



19-May-2015

URGENT PRODUCT CORRECTION NOTIFICATION
Artifacts Appearing in the Image Gallery for
CELLSEARCH® Circulating Tumor Cell Kits (IVD), (Product Code 7900001)

Dear Valued Customer:

This is to inform you of an Urgent Product Correction Notification for the following:

Product Name	Product Code	Lot	Expiry Date
CELLSEARCH® Circulating Tumor Cell Kits (IVD)	7900001	0094B	2015-12-12
		0074B	2015-10-08

This Urgent Product Correction Notification has been initiated by Janssen Diagnostics, LLC due to reports of an increase in artifacts appearing in the image gallery as unassigned events.

Investigation Summary

We received reports from customers about the intermittent occurrence of small bead-like structures or “artifacts” appearing in the image gallery for both control cells and patient samples of some CELLSEARCH® Circulating Tumor Cell Kits (IVD), (Product Code 7900001). The appearance of individual artifacts is not unusual. However, review of the data has demonstrated an increase of artifacts appearing in the image gallery as unassigned events. See the Question and Answer section for further details.

Required Actions

- When this type of artifact is present as described above, see Table 1 on page 2 to determine when patient samples are valid.
- It is acceptable to continue to use your current inventory.
- Report the occurrence of this type of artifact in patient samples and controls to Customer Technical Support.
- Complete and return the enclosed Confirmation of Receipt Form within 2 business days to acknowledge your reading and understanding of this notice.

Impact to Results

Artifacts are distinguishable from circulating tumor cells (CTCs) as they do not meet the criteria of a CTC. Therefore, they are not likely to be counted as CTCs when reviewing in the image

gallery. However, when testing patient samples, there is a low probability that this type of artifact could potentially obscure the presence of CTCs.

Table 1

For the following tests, if artifacts are present as described above, and the resultant CTC cell count is...		
mBC or mPC	mCRC	Then...
5 or more	3 or more	Results are valid
4 or less	2 or less	A re-test is advised

When seen in a control sample, the artifacts may automatically be counted as high control cells resulting in a high control cell failure. Low control cells are not impacted by the presence of artifacts because they are reviewed by the User and they are easily distinguishable from artifacts.

The controls should be repeated if this type of artifact is observed in the control image gallery and if you suspect they are impacting the control results, such as the high control failing high. If a control cell failure occurs, refer to the Instructions for Use for the CELLSEARCH® Circulating Tumor Cell Control Kit.

Patient results generated using CELLSEARCH® Kits should be used in conjunction with the overall clinical information derived from diagnostic tests (i.e., imaging and laboratory tests), physical examination and the complete medical history in accordance with appropriate patient management procedures.

It is important that you are aware of the potential occurrence of this type of artifact, as described above, and that you report the occurrence in patient samples and controls to Customer Technical Support.

Resolution

The cartridge has been identified as the most likely root cause and the investigation is ongoing to further determine root cause and corrective and preventive actions. At this time, the instrument and reagents are not implicated as the source of this type of artifact.

We apologize for the inconvenience this may cause your laboratory. We have anticipated questions you may have in the following Question and Answer section. If you have additional questions about this issue or if you are uncertain about a potential occurrence of artifacts, contact Customer Technical Support at **1800 5646 766**.



Sincerely,



Cherie Yip

Regulatory Associate

Questions and Answers

1. Can I use my current inventory?

Yes, the occurrence of artifacts is intermittent and is readily detectable if present. See the **Impact of Results** section of the letter for potential impact to results and Table 1 for guidance.

2. How will artifacts appear?

Though the sizes may vary, the artifacts are present in all channels. If present, you may see a large number of artifacts displaying these characteristics in your gallery.



3. Will I receive credit for my tests if I observe artifacts as described above?

Customers who have reported a complaint to Technical Support and are unable to report patient results or who have experienced a failed control will be issued a credit.

4. Can we visually inspect cartridges prior to use?

A visual inspection will not detect the presence of artifacts.

5. I have occasionally seen artifacts before. What makes this different?

It is not uncommon to see artifacts. When present, this type of artifact is on the inside of the cartridge surface and it appears in increased numbers within the image gallery.

6. Are there other lots available to replace my existing inventory?

Currently, the investigation to further determine root cause is ongoing. As such, it is recommended to continue to use your current supply with the additional directions as indicated in this letter.

7. What about previously reported results?

You should discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director or with the requesting physician. The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.