

Qiagen Sciences LLC. Recalls the AmniSure ROM Test Due to Lack of Control Line - Which May Lead to Misinterpretation of Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Product(s): AmniSure Rupture of (Fetal) Membrane (ROM)
- Kit Lot Numbers: US 557016546, 5600115, and 557016547
- Test Strip Lot Number: 557014371
- Manufacturing Dates: October 20, 2017 to December 20, 2018
- Distribution Dates: October 20, 2017 to March 23, 2018
- Devices Recalled in the U.S.: 1585 Kits (39,625 Tests)

Device Use

The AmniSure ROM (Rupture of Membranes) Test is an aid in the diagnosis of rupture of membranes (ROM) in pregnant women. The test is intended for use by health care professionals and is not intended as a standalone test. The test is intended to be used with other clinical assessments such as physical examination and other diagnostic tests.

Reason for Recall

Qiagen Sciences LLC is recalling the AmniSure ROM Test due to a potential manufacturing defect causing the control line to not display. A lack of a control line may lead to misinterpretation of test results. The test is designed to display one line (control line) if the result for the presence of amniotic fluid is negative, and two lines (control line and test result line) if the result for the presence of amniotic fluid is positive. Qiagen Sciences LLC received customer complaints that some tests were not displaying a control line. Failure of a control line to appear leads to an invalid test and delay in obtaining test results due to the need of repeat testing.

In addition, it is possible that the display of a test line in the absence of a control line could be misinterpreted as a negative test when it is a positive test. Inaccurate interpretation of these lab test results can lead to serious adverse events, including fetal deaths and health complications for the mother.

Who is affected?

- Patients being tested for rupture of membranes using the AmniSure ROM Test
- Health care providers and laboratory personnel who perform and interpret the AmniSure ROM Test

What to Do:

On May 18, 2018 Qiagen Sciences sent an Urgent Voluntary Medical Device Recall notice to affected customers. The notice asked customers to:

- Immediately discontinue use of all affected lots and return all unused product to Qiagen Sciences.
- Review the recall notice and ensure the appropriate staff is aware of the notice.
- Confirm receipt of the recall notification by completing and sending the Return Response form to Qiagen Sciences

Contact Information

Customers who have questions or need additional information or support regarding this recall should contact Qiagen's Technical Services at 1-800-344-3631.

Date Recall Initiated

May 8, 2018

Additional Resources

- [FDA Press Release – FDA alerts healthcare providers, women about risks associated with improper use of rupture of membranes tests \(/NewsEvents/Newsroom/PressAnnouncements/ucm616137.htm\)](#)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](#) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in [Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](#)

[2018 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm590900.htm\)](#)

[2017 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](#)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](#)