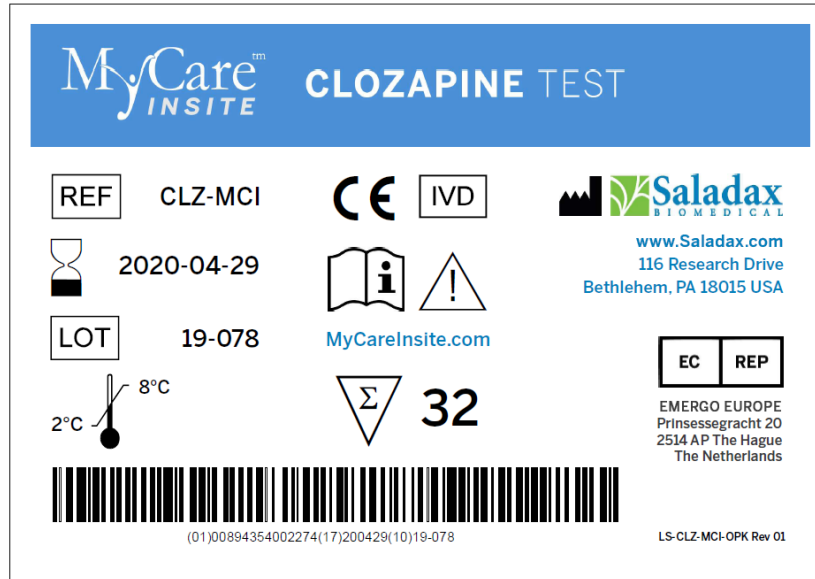


## ***Advisory Notice – Urgent: FIELD SAFETY NOTICE***

**New RFID cards are being provided for the MyCare Insite Clozapine Test, catalog number CLZ-MCI, lot 19-078 expiration April 20, 2020**



### **ISSUE DESCRIPTION**

**To ensure performance of the MyCare Insite Clozapine Test lot 19-078 until the test's expiration date, RFID cards with new parameters are being issued.**

**Quality control testing of the MyCare Insite Clozapine Test lot 19-078 at Saladax Biomedical, Inc. recommended that the test be recalibrated.**

**The exchange of the RFID cards is mandatory.**

**This action has no impact on previous results.**

**Control ranges as listed in the package insert have not changed.**

**The replacement covers tests being used by customers, evaluators, and in distributor inventory.**

**The appropriate Competent Authorities have been made aware of this Field Safety Corrective Action.**

## **ACTIONS REQUIRED**

**Continue using the current RFID cards until you receive replacements.**

**When the replacement cards are provided:**

- **Collect all MyCare Insite Clozapine Test lot 19-078 RFID cards from their respective test boxes in inventory or other places, including RFID cards that are on the MyCare Insite Analyser.**
- **Place the collected cards in the postage-paid return envelope.**
- **Complete the attached RETURN FORM, place it in the postage paid return envelope, with the RFID cards, seal and send back to Saladax Biomedical. Inc.**
- **Open the new RFID card package.**
- **Place new RFID cards into the lot 19-078 test boxes**
- **Continue using 19-078 as you would normally**

**Please pass this FIELD SAFTEY NOTICE to all those who need to be aware of it within your organization.**

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**Saladax Biomedical, Inc.**

## **QUESTIONS**

For questions or concerns pertaining to this Advisory Notice, please contact Saladax Technical Support by e-mail at [techsupport@saladax.com](mailto:techsupport@saladax.com) or by telephone at +1 610 419-6731, Option 1.



**RETURN RESPONSE FORM for MyCare Insite Clozapine Test Kit MCI-CLZ Lot 19-078 RFID cards**

**Please check ALL appropriate boxes:**

- I have read and I understand the instructions to replace RFID cards provided in the February 8, 2020 Advisory Notice/Field Safety Notice AN-028.
- I replaced (fill in #) \_\_\_\_\_ RFID cards
- I am sending back (fill in #) \_\_\_\_\_ RFID cards to Saladax Biomedical, Inc.
- (fill in #) \_\_\_\_\_ RFID cards were disposed of after all the tests in the box had been used.

Please explain if the number of RFID cards being sent back is not equal to the number of RFID cards replaced.

Organization: \_\_\_\_\_

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Tel. number: \_\_\_\_\_

Address: \_\_\_\_\_

Country: \_\_\_\_\_

Date: \_\_\_\_\_

PLEASE RETURN COMPLETED RESPONSE WITH ALL RFID CARDS IN THE ENCLOSED PRE-ADDRESSED ENVELOPE TO: Saladax Biomedical, Inc.  
116 Research Drive, Bethlehem, PA, 18015, USA  
OR FAX THE FORM TO +1 484 547-0590