

## ViviGen® Temperature FAQ

### What if a temperature excursion outside of the recommended storage conditions occurs? Is the graft still considered viable?

- ViviGen contains viable bone cells. It is important that the cells are kept alive prior to implantation. Temperature fluctuations during storage can impact cell health.
- In regards to cell viability, the following conditions should be considered if a temperature excursion is experienced. If the temperature excursions the grafts have experienced stayed within the limits identified below (temperature, time, and number of events); the grafts in question will be deemed acceptable per release quality criteria regarding cell viability:
  1. ViviGen grafts are stored at  $-70^{\circ}\text{C}$  or colder until ready to use (see recommended storage condition)
  2. At any point, ViviGen grafts must not experience a temperature higher than  $-50^{\circ}\text{C}$  for any amount of time. If the grafts experience temperatures higher than  $-50^{\circ}\text{C}$ , the cell viability cannot be assured as per the original release criteria.
  3. In case of an excursion beyond the requirement stated in bullet 1, ViviGen grafts must not experience temperatures between  $-70^{\circ}\text{C}$  and  $-50^{\circ}\text{C}$  for longer than 48 hours per occurrence for a total of three different occurrences. This means that:
    - a. If grafts experience excursions above  $-70^{\circ}\text{C}$  but below  $-50^{\circ}\text{C}$  for longer than 48 hours, the cell viability cannot be assured as per the original release criteria; and/or
    - b. If grafts experience more than 3 events of excursions above  $-70^{\circ}\text{C}$  but below  $-50^{\circ}\text{C}$ , the cell viability cannot be assured as per the original release criteria.

### What if a temperature excursion outside of the recommended storage conditions occurs? Is the graft still considered safe?

- Yes, the ViviGen graft is still considered safe. The temperature excursions expressed above would not impact the safety of the product through the expiration date.