



Subject: Urgent Field Safety Notice	Field Safety Notice:003
	Date: 21st March 2023
Commercial name of the affected product: <i>EasyScreen</i> [™] Sample Processing Kit (SP012) UDI-DI: 93511790SP012L7 Manufacturer SRN: AU-MF-000030901 Type of action: Recall	

Attention: Laboratory Manager or Director.

This notice contains important information pertaining to the above product, please distribute to all users within your facility.

Details of affected devices: Affected batches of SP012 are:

- **30SEP2022**
- **17OCT2022**
- **21NOV2022**
- **30NOV2022**
- **21DEC2022**

Description of the problem: Genetic Signatures is investigating a situation whereby some plasticware (wide mouth bottles) used for the Elution Buffer in the EasyScreen Sample Processing Kits (SP012) is not sealing fully and can lead to pH drift over time.

Potential impact: This can cause incomplete processing of the sample and lead to target and control failures in the downstream PCR.

Action: You may continue to use your device in the short term, provided the device controls are performing correctly. A Genetic Signatures representative will contact you to organize replacement of the listed batches of SP012 within a week of receiving this letter. Please sign and return the attached acknowledgement form. The relevant national competent authority has been advised.

Transmission of this Field Safety Notice: 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.

Please contact Genetic Signatures Limited if further information is required.

Sinead O'Sullivan

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QA/RA Manager, EMEA

Date: 20th March 2023

This document is produced electronically and valid without a signature

CUSTOMER ACKNOWLEDGEMENT FORM

The EasyScreen Sample Processing Kit

Item code: SP012

This letter acknowledges I have read the letter of the 21st March 2023 and understand that Genetic Signatures will exchange my SP012 kits for kits with narrow mouth Elution Buffer bottles

Signed _____

Date _____ -