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## Urgent Field Safety Notice

### *Recall*

#### Stringent Wash Buffer in HISTO SPOT<sup>®</sup> Reagent Kit

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Lich, March 26<sup>th</sup>, 2015

**Addressor:**

BAG Health Care GmbH  
Amtsgerichtsstraße 1-5  
35423 Lich / Germany

**Addressees:**

Users, Distributors

Dear customers,

Unfortunately, we have to inform you that there is a problem with the Stringent Wash Buffer in the HISTO SPOT<sup>®</sup> Reagent Kit leading to false positive probes with different HISTO SPOT<sup>®</sup> Typingkits for the following lots:

**Details on affected devices:**

Stringent Wash Buffer (lot 1408 STRG WASH/1) in HISTO SPOT<sup>®</sup> Reagent Kit (lot 1408K1)  
Stringent Wash Buffer (lot 1408 STRG WASH/4) in HISTO SPOT<sup>®</sup> Reagent Kit (lot 1408K4)  
Stringent Wash Buffer (lot 1410 STRG WASH/1) in HISTO SPOT<sup>®</sup> Reagent Kit (lot 1410K1)  
Stringent Wash Buffer (lot 1410 STRG WASH/2) in HISTO SPOT<sup>®</sup> Reagent Kit (lot 1410K2)

**Description of the problem / Root cause:**

The stringency in the wash buffer is salt concentration dependent and we assume that the precipitated salt crystals in the buffer might not have been dissolved completely before filling it in the bottles. This would also explain why some of the bottles of one lot produces false positive reactions and others not and why the effect is not always equally strong.

The consequence of the false positive probes usually is that the user has to do more editing in the interpretation. Sometimes they may lead to uninterpretable results.

**Advise on actions to be taken:**

Please do not use the above listed lots of the Stringent Wash Buffer anymore / Please inform your customers not to use the above listed lots of the Stringent Wash Buffer anymore. We will ship replacement. Please fill out the attached form and let us know how many replacement units you will need.

We apologize for the inconvenience and thank you very much for your cooperation.

**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 keep this information at least until the action has been completed.

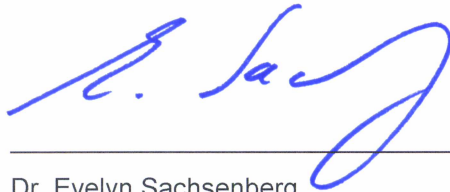
**Contact:**

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Kind Regards

**BAG Health Care GmbH**

A handwritten signature in blue ink, appearing to read "E. Sachsenberg", written over a horizontal line.

Dr. Evelyn Sachsenberg  
(Safety Officer)