

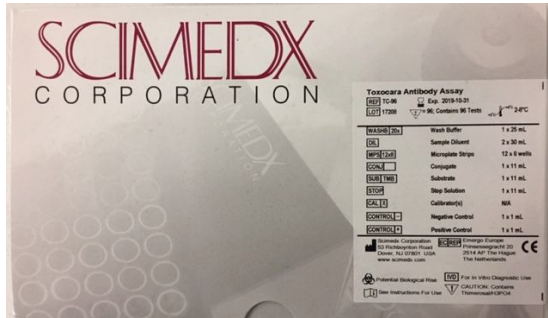


Urgent Field Safety Notice

August 2, 2019

Product: Scimedx Toxocara Microwell Serum ELISA (Catalog Number: TC-96)

Lot number: 17208



Dear Customer

This letter is to inform you that Scimedx Corporation initiated a recall to remove the following kit due to reduced sensitivity. The appropriate competent authorities have been info

Product: Toxocara Microwell Serum ELISA (Catalog Number: TC-96)

Lot number: 17208

Risks to Health	The above mentioned lot may yield false negative results. Because of this, a misdiagnosis is possible.
Actions to be taken by distributor	<ol style="list-style-type: none"> 1. Locate and quarantine affected unused devices. 2. Inform customers of risks and collect affected devices. 3. Either return affected unused devices to Scimedx for disposal or disposed by distributor 4. Scimedx will provide replacement kits for customers to retest patient samples. 5. Please complete the return slip and return by email to the Scimedx contact below.

Scimedx is committed to manufacturing only products of the highest quality standards. We regret this occurrence and any inconvenience it has caused you, your patients and your staff.

If you have any questions, please feel free to contact us under the following contact details:

email: service@scimedx.com

fax: 973-625-8796

Sincerely

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Urgent Field Safety Notice

Return Slip - Customer

Please complete and return this feedback information to service@scimedx.com after informing your customers of the removal from the market of:

Product: Scimedx Toxocara Microwell Serum ELISA (Catalog Number: TC-96)
Lot number: 17208

We confirm the receipt of this Field Safety Notice for Recall

In our facility we have _____(qty) concerned devices, which we will return.

_____ (qty) concerned devices have been discarded in our facility

Name:

Title:

Institution:

Country:

Signature/Date: