

Blood Storage Temperature Excursion Investigation Kit

Write down what happened, what you checked and what you did.

Fill in this PDF or print it. During a real event, follow your approved procedure first. Use record IDs, not patient or donor names. Only authorized staff may decide whether to move, release or discard products.

FDA Source Plasma inspection guide (1997/2001): storage events and corrective action

01 Record the event

Event / investigation reference

Site / storage unit / probe IDs

Investigation owner / responsible role

Written procedure (SOP) / version

Actual event or drill

Measurement units

Time zone / clock reference

02 Write down the times [1]

MILESTONE

DATE / TIME / ZONE

SOURCE / RECORD REFERENCE

Last known acceptable

First out of range

First notification

Action started

Returned to range

Recovery verified

Duration outside approved limits / units

How you worked out the time / any missing data

Write how long readings were outside the limits. If you do not know, mark it as an estimate or unknown and explain why.

Event summary / evidence packet reference

Check what happened

Use record IDs to link your notes to the original evidence.

Event reference - continue the same investigation

03 Check the readings and affected stock [1]

Approved limit / units / source document and version

Lowest / highest reading / units

Time between readings / record ID

Possibly affected stock / record ID for approved product review

A probe reading alone does not show the condition of the blood product. Add the record ID for the product review by authorized staff.

[1] 21 CFR 606.160: storage and equipment records

04 Record alarms and staff responses

TIME / ZONE

ALERT METHOD

SENT TO / ROLE

RECEIVED / ACTION / RECORD

Include failed alerts, who received each alert and who acted. A sent message does not prove someone read it.

05 Record actions allowed by your procedure [2]

What was done / time / approved by / record ID

06 Explain the cause and what is still unknown [2]

Known facts / possible cause / missing evidence / person following up

Correct, verify and close

[2] 21 CFR 606.100(c): investigate unexplained problems and record follow-up

Event reference - continue the same investigation

07 Plan fixes and prevent another event [2]

Action 1 - specific correction or prevention / linked finding

Owner / responsible role

Due date

Status / evidence reference

Action 2 - specific correction or prevention / linked finding

Owner / responsible role

Due date

Status / evidence reference

Action 3 - specific correction or prevention / linked finding

Owner / responsible role

Due date

Status / evidence reference

08 Check that the fixes worked

Expected result / check performed / actual result

Evidence reference / verification owner / date

09 Record who approved closure and any open tasks

Authorized reviewer / role

Review date

Closure / unfinished-task record

Could your current monitoring system populate this investigation automatically?

Check which readings and alarm records your system can export. Your team must still review the facts and approve decisions.

[Assess Your Monitoring Risk →](#)