

Memorandum

To: All clinical sites on active CARTITUDE studies

Date: 11 Jan 2023

Re: Addition of QR code on the EVO-DV10 shipper

Module 6, "Receipt and Storage of the Investigational Product" of Cell Therapy Product Procedures Manual (CTPPM) version 3.1 dated 28-Mar-2022 will be updated **to include a QR code on the lid** of the **EVO-DV10** LN₂ shipper containing the IP.

Upon receipt of the IP, to determine if the temperature is within range, the light indicator (Temperature Indicator Button – TIB) on the EVO-DV10 lid should be pressed. After 5 seconds from releasing the button, the indicator will emit a light. A steady light indicates that the temperature is within range. QR code on the shipper lid was added to allow visibility to actual temperature on arrival by scanning the QR code with a mobile device. This QR code is only available as a BACK UP solution in case the TIB fails.

Reason for implementation:

- There have been some instances reported where the TIB did not work. Therefore, a back-up process will be implemented.
- A QR code is displayed on the lid of each EVO-DV10 shipper to support visibility to the payload temperature. This feature allows users to view the last reported payload temperature using any smart device or QR scanner. The QR code only provides the last reported temperature; it does not provide information on an excursion that may have occurred historically.


How does it work?

- The QR code can be scanned by a smart device. It will guide the user to a web page that only displays the last reported payload temperature.
- Scanning the QR code automatically opens a link showing the last reported payload temperature of the shipper and a green checkmark ✓ or a red "x" ✗ will be displayed respectively indicating whether the temperature is in or out of range.
- The timestamp displays the last reported payload temperature and the time that elapsed since the last reported temperature.
- **Note:** The QR code label and the QR code display are correlated with the integrated data logger ID (86277XXXXXXXXX). Verify that the ID on the web page display exactly matches the QR code label ID and the Smart Cap label ID. If there is any ID mismatch, concerns regarding the QR code, and/or an out-of-range temperature, please contact central scheduling via email:
CENTRAL.SCHEDULING@its.jnj.com



Verify ID number matches the displayed ID number.

Biolife Solutions



ID: 862771041117220


-191.9° C

Last Reported: 15 Minutes Ago
Date / Time: 2022-10-19 21:41 GMT

Verify ID 862771041117220 exactly matches SmartCap label ID

[LOGIN](#)

Biolife Solutions



ID: 862771041117659

27.4° C

Last Reported: 19 Minutes Ago
Date / Time: 2022-09-19 13:45 GMT

Verify ID 862771041117659 exactly matches SmartCap label ID

[LOGIN](#)

Note: The shipper must be connected to the network to provide current data; if the device is not reporting current data, move the shipper to an area of known good network connectivity. Please note the temperature should be $\leq -120\text{C}$ or colder.

This change will become effective by February 2023. Please file a copy of this memo with CTPPM version 3.1 dated 28-Mar-2022.

Sincerely,

Janssen Clinical R&D and Supply Chain