

# Technical Bulletin

## Gamma Irradiation Identification

SAFC Biosciences provides additional assurance to our customers that each bottle of serum has been gamma irradiated as required. We have identified and validated an identification method that confirms gamma exposure to a frozen product. Many indicators are available, but typically only demonstrate a change in temperature due to the heat generated during the gamma irradiation process. Since SAFC Biosciences assures that serum remains frozen during every stage of our validated SER-TAIN™ controlled process, the challenge has been to locate an indicator that meets our criteria.

### Details

- The identification will be applied to all SAFC Biosciences' sterile filtered, packaged serum that is gamma irradiated.
- The indicator is a yellow dot approximately one inch in diameter (the size of a quarter) that is prepared in advance of the irradiation process.
- The yellow dot is printed by QA to include the SAFC Biosciences' item number and lot number, along with the statement "Red Indicates Irradiation Treatment."
- The yellow dot is applied to the curved portion (above the label, below the shrink banded neck) of each frozen bottle of serum prior to the irradiation process.
- The exposure to gamma irradiation turns the yellow dot red.
- Prior to release of product to our customers, in addition to QA review of all supporting documentation supplied by our irradiation contractor, each bottle of gamma irradiated serum is inspected to assure that it remains frozen and that the yellow dot has turned red.

SAFC Biosciences performs two handling procedures for gamma irradiation of serum. One method confirms inactivation of an entire lot predestined for stock requirements. The other method confirms gamma irradiation of product that was previously packaged and tested without inactivation. The two procedures are outlined as follows:

### Procedure 1

- When SAFC Biosciences gamma irradiates an entire stock lot of serum, the original, main product label will reflect this.

Example: Fetal Bovine Serum-Gamma Irradiated, Item 12107-500M, Lot 7A2123.

- The additional yellow dot is printed to include identical product identification and when applied to bottles, is used strictly as an exposure indicator.

Example: Item 12107-500M, Lot 7A2123.

Red  
Indicates  
Irradiation Treatment

7A2123  
12107-500M

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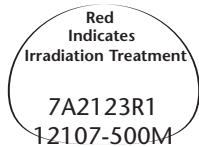
## Procedure 2

- When SAFC Biosciences gamma irradiates previously packaged catalog serum (not gamma inactivated), the original main product label remains on the bottle.

Example: Fetal Bovine Serum, Item 12103-500M, Lot 7A2123.

- The additional yellow dot is printed to include the new product identification and applied to bottles.

Example: Item 12107-500M, Lot 7A2123R1.



- The new lot number includes the original lot number, suffixed with an "R", followed by a number (sequentially issued for each irradiation event, ie. R1, R2, R3, etc.) that coordinates all documentation of the specified gamma irradiation event.
- The information on the irradiation indicator supersedes the information on the original label.
- Immediately after confirmation of the irradiation process, the new item number and lot number are referred to in all documentation covering the specific number of bottles irradiated during that event. This includes the batch manufacturing record, certificate of analysis, certificate of irradiation and inventory.

For more information about this subject or other SAFC Biosciences' products and services, please call our Technical Services department.

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Issued April 2006 T023  
0300 1005 1205

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