Quality Assurance
RadTag® 15/50 and 25/50 Gy Indicators

The RadTag® Blood Irradiation Indicator, a product of RadTag® Technologies, is manufactured in compliance with ISO 9001 guidelines.

RadTag® is a registered Class I medical device with the FDA, and also registered as a Class I medical device under Health Canada guidelines.

As part of the FDA requirement, the adhesive (Fasson S-815-B) used on the indicators is tested and fully approved for application to blood bags.

FDA Registration:
BK960068 (Gamma)
BK000008 (X-ray)

The active component of the indicator changes color upon irradiation. The shade of this color indicates the approximate dose of radiation received.

1. The RadTag® indicator is manufactured to the highest quality standards. Each batch is tested by irradiation in a Gammacell 1000, using a NIST (National Institute of Standards and Technology) traceable calibration.
2. Samples are measured to determine the optical density before and after exposure to radiation.
3. Finally, each individual indicator is tested in a proprietary way to ensure adequate response to irradiation.

The above QA procedure allows RadTag Technologies Inc. to manufacture the RadTag® Blood Irradiation Indicator in a reproducible and standard manner to allow for reproducible visual conformation of irradiated blood products.

When using the printed reference colors on the label itself, it is possible to reliably estimate that the delivered dose is within the FDA recommended range, thereby ensuring that the minimum dose has been delivered and that the maximum dose has not been exceeded.

The RadTag® indicator should not be considered to be a radiation dosimeter, but rather a semi-quantitative indicator of radiation dose.

The following lot numbers have been produced in accordance with the quality assurance guidelines stated above:

Signed: _____   Date: _____
    (Quality Assurance Manager)

RADTAG TECHNOLOGIES

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