Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-090-CG
December 16, 2022

FDA announced that, Detect, Inc. is voluntarily recalling specific lots of the Detect Covid-19 Test™, our molecular, over-the-counter test used to identify SARS-CoV-2 (the virus that causes Covid-19) in self-collected nasal swabs. The recall affects a total of 11,102 tests shipped to customers from July 26th, 2022 through August 26th, 2022. The test was granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on October 28, 2021.

RECOMMENDATIONS

1. Detect is notifying all customers and distributors affected by the recall. Anyone in possession of any unused tests from the affected lots should dispose of the tests. The outer packaging is recyclable while all the test components can be discarded as regular trash. Detect Hubs are not affected by the recall and do not need to be discarded.

2. Test users who attempt to use recalled tests will be notified in the Detect App™ that the test has been recalled and may not be used. Detect, Inc. will issue a refund* for the affected tests (as verified by Detect) upon customers' acknowledgement of receipt of the recall-related communication and confirmation that any affected tests in possession have been disposed of.

3. Detect is notifying all customers and distributors affected by the recall. Anyone in possession of any unused tests from the affected lots should dispose of the tests. The outer packaging is recyclable while all the test components can be discarded as regular trash. Detect Hubs are not affected by the recall and do not need to be discarded.

4. Detect, Inc. will issue a refund for the affected tests (as verified by Detect) upon customers' acknowledgement of receipt of the recall-related communication and confirmation that any affected tests in possession have been disposed of.

5. Please contact our customer support team for questions and further assistance.

Phone: (855) 322 3692
Email: support@detect.com

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

6. Review your inventory to identify existence of recalled products.

7. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

Voluntary Recall of Three Detect Covid-19 Test Lots

Summary:

Company Announcement Date:	December 08, 2022
FDA Publish Date:	December 12, 2022
Product Type:	Medical Devices Laboratory Tests
Reason for Announcement:	There is an increased chance that the tests from the lot numbers listed below may give false negative results
Company Name:	Detect, Inc.
Brand Name:	Detect
Product Description:	Over the counter Covid-19 Test

Company Announcement

Detect, Inc. is voluntarily recalling specific lots of the Detect Covid-19 Test™, our molecular, over-the-counter test used to identify SARS-CoV-2 (the virus that causes Covid-19) in self-collected nasal swabs. The recall affects a total of 11,102 tests shipped to customers from July 26th, 2022 through August 26th, 2022. The test was granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on October 28, 2021.

There is an increased chance that the tests from the lot numbers listed below may give false negative results. Detect has conducted a thorough investigation to identify this issue and has made the decision to conduct a voluntary recall for these lots. To date, Detect has not received any reports of false negative results related to the affected lots and is issuing this recall out of an abundance of caution. The reliability of positive test results is not affected.

Below is a list of the affected lots. The lot number can be found on the side of each test box along with the Use By date.

Lot Number	Use By Date	Number of Tests Shipped
HB264	1/1/2023	7,382
HY263	1/1/2023	1,800
HY264	1/1/2023	1,920

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507

T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726

MC-Rx.com

MC-Rx
Powered by ProCare Rx

FDA U.S. FOOD & DRUG ADMINISTRATION

Detect, Inc. is voluntarily recalling specific lots of the Detect Covid-19 Test™, our molecular, over-the-counter test used to identify SARS-CoV-2 (the virus that causes Covid-19) in self-collected nasal swabs. The recall affects a total of 11,102 tests shipped to customers from July 26th, 2022 through August 26th, 2022. The test was granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on October 28, 2021.

There is an increased chance that the tests from the lot numbers listed below may give false negative results. Detect has conducted a thorough investigation to identify this issue and has made the decision to conduct a voluntary recall for these lots. To date, Detect has not received any reports of false negative results related to the affected lots and is issuing this recall out of an abundance of caution. The reliability of positive test results is not affected.

Below is a list of the affected lots. The lot number can be found on the side of each test box along with the Use by date.

Detect is notifying all customers and distributors affected by the recall. Anyone in possession of any unused tests from the affected lots should dispose of the tests. The outer packaging is recyclable while all the test components can be discarded as regular trash. Detect Hubs are not affected by the recall and do not need to be discarded.

Test users who attempt to use recalled tests will be notified in the Detect App™ that the test has been recalled and may not be used.

Detect, Inc. will issue a refund* for the affected tests (as verified by Detect) upon customers' acknowledgement of receipt of the recall-related communication and confirmation that any affected tests in possession have been disposed of.

**Detect Hubs, unrecalled tests, and shipping charges are not eligible for a refund.*

We apologize for any inconvenience and thank our Detect customers.

Please contact our customer support team for questions and further assistance.

Phone: (855) 322 3692
Email: support@detect.com

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com