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## Urgent Field Safety Notice

**Commercial name of the affected product:**

Disposable Collection Tubes of Virus Samples

**FSCA-identifier:** CAPA202210004

**Type of action:** Chapter 4 definition of a FSCA

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Date: 2022.11.04

Attention: ////////////////

**Details on affected devices:**

*Catalogue number: PH02010S03T2050, PH03010S03T2050*

*lot/batch number(s): 20220907, 20220907*

*Device Manufacturing date: 2022.09.07*

*Expiry date: 2024.09.07*

**Description of the problem:**

*Disposable Collection Tubes of Virus Samples has been contaminated with cultures of Stenotrophomonas maltophilia and Pseudomonas sp, there is no injuries to people.*

*If continue to use this batch of products, the microorganism in the products may contaminate the patients and environment in which they are used.*

**Advise on action to be taken by the user:**

*Include ,as appropriate:*

- Identify and isolate this batch of products to ensure no further use of this batch of products.*
- Dispose this products as medical waste to avoid harm to people and the environment.*

**Transmission of this Field Safety Notice:** (if appropriate)

- This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)*
- Please transfer this notice to other organisations on which this action has an impact. (If appropriate)*
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- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)*

**Contact reference person:**

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