

RAD-CONTROL

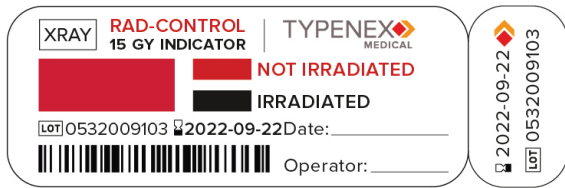
15 Gy X-Ray Irradiation Indicator for Blood Products

1. Product description

RAD-CONTROL is used to verify blood product irradiation. It is intended for use during X-ray irradiation with a target of 15 Gy. A change in the indicator color from RED to BLACK indicates that the product was exposed to irradiation.

2. Application

a) Indicator appearance **BEFORE** irradiation (below is an example of a 15 Gy indicator).



b) Fill in the information for "Operator" (user) and "Date" (date) per your facility's protocol.

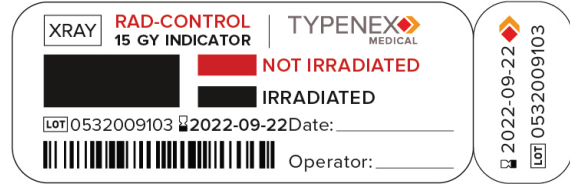
c) Prior to irradiation a RAD-CONTROL label is affixed to the blood bag.

Be sure to wipe off any condensation before affixing the label and apply the indicator firmly to a clean, dry place on the blood bag. Remove a label from the sheet by touching the adhesive side as little as possible. Use thumbs to apply pressure to the irradiation tag to help keep the tag in place. You may use the peel-off sticker with the irradiation tag expiration date and LOT number for record keeping purposes or you may discard it.

d) Make sure that the indicator field appears RED in color and apply irradiation.

3. Evaluation

a) Indicator appearance **AFTER** irradiation (example):



b) Verify that the indicator field has turned black after irradiation. Because of variation in lighting conditions, product batches, and user eyesight, indicators may have a reddish tint after irradiation. If there is a concern that the indicator field did not function correctly, the process should be verified. In such cases, please refer to your dose map and follow your in-house standard operating procedures (SOPs) to verify the blood unit received the appropriate cycle.

c) Change in the color of the indicator serves as an indication that irradiation has taken place. The blood product can now be passed on to its intended use. The label may be used one time only.

NOTE: RAD-CONTROL indicators only show that irradiation was applied. They do not indicate or determine a specific irradiation dosage. They must be used with irradiators that are working properly and are properly calibrated.

4. Transportation and storage

Transport instructions: keep product in the original package, temperature limits -18°C to 50°C



LOT number



Storage temperature: keep product at room temperature (15°C to 25°C) and keep away from radiation sources



Single use only



Keep away from sunlight



Expiration date of irradiation indicator tag



Manufactured for:
Typenex Medical LLC
303 East Wacker Drive, Suite 1030
Chicago, Illinois 60601
www.typenexmedical.com
Phone: 866-897-3639