

HOW TO PROPERLY USE TCP PRODUCTS

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HOW TO PROPERLY USE TCP PRODUCTS

TCP insulated Totes combined with our various Phase Change Materials (PCMs) can transport specimens refrigerated, frozen or ultra-cold. The PCMs are able to store large amounts of energy maintaining precise temperatures. Currently TCP is providing refrigerated PC0 engineered to maintain 0° Celsius, PC-7, PC-16 engineered to maintain -7° and -16° Celsius respectively, and ultra-cold PC-21 engineered to maintain -21° Celsius.

Prior to use, the PC0 , PC-7 PC-16 and PC-21 must first be frozen solid. PC0 and PC-7 freeze easily in a typical household freezer (around -19 Celsius). We recommend freezing the PCM for 24 hours before use (See Freezing Times for TCP PCMs Chart below). The units should be rock hard and turn from clear liquid inside to a cloudy color. PC-16 is more difficult to freeze and requires that the freezer be colder than -16 Celsius. Some household freezers may only reach -15° Celsius and therefore the PC -16° will not freeze. The freezer must be at least -19° Celsius, otherwise the PCM may take several days to freeze. In household freezers that reach a measured temperature of -20° Celsius, the PC-16 will freeze in 24 hours. The PC-16 must become cloudy in color and rock hard, otherwise it will not perform correctly. Please see photographs below showing frozen and non frozen PCMs. PC-21 requires an ultra-cold freezer to prepare. In a -45° Celsius freezer, it is rock hard in 34 hours or less. Of note, PCMs stacked together will take longer to freeze.

| Non-Frozen | Frozen | Non-Frozen | Frozen | Non-Frozen | Frozen |
|------------|--------|------------|--------|------------|--------|

FREEZING TIMES FOR TCP PCMs

| FREEZING | IES FOR IC | r r civis | Ϋ́. | | | | |
|----------------------------|--------------------------------------|----------------------|------------------|----------------------|----------------------------|----------------------------|----------------------------|
| | | 3 Hours | 6 Hours | 7 Hours | 22 Hours | 24 Hours | 34 Hours |
| Ultra Cold Temp -40.5 (| PC0 2 LB 5 LB | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen |
| | PC-7 2 LB 5 LB | Frozen 90% Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen |
| | PC-16 2 LB 5 LB | No No | No No | No 1/4 Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen |
| | PC-21 2 LB 3 LB 5 LB | No No No | No No No | No No No | Frozen Frozen Frozen | Frozen Frozen Frozen | Frozen Frozen Frozen |
| Upright Temp -20 C | PC0 2 LB 5 LB | Frozen No | Frozen No | Frozen Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen |
| | PC-7 2 LB 5 LB | No No | Frozen No | Frozen 90% Frozen | Frozen Frozen | Frozen Frozen | Frozen Frozen |
| | PC-16 2 LB 5 LB | No No | No No | No No | Frozen No | Frozen 90% Frozen | Frozen Frozen |
| | | | | | | | |



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MAINTAINING FROZEN SPECIMENS

Plasma and most blood products are approximately 92 percent water with some salts and proteins. These products remain frozen just under 0° Celsius. TCP recommends using PC-7 if the facility has older household freezers or under counter laboratory freezers, so that the PCM will freeze easily. Of course, any of our frozen PCMs will maintain blood specimens frozen. In the US, regulations require maintaining allografts at -21° Celsius if they are not used and if the desire is to return them to long term storage. Therefore, the PC-21 is the perfect fit for allograft transport. One of our largest US health care systems also uses PC-21 to transport allergy specimens. PC-21 has less energy than PC-16 and PG-7, and will maintain targeted temperatures for a shorter duration (PC-21 has 222 kJ/kg latent heat of fusion, PC-7 has 290 kJ/kg, and PC-16° has 289 kJ/kg).

MAINTAINING REFRIGERATED SPECIMENS

In the United States, blood and blood products must be maintained at 1° to 6° Celsius for storage, and 1° to 10° Celsius for transport. TCP recommends using PCO with the custom insulator between the blood units and the PCM to maintain the blood at it's desired temperature. More importantly, our PCMs, Totes and insulators prevent blood from falling below 1° Celsius, which is out of specification.

PREVENTING SPECIMENS FROM BECOMING FROZEN

In colder environmental temperatures, it is sometimes difficult to prevent specimens from freezing. Canada requested that TCP address this issue. Testing was done in Totes with thicker insulation which did maintain the specimen from freezing longer, but only by approximately 20 percent. TCP is currently testing PC29 specifically for this purpose. Our goal is to maintain specimens above freezing for significantly longer. This product has been used in the Arctic Circle to prevent products from freezing for the US military. PC29 is prepared at 45° Celsius until it melts, then placed in the Totes. Initial testing showed that PC 29 when placed with the specimen in one of TCP's Small Totes maintained the specimen between 20° to 24° Celsius in a frozen environment fluctuating between-14.6° and -18.8°Celsius. For this test, 3 pounds of PC29 were placed above the specimen and 3 pounds of PC29 below the specimen. In the chart below, the red line represents the specimen temperature and the black line is the environmental temperature. PC29 is a new product and in limited supply.

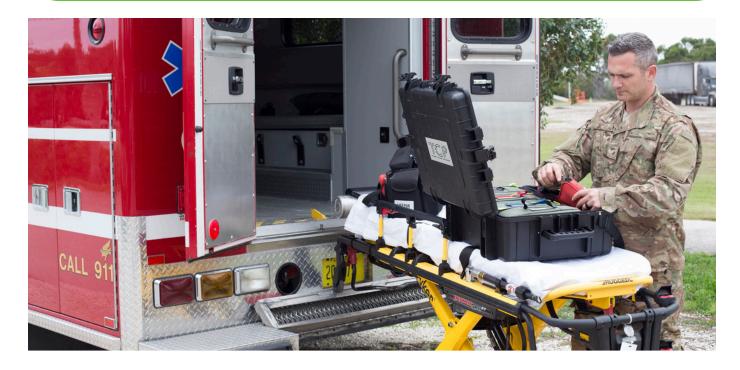




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PC29 Test 5 6# Freezer Test

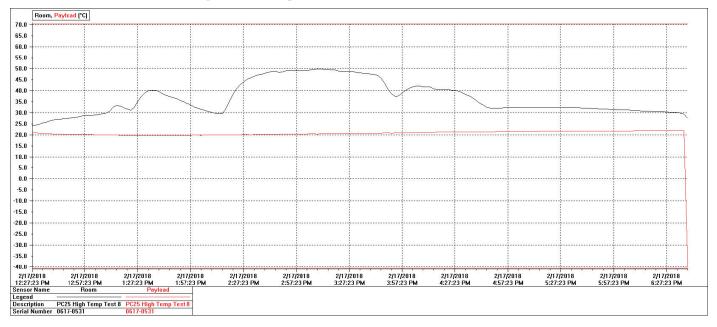
| \square | | | | | | | | | | | | | | | | | | | | |
|---------------------|----------------|---------------------|----------------|--------------------|-------------------|-----------|-------|--------|-------|---------------|--------|----------|--------|--------|--------|--------|--------|-------|-----------------|------|
| | | Payload (' | C] | | | | | | | | | | | | | | | | | |
| 70.0 - | | | | | | | | | | | | | | | | | | | | |
| 65.0 | | | | | | | | | | | | | | | | | | | | |
| 60.0 - | | | | | | | | | | | | | | | | | | | | |
| 55.0 - | | | | | | | | | | | | | | | | | | | | |
| 50.0 - | | | | | | | | | | | | | | | | | | | | |
| 45.0 - | | | | | | | | | | | | | | | | | | | | |
| 40.0 - | | | | | | | | | | | | | | | | | | | | |
| 35.0 - | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |
| 30.0 - | | | | | | | | | | | | | | | | | | | | |
| 25.0 | - | | | | | | | | | | | | | | | | | | | |
| 20.0 - | ·} | | | | | | | | | | | | | | | ····· | | | | |
| 15.0 - | 1 | | | | | | | | | | | | | | | | | | | |
| 10.0 - | | ····· | | | | | | | | | | | | | | | | | | |
| 5.0 - | | | | | | | | | | | | | | | | | | | | |
| 0.0 - | | | | | | | | | | | | | | | | | | | | |
| -5.0 - | | | | | | | | | | | | | | | | | | | | |
| -10.0 - | | <u>}</u> | | | | | | | | | | | | | | | | | | |
| -15.0 - | | 1 | | \sum | | ~ | | \sum | | \wedge | ~ | \wedge | | \sim | | \sim | | | / | ~ |
| -20.0 - | | | | | ····· | | | · | ~ | ····· | \sim | ····· | \sim | | \sim | | \sim | | \leq | |
| -25.0 - | | | | | | | | | | | | | | | | | | | | |
| -30.0 - | | | | | | | | | | | | | | | | | | | | |
| -35.0 - | | | | | | | | | | | | | | | | | | | | |
| -40.0 - | | l | | | | | | | | | | | | | | | | | | |
| 2/14/ | 2018 | 2/14/2 | 018 2/1 | 4/2018 | 2/14/ | 2018 | 2/14/ | 2018 | 2/14 | 2018 59 PM | 2/14/ | 2018 | 2/15/ | 2018 | 2/15/ | 2018 | 2/15 | 2018 | 2/15/ 7:21:0 | 2018 |
| 11:21: Sensor | by AM Name | 1:21:59 | PM 3:2 Room | 1:59 PM | 5:21:5 Payload | 9 PM | 7:21: | 59 PM | 9:21: | 9 PM | 11:21: | 59 PM | 1:21:5 | 9 AM | 3:21:5 | 9 AM | 5:21: | 59 AM | 7:21:5 | MA B |
| Legend | | - | | | | | | | | | | | | | | | | | | |
| Descrip Serial N | tion Jumber | PC29 6# 0617-053 | Freezer Test | 4 PC29 6 0617-0 | | r l'est 4 | | | | | | | | | | | | | | |
| Senar | amper | 0017-033 | | 0017-03 | 331 | | | | | | | | | | | | | | | |





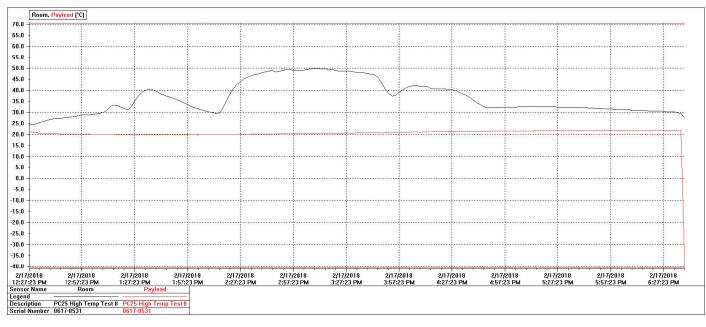
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4985 East 10th Avenue Hialeah Florida 33013 We have started work on another new product, PC25. PC25 maintains 20° to 24° Celsius in a hot environment. The PC25 6- pound High Temperature Test 8 and Test 9 below show that the specimens remained between 20° to 24° Celsius when the Small Tote with the PC25 was placed in an environment that reached 49.8° C, and averaged 36.8° C for over 6 hours. In Test 8, the environment increased to 46.8°, and averaged 37.4° Celsius. The tests were conducted with one 3 pound PC 25° above and one PC25 below the specimen. Both PC29 and PC25 are currently in development, and will be manufactured if there is sufficient demand.



PC25 6 Pound High Temperature Test 8

PC25 6 Pound High Temperture Test 9



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Small and Medium Totes use one 3 pound PCM placed on top of the specimens. The numbered photos below show exactly how to setup both the Small Totes and the Medium Totes







Small Tote empty

Small Tote with specimens placed in well



Small Tote with PCM placed over the specimens



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MEDIUM TOTE



Medium Tote empty



Medium Tote with specimens placed in well



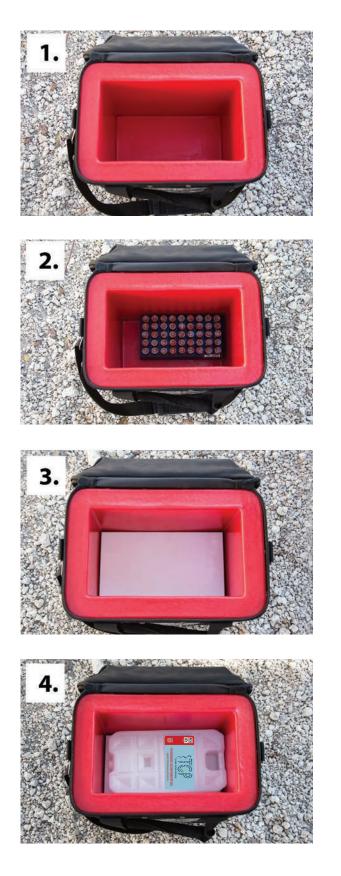
Medium Tote with PCM placed over the specimens

Small and Medium Tote Whole Blood Transportation

When transporting whole blood that must be maintained between 1° to 10° Celsius with the Small and Medium Totes, TCP recommends placing our custom insulators above the specimens, then the PCM so the PCO and the blood do not touch. This will prevent the blood from becoming colder than 1° Celsius (see photographs and descriptions below).



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Empty Small Tote

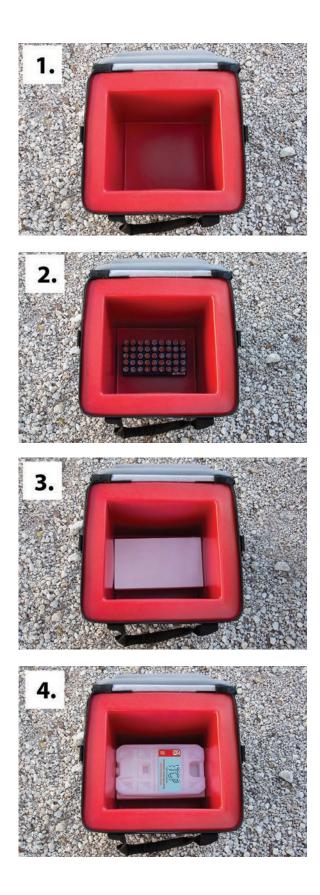
Small Tote with red top whole blood specimens

Small Tote with custom
insulator over red top whole
blood specimens

PC0 on TOP of custom insulator



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Empty Medium Tote

Medium Tote with red top whole blood specimens

Medium Tote with custom
insulator over red top whole
blood specimens

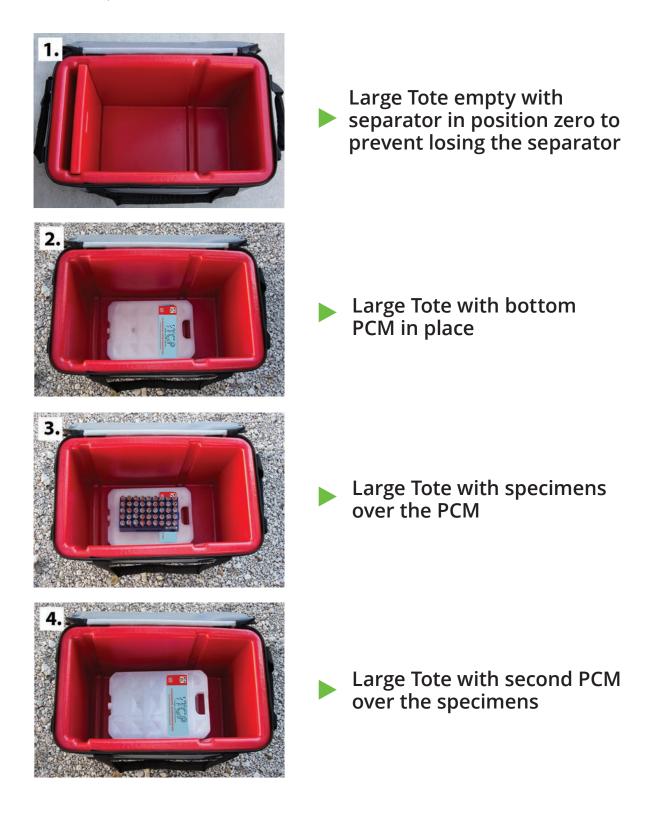
Medium Tote with PC0 on TOP of custom insulator



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USING THE LARGE TOTE

The Large Tote requires two PCMs, one above and one below the laboratory specimens, with the exception of whole blood specimens which demand maintenance between 1° and 10° Celsius.



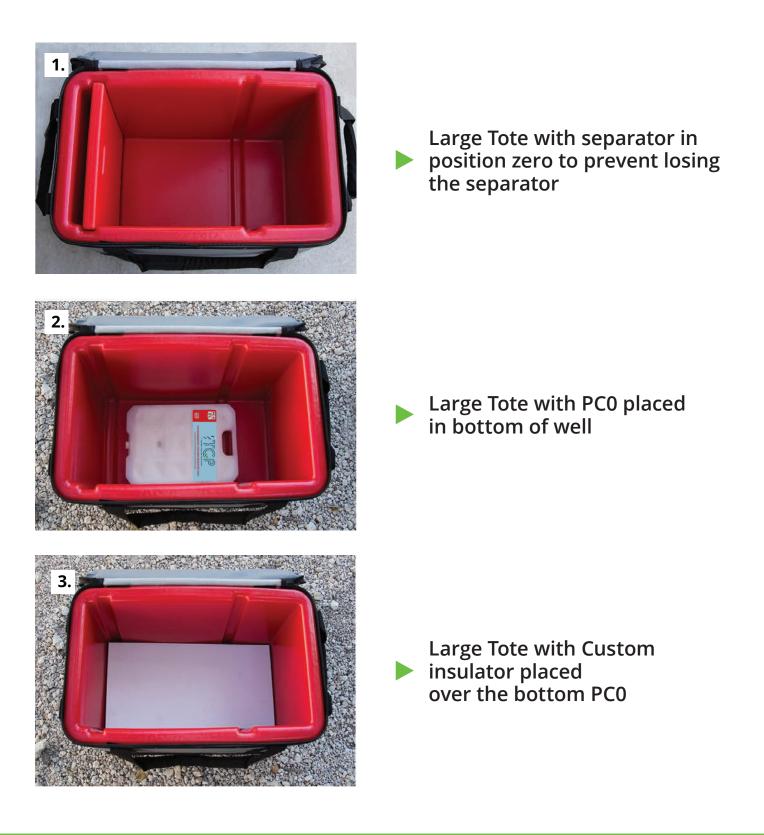


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Large Tote Whole Blood Transportation

When transporting whole blood in the Large Tote that must be maintained between 1° to 10° Celsius, TCP recommends using two custom insulators, one over the bottom PC0 and one under the top PC0 so the PC0 and the blood do not touch. This will prevent the blood from becoming colder than 1° Celsius (see photographs and descriptions below).





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 Large Tote with whole
blood specimens placed on top of custom insulator



 Large Tote with custom
insulator placed over the whole blood specimens



Large Tote with top PC0
placed over the custom insulator

TOP

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In most circumstances, using the 2.5 pound PCMs above and below the specimens is more than sufficient, and will keep the Tote lighter. For extended use, we recommend using the 4 pound PCMs above and below the specimens in the Totes.

How to choose the proper temperature PCM

In the Tote, use PC0 for refrigerated specimens, and PC-7, PC-16 or PC-21 depending on the frozen temperature desired.

For frozen specimens in any of our Totes, custom insulators are not necessary.

DISCLAIMER

All Thermal Custom Packaging (TCP) products are guaranteed for one year from the date of purchase against any manufacturing defects in material and workmanship. Extreme Duty Blood Transportation Units (EBTU) are guaranteed for five years from the date of purchase against any manufacturing defects in material and workmanship. This warranty does not cover normal wear and tear, abuse, misuse, accidents, improper installation, damage you cause, or anything you place in the TCP product. You are responsible for complying with all instrucions, and applicable regulatory requirements related to the use of your TCP product. In using a TCP product you do so at your own risk. To the extent permitted by law, all other warranties, express or implied, are disclaimed and excluded, and manufacturer's liability for any type of claim whatsoever, is strictly limited to either the repair and replacement cost of your TCP product, or the purchase price of your TCP product, whichever is less in manufacturer's sole discretion. Altering your TCP product voids all warranties. To make a warranty claim, review the instructions for using a TCP product, or to see the full limited warranty for your TCP

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