

RAD-CONTROL BARCODE

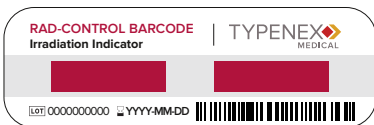
Irradiation Indicator for Blood Products

1. Product description

RAD-CONTROL BARCODE is used for the electronically readable verification of blood product irradiation. It is intended for use during gamma or X-ray irradiation. Irradiation is indicated by a discoloration of the two indicator areas to form a barcode and the word "IRRADIATED".

2. Application

a) Indicator appearance **BEFORE** irradiation (below is an example):



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

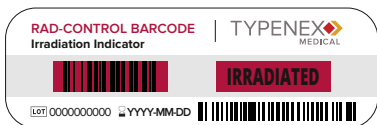
Be sure to wipe off any condensation before affixing the label and apply the indicator firmly to a clean, dry place on the blood bag. Remove a label from the sheet by touching the adhesive side as little as possible. Use thumbs to apply pressure to the irradiation tag to help keep the tag in place.

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

NOTE: The barcode must not be readable electronically before irradiation. If in doubt, perform a test with the scanner.

3. Evaluation

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



b) After the irradiation, the barcode indicator appears as well as the display of the word "IRRADIATED". The barcode can be read with a scanner and the result can be recorded electronically. For optimal readability adjust the distance of the scanner to the barcode. Proper readability of the barcode serves as an indicator that irradiation has taken place. The irradiation can alternatively be verified if the word "IRRADIATED" is displayed. If the barcode is not readable the process should be verified. In such cases, please follow your in-house standard operating procedures (SOPs).

c) The blood product can now be passed on to its intended use. The label may be used one time only.

NOTE: The FDA recommends a minimum dosage of 15 Gy with a target central dose of 25 Gy. 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

ATTENTION: In order to prevent false signals, the indicator has to be protected against light during storage and specifically must not be exposed to direct sunlight!

LOT LOT number

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

② 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