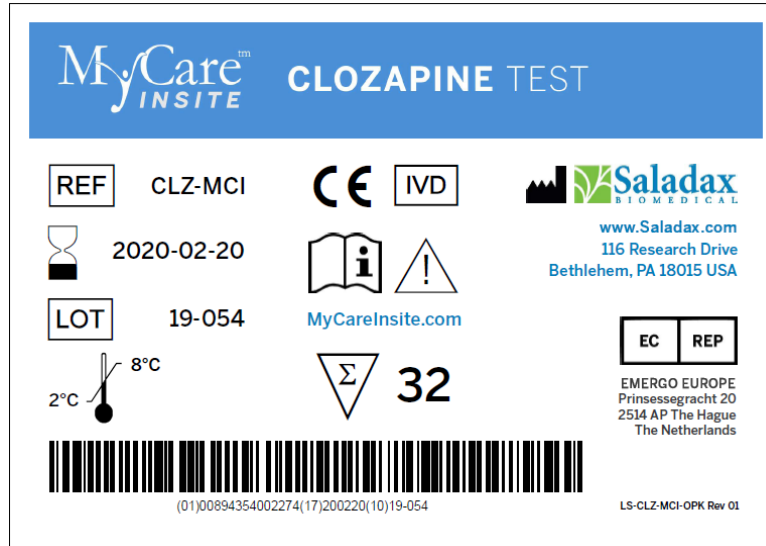


Advisory Notice – URGENT: MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE

Saladax Biomedical, Inc. is recalling the MyCare Insite Clozapine Test, product ID CLZ-MCI, lot 19-054 expiration February 20th, 2020



ISSUE DESCRIPTION

The MyCare Insite Clozapine Test lot 19-054 has generated control results that are not in the range specified in the package insert. The controls under-recover. Investigation at Saladax confirmed that low control failures occur with lot 19-054.

Control results outside of the specified range indicate that the test is not performing correctly. There is the potential that patient values may be reported as lower than their actual value.

The reason for the under-recovery of the low control is being investigated.

The recall 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

Cease use and distribution of MyCare Clozapine Test lot 19-054.

Immediately identify your customers and evaluators who have the recalled product and instruct them to cease use and destroy the affected lot per the instructions in this letter.

Immediately examine your inventory and destroy all MyCare Clozapine Test lot 19-054 units in accordance with local regulations.

Immediately complete the enclosed RECALL RETURN RESPONSE FORM to confirm receipt of this information and the destruction of the affected tests. Return the form in the enclosed envelope, or fax the form to +1 484 547-0590.

Upon return of the enclosed form confirming destruction of all tests shipped to you, replacement tests will be supplied free of charge.

xxx

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 or by telephone at +1 610 419-6731, Option 1.



RECALL RETURN RESPONSE FORM for MyCare Insite Clozapine Test Kit MCI-CLZ Lot 19-054

Please check ALL appropriate boxes:

- I have read and I understand the recall instructions provided in the January 24, 2020 Advisory Notice/Field Safety Notice AN-025.
- I have ceased use and distribution of lot 19-054.
- I have identified customers and evaluators who have the recalled product and instructed them to cease use and destroy the affected lot per the instructions in Advisory Notice AN-022.
- I have examined my inventory and have destroyed all MyCare Insite Clozapine Test lot 19-054 in accordance with local regulations.

Specify quantity, date and method:

Quantity Destroyed: _____ tests (32 tests per unopened box)

Date Destroyed: _____, 2020

Method of Destruction: _____

- I have examined my inventory and there is no inventory of MCI-CLZ lot 19-054 tests.

Organization: _____

Name: _____ Signature: _____

Title: _____

Tel. number: _____

Address: _____

Country: _____

PLEASE RETURN COMPLETED RESPONSE 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