run. In addition, please load an empty buffer cartridge which can be reused as well.
  - **If you don't have an empty cartridge at hand, please take a buffer cartridge** out of the kit, empty it, wipe it dry with a paper towel and load it into the device. The cartridge will be filled with some water by the device, after the run is completed, please discard the water from the cartridge and reuse it for the next extraction run. No other additional vials, like enzyme vials etc. are required. Please load all functioning positions as usual and start the extraction run.

Please acknowledge receipt of the security information (in writing by email or fax) within 1 week of receipt of this letter.

We kindly ask you to please inform Molzym about affected devices including serial number of the device and affected positions, e.g., SNP-004 positions 1 and 3, either via your direct contact or the contact person indicated below.

**Contact person**

Name: Malin Wollens

Phone: +49 421 69 61 62 17

Fax: +49 421 69 61 62 11

With best regards,

Dr. Michael Lustig (COO)