Alberta Vaccine Storage and Handling for COVID-19 Vaccine

Revised: December 27, 2020

This policy is evergreen and will be updated as new information becomes available.

Objectives:

- Protect vaccine safety and efficacy;
- Ensure a potent and safe vaccine is administered; and
- Minimize and reduce the cost of vaccine wastage due to cold chain excursions.

See the Alberta Vaccine Storage and Handling for Provincially Funded Vaccines for:

- accountabilities, roles and responsibilities for staff and immunizers in maintaining vaccine viability for provincially funded vaccines; and
- cold chain (storage, transport, and handling) requirements for staff and immunizers in order to maintain the safety and efficacy of provincially funded vaccine.

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VACCINE STORAGE REQUIREMENTS

Vaccines that require storage at -70°C

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Vaccines should remain in the freezer until ready to immunize.
Vaccine can be stored at 80°C to -60°C for 6 months in a laboratory grade ultra low temperature freezer
NOTES:

- **Vaccine must to be thawed prior to adding the diluent for reconstitution**
- **It takes 30 minutes to thaw the vaccine at room temperature from frozen state**
- **The vaccine can be thawed in a vaccine fridge +2 to +8°C from frozen state**
- **Once thawed - Do not refreeze**

See www.CVDvaccine.ca for additional information.

Laboratory Grade Ultra Low Temperature Freezers	• Must continuously keep temperature at -70°C within +/- 10°C from the set point. • Must have an alarm setting that provides audible sound in the event that the temperature of the unit deviates beyond the alarm set points or if the door is ajar. • Must have adjustable alarm set points/range. • Adjustable temperature set points or temperature controls. • Should have a digital temperature display on front that displays current temperature to 1°C degree resolution. • Adjustable shelves with minimum 100 pounds capacity per shelf. • Minimum interior measurements: 23 cubic feet. • Type B plug (120 volts) or equivalent. • Capped access portholes. • Locking castor on bottom of unit.
Manufacturer provided thermal shippers	The vaccine is stable in the manufacturer's provided thermal shipper for up to 30 days with appropriate handling and re-icing. See below for more information.
Safe storage and handling of dry ice	• Do not store in an airtight container, as it may explode. The dry ice rapidly expands to a gas when exposed to temperatures above -78°C. • Work in a well-ventilated space, as asphyxiation is a main hazard of dry ice. • Wear insulated (cryogenic) gloves: Wear heavy rubber gloves that insulate against the cold where contact with dry ice may occur. This prevents cold burns and frostbite. • Wear safety glasses with side shields, safety goggles or a face shield • Use dry ice tongs or a dry shovel or scoop. Avoid materials incompatible with cryogenic use; some metals such as carbon steel may fracture easily at low temperature. • See the product's Material Safety Data Sheet (MSDS) for more information. • Pfizer's dry ice MSDS can be found here.
Unpacking vaccine from thermal shipper	• Do not discard the original thermal shipper or any of its components. • There are two types of thermal shippers: a **Softbox** thermal shipper and an **AeroSafe** thermal shipper. Their outer appearance is different, but their components are very similar. • The thermal shippers can weigh up to 36.5 kg (81 lbs) and should be opened on the floor.

Unpacking vaccine from thermal shipper (cont.)	**Steps for unpacking the thermal shipper** 1. Refer to the dry ice safety data sheet before accessing the contents of the thermal shipper. 2. Break the seal open. 3. When you open the container you will see a temperature monitoring device embedded in the foam lid. ○ **Softbox**: The lid is permanently attached to one flap of the container. Do not pull this flap. When opening the lid, use the three-finger holes in the foam lid, which will allow the lid to swing open. ○ **Aerobox**: Gently remove the entire lid, with the temperature-monitoring device, from the inner lid. 4. Press and hold the stop button of the temperature-monitoring device for **5 seconds.** Information about temperature monitoring, including devices, can be found at www.CVDvaccine.ca. 5. Don the appropriate personal protective equipment as outlined in the section above. 6. Remove the dry ice pod. 7. You will now see the box that holds the vial trays. Open the box and you will see the vial trays. Remove the box that holds the vial trays from the container. **Do not open the vial trays or remove the vials until you are ready for thawing.** 8. Immediately store the vaccine in the ultra-low-temperature freezer. Keep tray at room temperature for less than 5 minutes. 9. Dispose of dry ice (see section below). 10. Return the thermal shipper and temperature-monitoring device to the manufacturer.
Returning the thermal shipper	• When the thermal shipper is ready to be returned and all the components are inside, seal it with tape. • A preprinted return shipping label will be included inside the thermal shipper or already affixed to the inner flap of the thermal shipper. ○ **Softbox** - apply the preprinted return shipping label over the existing shipping label. ○ **AeroSafe** - follow instructions on the inner flap of the thermal shipper to ensure the return label is facing outside. • Elements required for return (**Softbox** and **AeroSafe**) ○ Temperature-monitoring device ○ Foam lid (remains attached to box) ○ Dry ice pod ○ Box that holds the vial trays Note: Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipper are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice. • Discard empty vial trays as medical waste so they cannot be reused.
Disposal of dry ice	• Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily turn from a solid to a gas. • DO NOT leave dry ice in an unsecured area. • DO NOT drain or flush in toilet. • DO NOT dispose in the trash. DO NOT place in a closed area, such as an airtight container or walk-in cooler.dry ice is no longer needed.

Vaccines that require storage at -20°C

Vaccines that require storage at -20°C Vaccines should remain in the freezer until ready to immunize. Store at -25°C to -15°C Vaccine can be thawed in two ways: • From the freezer to room temperature (+15°C to +25°C), thaw for 2 hours and 30 minutes from frozen state. • From the freezer to a vaccine fridge (+2°C to +8°C); thaw for 1 hour from frozen state. Let vial stand at room temperature for 15 minutes before administering.	
Laboratory Grade Freezers	• Must continuously keep temperature at -20°C within +/- 5°C from the set point. • Must have an alarm setting that provides audible sound in the event that the temperature of the unit deviates beyond the alarm set points or if the door is ajar. • Must have adjustable alarm set points/range. • Should have adjustable temperature set points/temperature controls. • Digital temperature display on front that displays current temperature to 1°C degrees resolution. • Adjustable shelves with minimum 100 pounds capacity per shelf. • Minimum interior measurements: 23 cubic feet. • Type B plug (120 volts) or equivalent. • Capped access portholes. • Locking castor on bottom of unit

Vaccines that require storage between +2°C and +8°C

Vaccines that require storage between +2°C and +8°C Must remain in the refrigerator, except when being administered	
Laboratory Grade Refrigerators	• A digital feedback system that ensures narrow tolerances with internal temperatures. • Ongoing air circulation that ensures that the temperature distribution is even. • System for vaccine storage. • A set-point temperature is kept within the range specified in the product monograph. • Temperature recovery system is appropriate. • Built to handle ambient temperature changes.
Vaccine Bags/Qualified Insulated Container	• Must be inspected for integrity prior to each use and an appropriate temperature monitoring device must be used to transport vaccine. If the vaccine bag is showing signs of wear due to material break down or damage, it must not be used. • Must be tested for their ability to maintain a stable temperature between +2°C and +8°C or at temperature specified in product monograph. • Vaccine bags must be replaced periodically (e.g. every 2 years), due to material break down and decreased effectiveness of ability to maintain temperature.

TEMPERATURE MONITORING

The minimum, maximum, and current temperature of all refrigerators/freezers where vaccine is stored must be monitored and recorded.	
Temperature Monitoring Devices	The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are: • Minimum and Maximum Thermometer. • Data Logger - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Alarmed Temperature Monitoring System - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Chart **Recorder in combination with a min/max thermometer** Note: Chart recorders can be hard to interpret, inaccurate, and difficult to ascertain minimum and maximum temperatures. In addition, if chart recorders are on the same power supply as the fridge (and do not have back-up power) and the power goes out – there is not enough data to make a decision on vaccine viability. **Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are NOT acceptable**.
Continuous Temperature Recording Devices	These include: • Chart Recorders (in combination with a min/max thermometer); OR • Data Loggers (downloaded twice a day); OR • Alarmed Temperature Monitoring System (downloaded twice a day)
Temperature Recording	At minimum, the temperature must be recorded and reviewed at the beginning and end of each business day (separated by at least 8 hours) for each refrigerator/freezer storing vaccine.

VACCINE TRANSPORT

Cold Chain must be maintained during transport to another location.	
Packing Vaccines	Vaccines must be packed for transport taking into account: • Type of transport; • Amount of vaccine to be transported; • External air temperature; and • Length of time the vaccine will be in a Qualified Insulated Container/Package. • Packing configurations will vary on a seasonal basis.
Container	‘Ultra frozen’ Vaccine • Manufacturer provided thermal shippers ‘Frozen’ Vaccines • Manufacturer provided container ‘2-8°C Vaccines’ • Qualified Insulated Container or Vaccine Bag
Temperature Monitoring	An appropriate temperature monitoring device must be used to transport vaccine unless utilizing a pre-qualified container with phase-changing technology.
Receiving Vaccine	• When a vaccine shipment is received, it must be examined and stored as specified in the product monograph. • Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.

COLD CHAIN EXCURSIONS

Ultra Frozen Vaccine

Cold Chain must be maintained during transport to another location.

Each cold chain excursion will need to be assessed to determine if it is a cold chain break and vaccine needs to be quarantined.

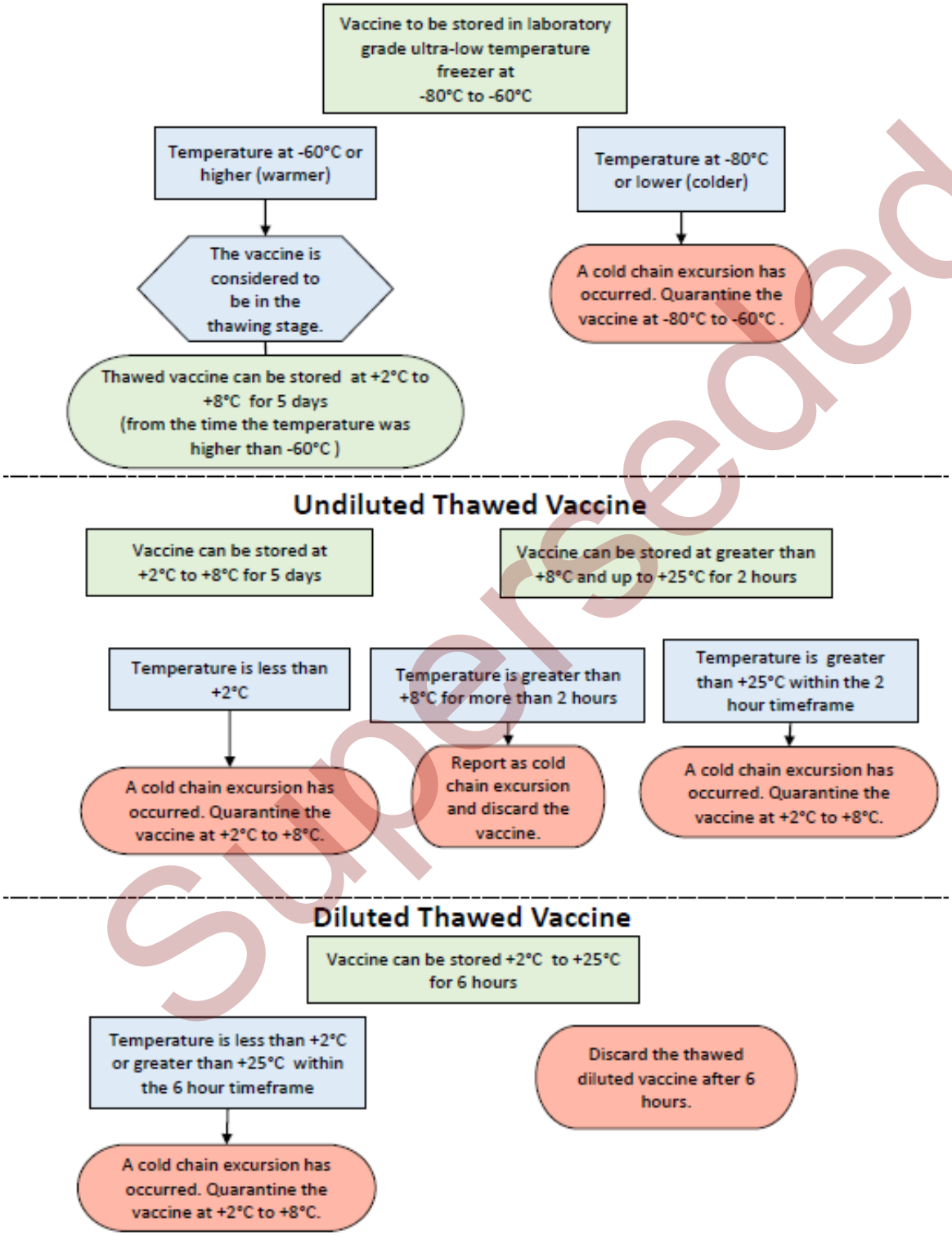
Ultra Frozen Vaccine	**Ultra Frozen state**
	• Vaccine is to be stored -80°C to -60°C in a laboratory grade ultra low temperature freezer while in a frozen state.
	• If the temperature is higher than -60°C, the vaccine is considered to be in the thawing stage and needs to be stored in a vaccine fridge at +2°C to +8°C. Do not refreeze.
	• If the temperature is lower than -80°C, quarantine vaccine and mark as "DO NOT USE", and store in ultra low freezer at -80°C to -60°C until viability has been assessed.
	Undiluted thawed vaccine can be stored at:
	• +2°C to +8°C for 5 days
	  ○ If the temperature is lower than +2°C, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Greater than +8°C up to +25°C for 2 hours
	  ○ If the temperature is greater than +8°C for more than 2 hours, report as cold chain excursion and discard the vaccine.
	  ○ If the temperature is over +25°C (room temperature) within the 2 hour timeframe, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	Diluted thawed vaccine can be stored at +2°C to +25°C for 6 hours
	• If the temperature is less than +2°C or more than +25°C within the 6 hour timeframe, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Diluted thawed vaccine is to be discarded after 6 hours.
	
	See Pfizer BioNTech COVID-19 vaccine Cold Chain Excursion Tool.

Frozen Vaccine

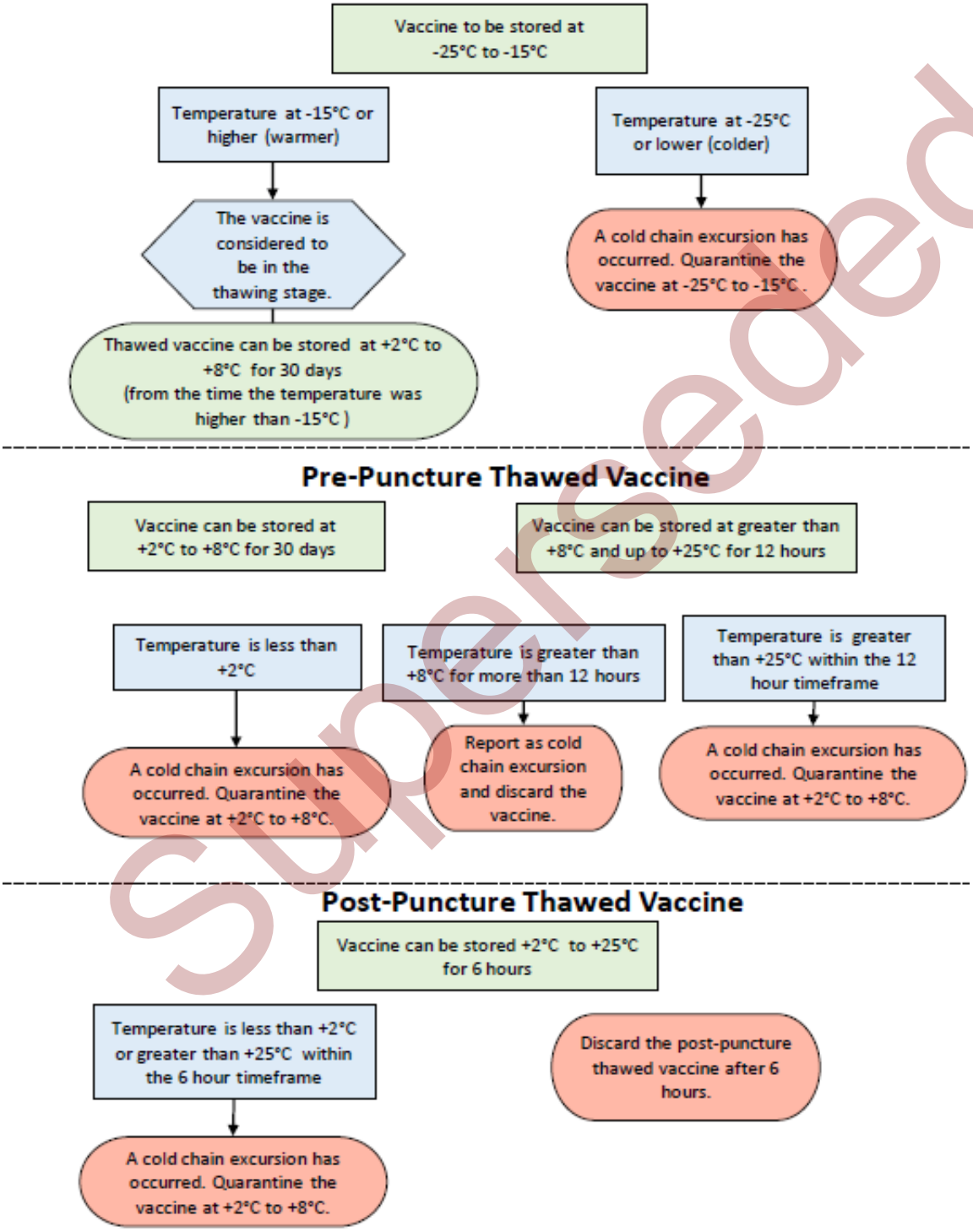
Frozen Vaccine	**Frozen state**
	• Vaccine is to be stored -25°C to -15°C while in a frozen state.
	• If the temperature is higher than -15°C, the vaccine is considered to be in the thawing stage and needs to be stored in a vaccine fridge at +2°C to +8°C. Do not refreeze.
	• If the temperature is lower than -25°C, quarantine vaccine and mark as "DO NOT USE", and store in freezer at -25°C to -15°C until viability has been assessed.
	Pre-puncture thawed vaccine can be stored at:
	• +2°C to +8°C for 30 days
	  ○ If the temperature is lower than +2°C, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• +8°C to +25°C for 12 hours
	  ○ If the temperature is greater than +8°C for more than 12 hours, report as cold chain excursion and discard the vaccine.
	  ○ If the temperature is over +25°C (room temperature) within the 12 hour timeframe, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	Post-puncture thawed vaccine can be stored at +2°C to +25°C for 6 hours
	• If the temperature is less than +2°C or more than +25°C within the 6 hour timeframe, quarantine vaccine and mark as "DO NOT USE", and store in a vaccine fridge at +2°C to +8°C until viability has been assessed.
	• Post-punctured thawed vaccine is to be discarded after 6 hours.
	
	See Moderna COVID-19 vaccine Cold Chain Excursion Tool.

Quarantine Vaccine	Affected vaccines must be isolated and marked as "DO NOT USE" until viability has been assessed.

Pfizer-BioNTech COVID-19 Vaccine Cold Chain Excursion Tool



Moderna COVID-19 Vaccine Cold Chain Excursion Tool



Questions:

Pfizer COVID-19 Vaccine Storage and Handling

1. Question: Undiluted thawed vaccine has been at room temperature for 1 hour and 45 minutes. Can it be placed back in the fridge and stored at 2°C to 8°C up to 5 days?
   OR once committed to room temperature does it need to be diluted within that 2 hours and administered within 6 hours?
   Answer: It can be put back in the fridge and stored at 2°C to 8°C up to 5 days but it will be important to keep track of **total cumulative time at 2°C to 8°C and at room temperature**.
   This is important to apply as when the vial is removed for use, it will only have 15 minutes remaining at room termperature prior to being diluted for use.