

Field Safety Notice

Syphilis TP Control Set

Product Name	Reference number REF	Lot Number	Expiration Date	UDI
Syphilis TP Control Set	A53711	50937	06/2028	(01)08058056681515(17)280630 (10)50937(240)A53711

SRN - Manufacturer
IT-MF-000012556

Date: August 04, 2025

Details on affected devices:

This letter contains important information regarding 'Syphilis TP Control Set' REF. A53711 lot 50937.

Please review the below information carefully and follow the necessary actions.

Description of the problem:

Sentinel detected an expiry date error on the labelling of the product 'Syphilis TP Control Set' REF. A53711 lot 50937.

The labelling reports a shelf life longer than expected and the product should not be distributed.

Patient Impact:

There is no risk for the patient since the product was not distributed to end users.



Actions to be taken by the distributor:

1. Stop distributing the product 'Syphilis TP Control Set' REF. A53711 lot 50937 and segregate the remaining stock.
2. Destroy the kits that were sent to other distribution centers.
3. Send back to Sentinel the residual kits you have received.
4. Fill in the "Field Safety Notice Receipt" and return it to Sentinel Customer Support within 31/08/2025.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization/individuals where the potentially affected devices have been transferred.

Reference person:

If you or any of your customers have any questions regarding this information, please contact Sentinel Customer Support.

We apologize for any inconvenience this may cause and thank you for your collaboration.

Best Regards.

