



April 3, 2014

## IMPORTANT NOTIFICATION Update to CellSave Preservative Tube Instructions for Use

Dear Customer,

Janssen Diagnostics, LLC has updated the Instructions for Use (IFU) for the CellSave Preservative Tube (Product Ref. 7900005 / 9528-20), starting with LOT 407711 (50,000 tubes) and 408024 (50,000 tubes).

The updated CellSave Preservative Tube IFU (Pub. No. e631600041 dated 2013-08) adds risk (R43) and irritant information (Xi irritant symbol) for Imidazolidinyl Urea. A conservative approach was taken concerning the addition of this safety information, which was based on a non-compulsory recommendation from the Denmark Advisory.

Please note that the formulation has not changed.

Imidazolidinyl Urea is now specified as a hazardous material with the following indications:

- R43 (Risk statement): May cause sensitization by skin contact.
- S24 (Safety statement): Avoid contact with skin.
- S37 (Safety statement): Wear suitable gloves.



The Xi – Irritant symbol is added to the CellSave Preservative Tube IFU and is included as part of the Revision History.

The updated CellSave Preservative Tube IFU is available for download at [www.cellsearchctc.com](http://www.cellsearchctc.com). Click **Support and Resources**, then **Instructions for Use**. Select a **Country** and then a **Language** from each drop-down. Click the link that displays to open the IFU.

If you have any questions regarding this notification, please contact Customer Technical Services at 1-877-837-4339 or contact your sales representative.

Sincerely,

Michael McGrath  
Director, Customer Technical Services