

**URGENT FIELD SAFETY NOTICE**

**Claritex WhiteCoat slide**

**15 Oct 18**

**Quarantine & Return/collection**

**ACTION: Customers, Distributors who receive Claritex WhiteCoat slide**

**INFO: MHRA**

**1. Details of affected devices:**

Item Code	Description	Lot
MAF-0102-03A	Claritex WhiteCoat slide	ZP171218054

**2. Description of Problem:**

There has been an incident with Claritex WhiteCoat slides (MAF-0102-03A Lot ZP171218054), where paint spots on a slide have obscured cellular detail and look like carry over, essentially rendering the slides unusable requiring sections to be recut. In some cases, macroscopic inspection does not detect the paint spots.

**3. Advice on action to be taken by the User:**

Identify and quarantine any Claritex WhiteCoat slides (MAF-0102-03A Lot ZP171218054)

Confirm to CellPath ([info@cellpath.co.uk](mailto:info@cellpath.co.uk)), by 19 Oct 2018:

- That you have received and understood this FSN.
- The quantity of MAF-0102-03A Lot ZP171218054 that you have quarantined (CellPath will then organise for quarantined slides to be collected – do not dispose of slides)

**4. Transmission of the FSN:**

This Notice must be passed to all those who need to be aware in your organisation or to any organisation where these slides are used.

Please transfer this Notice to other organisations where this has an impact.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**5. Contact:**

Trevor Turner  
QHS&E Manager

CellPath Ltd  
80 Mochdre Enterprise Park  
Newtown  
Powys  
SY18 4LE  
UK

The undersigned confirms that this Notice will be notified to the MHRA.

Date: 15 Oct 18

Signature:

