who has a two-part quality system for blood irradiation confidence?

rad-sure™ blood irradiation indicators

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dose-map™ dosimetry system

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two product families together providing end to end assurance of irradiated blood product safety

Ashland's rad-sure™ blood irradiation indicators combined with our dose-map™ dosimetry system provides end-to-end assurance that irradiated blood products are treated with the highest level of efficacy to ensure patient blood safety. who provides easy visual verification of blood irradiation?

rad-sure[™] blood irradiation indicators

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rad-sure[™] blood irradiation indicators

indicators for positive visual identification of irradiation

Transfusion-associated graft-versus-host disease (TA-GvHD), a rare complication of blood transfusions, is usually fatal. Patients in certain clinical categories including bone marrow transplants, solid tumors, and acquired T-cell defects are at greater risk of developing TA-GvHD. TA-GvHD can be prevented by irradiation of cellular blood products prior to transfusion.

Ashland developed rad-sure[™] blood irradiation indicators to provide positive visual verification of irradiation. When attached to blood products, rad-sure[™] blood irradiation indicators show whether the blood products have been irradiated or not.

Ashland provides two products to meet the blood industry needs: rad sure[™] blood irradiation indicators and rad-sure[™] chromicVue[™] blood irradiation indicators. Both indicators provide the same easy visual verification of proper radiation for blood products. Rad-sure[™] chromicVue[™] indicator is a smaller size ideally for use with standard blood bags and other blood product packaging. Before a blood product and its attached indicator have been irradiated, the indicator reads "NOT Irradiated". After the blood product and its attached indicator are irradiated, the word "NOT" in the window is obscured and the indicator reads "Irradiated." Rad-sure™ blood irradiation indicators only indicate irradiation. They should not be used as a dosimeter to measure the dose delivered by the irradiator.

Rad-sure[™] blood irradiation indicator products are available for a minimum dose of 15 Gy and 25 Gy doses. Rad-sure[™] chromicVue[™] blood irradiation indicator is available for a minimum dose of 25 Gy. Both indicators are compatible with gamma and x-ray irradiation sources.

rad-sure[™] blood irradiation indicators are FDA-listed medical devices

registration	listing number	description	
FDA	A976736	rad-sure [™] 15 Gy and 25 Gy blood irradiation indicators	
TDA	A770730	rad-sure™ chromicVue™ 25 Gy blood irradiation indicators	

ordering information

rad-sure[™] blood irradiation indicators

version	product code	indicators per box
rad-sure™ 15 Gy blood irradiation indicators	976631	200
rad-sure [™] 25 Gy blood irradiation indicators	976792	200
rad-sure™ 25 Gy NBF* blood irradiation indicators	977365	200
rad-sure [™] chromicVue [™] 25 Gy blood irradiation indicator	976631	250

*NBF = No Blank Fields

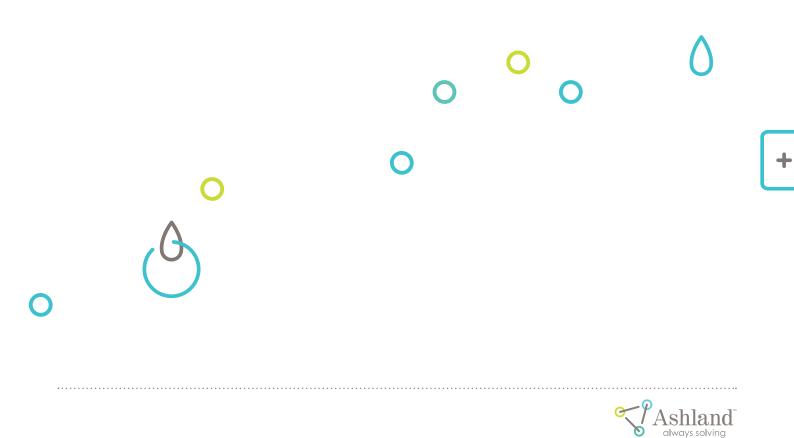
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examples of rad-sure[™] and rad-sure[™] chromicVue[™] blood irradiation indicators before and after irradiation



Additional versions of rad-sure[™] blood irradiation indicators are available.



who helps ensure blood irradiator systems are functioning properly?

dose-map™ dosimetry system

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dose-map[™] dosimetry system

accurate, quantitative dosimetry for blood irradiators

Dose-map[™] dosimetry system provides a simple and proactive method of assuring the dose delivered by a blood irradiator. It's a quick and easy procedure anyone who knows how to operate a blood irradiator can do.

The dose-map[™] cassette is placed in your irradiator and run through the same irradiation cycle that is used for blood products (see exhibit 1). After irradiation, the dose-map cassette is returned to Ashland for analysis, and then a report is issued with pertinent data on your irradiator.

Inside the dose-map[™] cassette is a piece of gafchromic[™] film that allows for a clear and accurate picture of how the irradiator is operating during a normal irradiation cycle. After irradiation the film medium darkens in response to the ionizing radiation providing instant imaging of the dose distribution of the cassette.

Additionally, the dose-map[™] cassette measurements are indexed to alanine which is co-irradiated with the gafchromic[™] film. Alanine is an internationally recognized dosimetry transfer standard. Dose-map[™] dosimetry system is designed to measure commercial gamma blood irradiator systems that contain a cylindrical cannister. Compatible gamma blood irradiator systems utilize either cesium-137 or cobalt-60 sources to generate gamma irradiation.

Upon return to Ashland, the cassette is disassembled, and the entire film (see exhibit 2) and alanine pellet are analyzed. The final report (see exhibits 3 and 4) issued to the customer consists of:

- a dose distribution chart showing the centerline, left edge, and right edge of the canister
- a color-coded dose contour plot showing the dose distribution of absorbed dose in the canister
 - minimum and maximum axial dose
 - minimum and maximum dose

ordering Information

dose-map[™] dosimetry system

Contact customer service and our team will help you with your dosimetry service requests needs.

Ashland's customer service team can be reached at: DiagnosticFilmOrders@Ashland.com

DOSE-MAR Dose-Map cassette Water-filled Irradiator chamber canister exhibit 2 exhibit 3 exhibit 4 3500 g 2 mm S. E. e. 3300 3100 8 mn 2900 cgy 2700 53 m 2500 dose, 2300 o... 2100 1900 1700 1,500 25 50 100 125 150 75 distance from top (mm)

center

left side

film to be analyzed

right side



JM AXIAL DOSE

2018 cGv

MINIMUM AXIAL DOSE:

3284 cG

2010 cGv

exhibit 1

regional centers

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