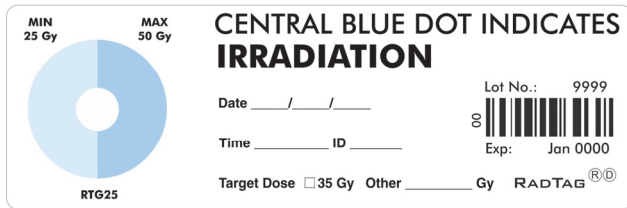
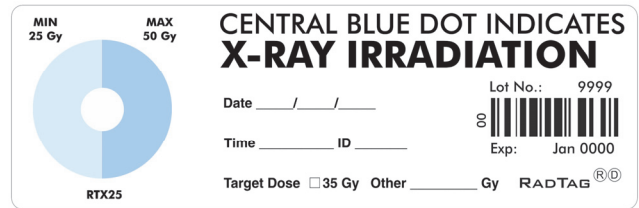




Process Verification for Blood Irradiation PRODUCT INFORMATION SHEET



RTG25 Gamma Irradiation Indicator
(RTG15 also available)



RTX25 X-Ray Irradiation Indicator
(RTX15 also available)

An Innovative Way to Confirm Your Blood Products Were Irradiated

RadTag®, an innovative blood irradiation indicator gives you more than just a yes or no. It indicates if the product received the minimum dose (25 or 15 Gy), or exceeded the maximum allowable dose of 50 Gy.

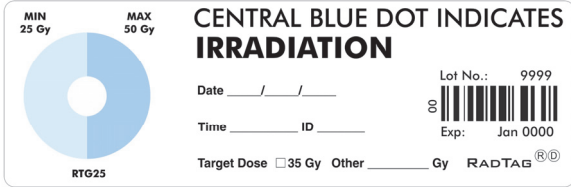
Simply confirm the sensitive blue dot is the same as or darker than the 25 Gy (or 15 Gy) colour and if necessary, not darker than the 50 Gy colour. It's that simple.

The RadTag® Irradiation Indicator is attached to a blood bag prior to the bag's placement in an irradiator. The sensitive portion of the indicator is white initially and changes to a blue colour upon exposure to ionizing radiation; the shade of blue is an approximation of the amount of radiation dose delivered. The colour change is permanent and immediate and does not require any further processing or development. The amount of colour change has been optimized to give a clear indication that the blood bag has been processed at levels of irradiation currently used in the industry. A typical processing unit will target a 35 Gy (or 25 Gy) dose to the central part of the irradiation container and a minimum of 25 Gy (or 15 Gy) to any other part.

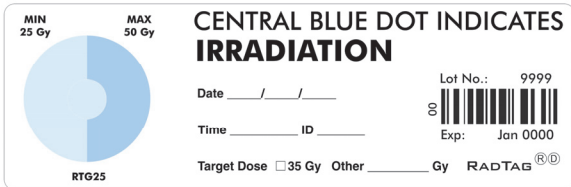
Features	Benefits
<ul style="list-style-type: none"> Utilizes a unique colour changing material 	<ul style="list-style-type: none"> Quick and easy to interpret
<ul style="list-style-type: none"> Can be a simple yes/no process verification of dose delivered 	<ul style="list-style-type: none"> Blue colour = positive No colour = negative
<ul style="list-style-type: none"> Can also be a semi-quantitative indicator of radiation dose 	<ul style="list-style-type: none"> Verifies if irradiation has taken place using a colour reference system Reveals that the range of dose delivered is within recommended limits for blood and blood components (25 or 15 Gy to 50Gy)
<ul style="list-style-type: none"> Both Gamma and X-ray versions available Lot number and expiry date on label Barcode readable 	<ul style="list-style-type: none"> Support for users of either radiation source Convenient for documentation
<ul style="list-style-type: none"> Flexible adhesive label 	<ul style="list-style-type: none"> Less rigid than other labels Easier to apply to blood bags and syringes
<ul style="list-style-type: none"> Accepted and approved by regulatory agencies 	<ul style="list-style-type: none"> Registered with HPFD and cleared by FDA Quality Management System registered to ISO 9001:2008 CE Marked

To order, contact your distributor:

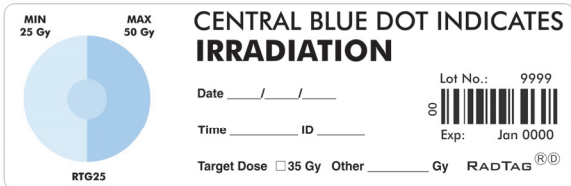
Sample Interpretation



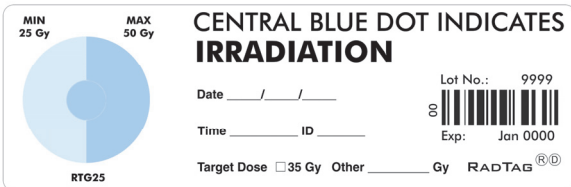
Negative



Minimum



Mid-Range



Maximum

Guidelines for Use

STORAGE

To maintain product viability, RadTag Blood Irradiation Indicators should be stored at a safe distance from all sources of penetrating radiation, which include gamma rays, x-rays and electron beams.

To avoid exposure of un-irradiated indicators to direct and indirect sunlight, ultraviolet radiation and heat, it is recommended that the indicators be stored in a refrigerator or freezer with temperature range: +6°C to -20°C.

USE

1. Remove required number of indicators from box.
2. Replace box and its contents in a refrigerator or freezer.
3. Ensure the central dot is white prior to irradiation.
4. Print or check on the indicator: targeted central dose, date, time, and operator ID.
5. Attach indicator to clean dry location on the blood bag prior to irradiation.
6. Perform irradiation.
7. After irradiation, confirm that the colour of the sensitive dot is the same as or darker than the minimum reference colour, and, if necessary, not darker than the maximum reference colour.

NOTES

If target dose is 35 Gy (or higher), using the RTG25/RTX25, confirm the colour is the same as or darker than the 25 Gy minimum and not darker than the 50 Gy maximum.

If target dose is 25 Gy, using the RTG15/RTX15, confirm the colour is the same as or darker than the 15 Gy minimum and not darker than the 50 Gy maximum.

Regulatory Information

The base label (Fasson® FDA 815-S) meets the FDA's Code of Federal Regulations guidelines and is in compliance with 16CFR Part 1500.41 for direct skin contact and 21CFR Part 175.105 of the Code of Federal Regulations pertaining to indirect food additive regulations.

Ordering Information

RTG15	RadTag 15/50Gy Min/Max	Gamma	200/Box
RTX15	RadTag 15/50Gy Min/Max	X-Ray	200/Box
RTG25	RadTag 25/50Gy Min/Max	Gamma	200/Box
RTX25	RadTag 25/50Gy Min/Max	X-Ray	200/Box

Note: RadTag® indicators should not be considered as radiation dosimeters, but rather as semi-quantitative indicators of radiation dose. It is recommended that regular maintenance be performed by the manufacturer of the irradiator.

Manufactured by:



Version 8.7ROW
03/07/2017