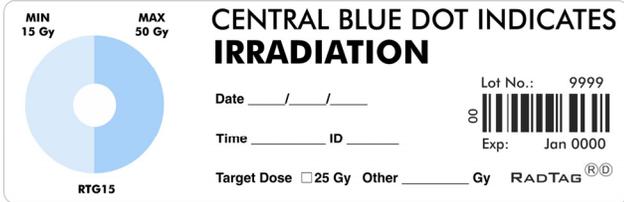




RADTAG

Process Verification for Blood Irradiation PRODUCT INFORMATION SHEET



**RTG15 Gamma Irradiation Indicator
(Target Dose 25 Gy)**



**RTX15 X-Ray Irradiation Indicator
(Target Dose 25 Gy)**

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 additionally indicates if the product received the minimum dose of 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 15 Gy color and if necessary, not darker than the 50 Gy color. 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 color upon exposure to ionizing radiation; the shade of blue is an approximation of the amount of radiation dose delivered. The color change is permanent and immediate and does not require any further processing or development. The amount of color 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 25 Gy (2500 rads) dose to the central part of the irradiation container and a minimum of 15 Gy (1500 rads) to any other part.

Features	Benefits
<ul style="list-style-type: none"> Utilizes a unique color 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 color = positive No color = 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 color reference system Reveals that the range of dose delivered is within FDA and AABB recommended limits for blood and blood components (15Gy to 50Gy) Assures compliance with FDA/AABB guidelines for min/max dose limits
<ul style="list-style-type: none"> Both Gamma and X-ray versions available 	<ul style="list-style-type: none"> Support for users of either radiation source
<ul style="list-style-type: none"> Lot number and expiry date on label Barcode readable 	<ul style="list-style-type: none"> 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 9001:2015

To order, contact your distributor:

Sample Interpretation



Negative



Minimum



Mid-Range



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.

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:



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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 a temperature range of +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 color of the sensitive dot is the same as or darker than the minimum 15 Gy reference color, and, if necessary, not darker than the maximum 50 Gy reference color.

Ordering Information

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