

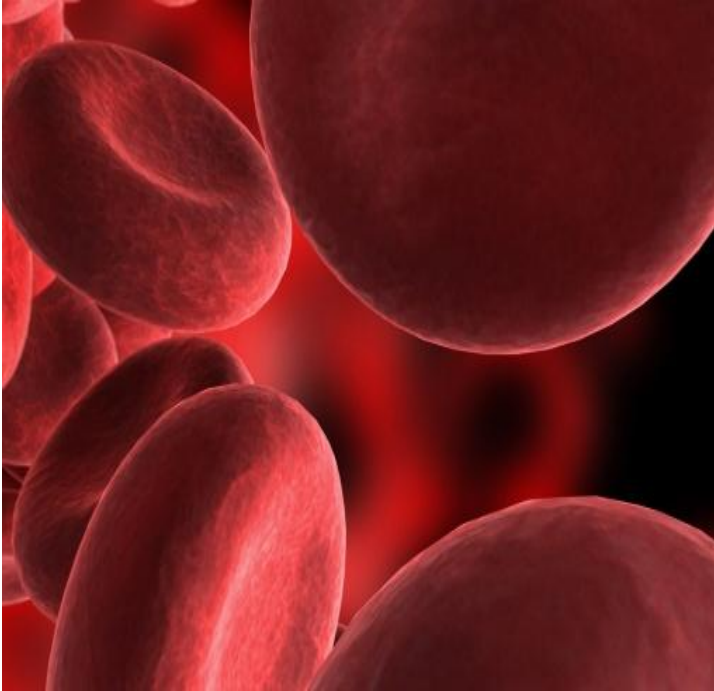


Quality Answers: How Do I Manage a Product If the Blood Center Calls?

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American Red Cross

Objectives



- Definition of SQulPP
- Characteristics of a product that meets SQulPP
- Examples of what could cause the blood center to call about a product.
- What to do once the blood center calls regarding a product.



What is SQuIPP?

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What is SQulPP?

SAFETY

QuALITY

IDENTITY

POTENCY

PURITY



Definition of SQuIPP

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SQUIPP defined...

Safety

refers to the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

SQulPP defined...

Quality

means the conformance of a product or process with pre-established specifications or standards.

SQulPP defined...

Identity

means that the blood bag contains the properties and solutions described on the container label, including pertinent information in the Circular of Information.

SQulPP defined...

Potency

refers to the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to affect a given result.

SQulPP defined...

Purity

refers to the relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. Purity includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.



**Why would a blood center
call about a product &
what to do with it...**

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Donor call back - travel

Scenario 1

A donor calls the blood center because he just remembered that he took a trip to Mexico 9 months ago and he forgot to tell the blood center staff when donated last week.

Why is the blood center calling?

Since the donor traveled to an area in Mexico where there's a risk of malarial infection there's a potential the donor could be infected.

What should the hospital do?

DISCARD

Equipment Malfunction

Scenario 2

A WBC count on an Amicus leukoreduced apheresis platelet selected for routine finished product QC is greater than 5.0×10^6 and the product is not considered leukoreduced.

Why is the blood center calling?

There's a potential that prior products are not leukoreduced. The blood center must investigate to determine if prior products collected on the same Amicus apheresis machine are also affected.

What should the hospital do?

QUARANTINE

Bacterial Detection

Scenario 3

A bacterial detection culture bottle turned positive after 3 days of incubation. The apheresis platelets associated with the bottle are located at the hospital.

Why is the blood center calling?

There's a potential that all products collected from the apheresis donation are contaminated with bacteria. The blood center must perform additional testing on the products.

What should the hospital do?

RETURN

Sterility

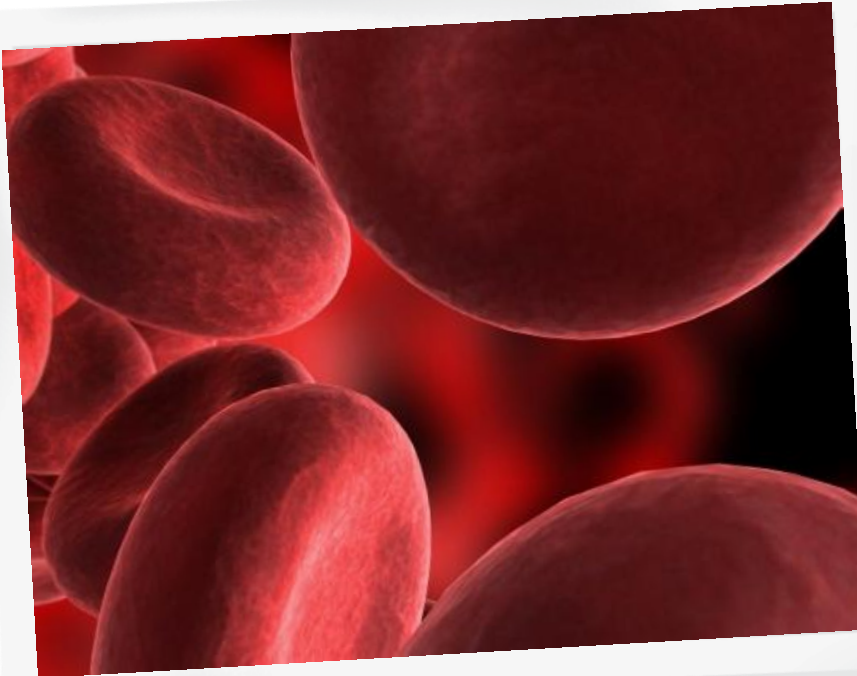
Scenario 4

While filing paperwork a blood center staff member noticed that a weld inspection was not documented to indicate the weld created to add a leukoreduction filter to a RBC product was acceptable.

Why is the blood center calling?

There's a potential that the weld was not inspected after adding the filter. If the weld was not inspected there's a potential that the weld failed and air was allowed into the bag and contaminate the RBC product.

What should the hospital do? DISCARD



Questions
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