FEATURE ARTICLE
Blood Plasma

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Question Of The Month

Marine Newslink

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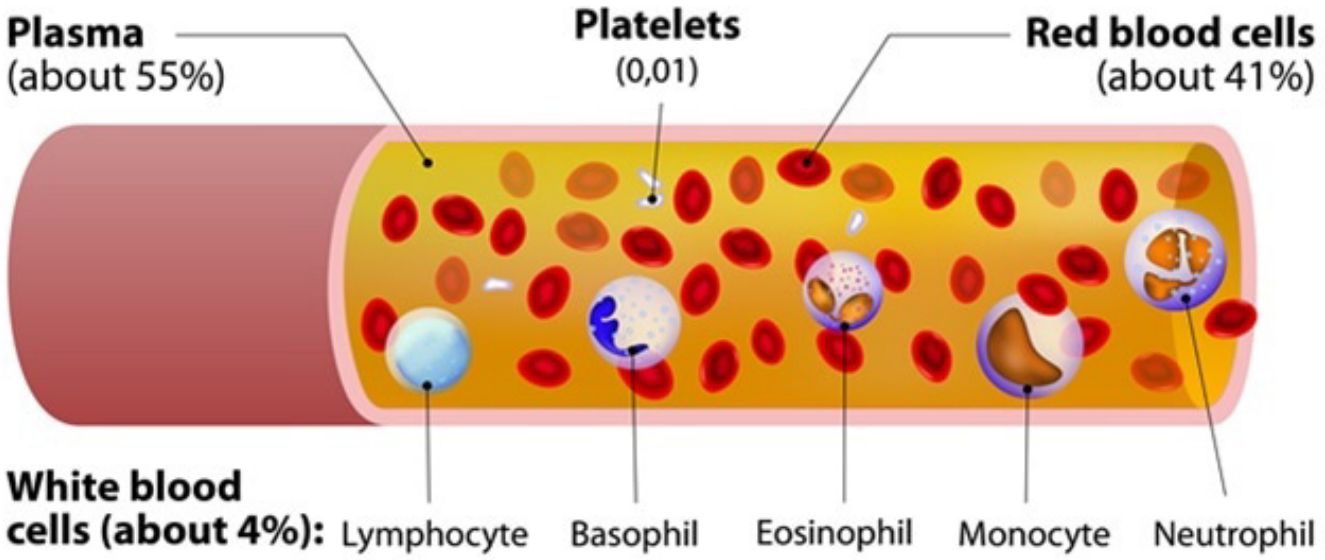
WITH YOU ALWAYS

April 2020

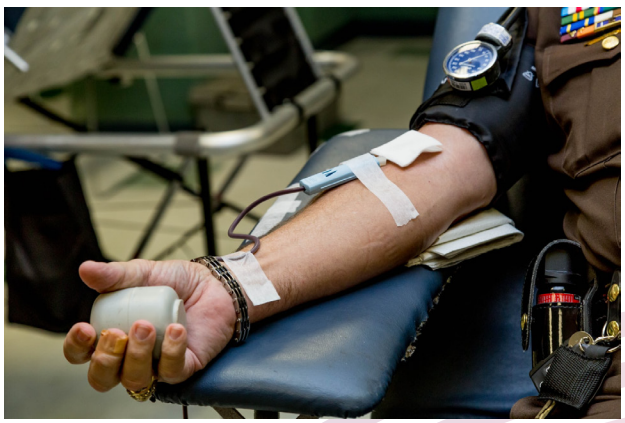
THE ELEMENTS OF BLOOD



Blood plasma is a blood substance that contains the blood cellular components in suspension. They include erythrocytes (red blood cells), leukocytes (white blood cells) and thrombocytes (platelets). It is a slightly cloudy liquid, the colour of which ranges from pale yellow to bright green, from person to person. It makes up about 55% of the total blood volume, as calculated by centrifuging. Blood plasma that does not contain clotting factors is referred to as blood serum.

Blood plasma is 90% water. The remaining 10% is made up of substances dissolved in water: plasma proteins, electrolytes and low molecular substances such as vitamins, trace elements, hormones and nitrogen excretory materials. One of the most critical functions of blood plasma is to act as a way of transporting cellular components.

Blood plasma is obtained by centrifuging whole blood donations or by plasma apheresis. All donated blood is screened for pathogens (e.g. HIV, hepatitis). Only plasma that has tested negative is permitted to be used or processed. Blood plasma is quarantined for at least 4 months (transfusion plasma) or 60 days (industrial plasma) before use.



Blood plasma can be prepared in three different ways:

Type	Features	Source material	Use
Frozen Fresh Plasma (FFP)	Frozen at approximately -30 °C; ready for use after thawing in a quality-controlled process; when thawed, it is a clear liquid with no solid substances	Plasma from a single donor	Transfusion or industrial processing
Lyophilized Human Plasma (LHP)	Freeze-dried, white or yellowish powdery substance; ready for use for injection purposes after a few minutes when dissolved in water; cell-free	Plasma from a single donor	Transfusion
Virus-Inactivated Plasma (SDP – solvent-detergent plasma)	Virus-inactivated with a special process (typically solvent-detergent); cell-free; approximately 10-15 % lower clotting factor activity than with FFP or LHP; quarantine not necessary; supplied frozen or freeze-dried	Plasma pool (plasma from 500 – 1600 individual donors)	Transfusion or industrial processing

After the plasma has been thawed or dissolved, it must be used within 6 hours in order to prevent contamination. The manufacturer's instructions with respect to correct use, transportation and storage must always be observed.

There are two main areas of application: Transfusion Plasma Applications & Plasma Derivative Applications. These are highly effective medicinal preparations made from 100-plus plasma proteins by fractionation. Transfusions of blood plasma must always be ABO-compatible. In cases of emergency, where it may not be possible to test the blood group of the recipient, AB group plasma can be used for transfusion, because this is compatible with all other blood groups.

PACKAGING

Blood plasma is extremely sensitive to contamination. However, because the primary packaging must be hermetically sealed, contamination can only arise when the containers are opened (during transfusion or fractioning).

Both plastic and glass can be used as primary packaging for blood plasma, with glass containers only being used for lyophilized plasma.

Plastic containers are generally made of polyethylene, polypropylene and plasticized PVC. Permitted additives include antioxidants, plasticizers, stabilizers and lubricants. The plastic containers must be capable of withstanding extremely low temperatures. Plastic bags come in sizes designed for storing between 250 ml and 750 ml. The plastic bottles generally contain between 650 ml and 850 ml, depending on the volume donated, but it is also possible for them to contain less.

Glass containers are made from soda-lime glass with a high hydrolytic resistance. The interior and exterior surfaces of the glass may be treated to optimize its chemical and physical properties. Glass containers must not be reused. The glass bottles generally contain 200 ml of lyophilized plasma, which is dissolved in 200 ml of water for injection purposes.

Because the primary packaging is in direct contact with the blood plasma, the packaging material used must give off no substances to the blood plasma that can in any way impact on its purity or effectiveness or that represent a toxicity risk. The containers must be transparent to permit visual inspection. It must also be possible to hermetically seal the containers and it must be possible to open or dismantle them easily.

A traceability system is obligatory. This system must use an exact identification process, a specific labeling system and precisely defined documentation processes in order to absolutely guarantee that each blood preparation can be reliably assigned to both the donor and to all recipients. Suitable labeling with no chance of errors is vital in achieving this.

LABEL

As a minimum, the following details must be provided on the labels:

- The official designation of the blood component
- The volume and weight of the blood product
- A uniform numeric/alphanumeric identifier for the donation
- The name and address of the blood donation organization or pharmaceuticals company that manufactured the product
- The ABO group (transfusion plasma only)
- Any expiry dates
- The required storage temperature
- If applicable, the virus inactivation method used
- The necessary details on the anticoagulant used.
- If virus-inactivated fresh plasma is used, the batch name must also appear on the label, as is also the case with plasma derivatives. This does not apply to normal transfusion plasma, which is not manufactured in batches.

All data that permits comprehensive traceability must be retained for at least thirty years and must be able to be accessed immediately.

HANDLING

Frozen Blood Plasma is largely insensitive to mechanical influences.

Lyophilized Human Plasma (LHP) is principally transported and stored in glass containers, which are highly sensitive to impact. Damage to the glass containers can lead to contamination of the plasma. The transport packaging should therefore be designed in such a way that it is able to absorb the loads experienced when it suffers impact or is dropped. The packaged goods should also be protected from knocking against each other.

TRANSPORTATION LEGAL REQUIREMENTS

When transporting and storing blood plasma, the "Good Manufacturing Practices" (GMP) and "Good Distribution Practices" (GDP) must be observed. These stipulate standard operating procedures (SOPs). Standard operating procedures are drawn up by each manufacturer and will normally form part of the framework agreements with the shipping agents and carriers. If any deviations from the standard operating procedures are identified or if any damage is discovered during transportation, this must be analyzed and assessed by the manufacturer's quality department. The quality department then decides whether any damage has occurred or whether the deviation is within acceptable tolerances.

In some countries, the companies and means of transport used for the transportation of blood plasma may be regulated in accordance with legislation pertaining to pharmaceutical products and may therefore need to provide approval documentation or to have completed examinations as laid down in national law.

In order to avoid interruption of the cold chain as far as possible, the product should be transported directly wherever this is feasible. The specified temperatures must always be observed during cargo handling. In order to protect staff and the blood plasma, the packaging that has been used must not be damaged. Glass containers and plastic containers are sensitive when frozen hence cargo handling should therefore be carried out as carefully as possible. Wherever possible, a sensitive force impact indicator should also be placed on outer box so that any handling damages can be easily identified.

Guidelines for Sample Transport

Ensure all collected specimens and accompanying paper work are picked up timely in a cooler box.

Before pickup/delivery, the driver:

- Makes sure each cooler box has:
  - ✓ frozen ice packs
  - ✓ a thermometer/ data logger
  - ✓ a specimen transport log
- Inspects the spill kit in vehicle weekly and replace any missing items.

After receiving the cooler box, the driver:

- Completes and sign the transport log.
- Only makes approved stops along the route.
- Upon arrival, delivers the cooler box and paper work to the designated receiver; ensures that person signs and fills in the time and date of receipt.
- Picks up any cleaned (decontaminated) cooler boxes and racks for return to the clinics/health centers.
- In case of a spill of biohazardous waste in the transport vehicle, reports the incidence and disposes the waste in bins designated for biohazardous waste.

The demands of the refrigeration units and means of transport used must be taken into account in order to ensure refrigeration during transportation. There must be adequate air circulation between the refrigeration unit and the warm air in the container of the means of transport in order to make sure that the units operate efficiently. This means that the air must be able to flow between the side walls or container walls and around the cargo. If there are no corrugations or similar in the loading bed, the cargo should be placed on pallets. The side walls are often marked to indicate the maximum loading height. These should not be exceeded in order to ensure good air circulation

Cleanliness of the means of transport and warehouses is an essential requirement. The storage conditions laid down by the manufacturer must be observed throughout the entire transport chain for pharmaceutical products.

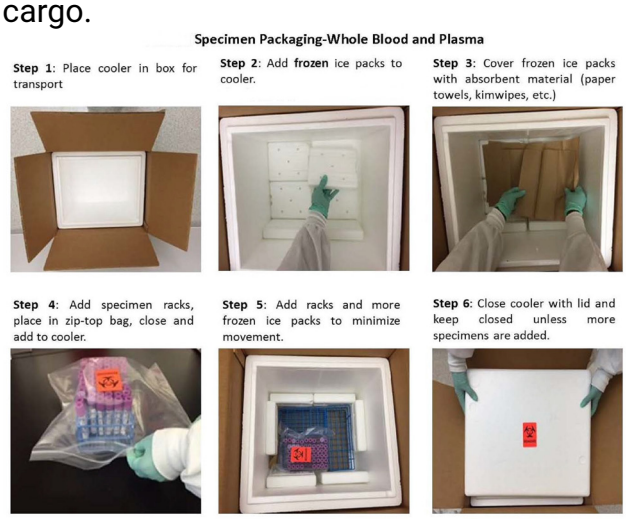
TRANSPORTATION

- Frozen Fresh Plasma (FFP)
  - Statutory requirement: < -20 °C
  - Recommendation based on the eutectic point: < -27 °C
- Lyophilized Human Plasma (LHP): +2 °C through +25 °C

Blood plasma must be deep frozen as soon as possible after centrifuging or after it has been obtained by means of plasma apheresis. Ideally, this should be done within the first six hours. Statutory regulations prescribed a maximum of 24 hours. Regulations require a freezing method that guarantees complete freezing to at least -30 °C within one hour. It is critical that the temperature falls below the eutectic point, which is -23 degrees Celsius for plasma.

Once the plasma product has been packed in primary packaging, it is stored in sub-zero temperatures. At the time of shipping, this temperature must be maintained. Hence primary packaging is placed in usually a white colored single ply carton box. This box is placed inside an insulated box surrounded by pre-frozen gel-packs. The gel-packs can maintain temperatures for a specific duration of time, and this is usually selected after determining the probable transit time. This insulated box is then placed inside a strong cardboard box that should primarily be white colored but generally brown boxes are also used.
This outer box must boldly display TIME & TEMPERATURE information for the packed cargo.

Specimen Packaging-Whole Blood and Plasma



Before the plasma is stowed in the reefer container, the current internal temperature of the hold/container must be checked. The product should only be stowed if the transportable temperature is achieved. Reefer containers should therefore be pre-cooled prior to loading.

The reefer containers must be equipped with temperature monitoring equipment that permits continuous monitoring to allow constant recording and documentation of the temperature. Specified temperatures should be recorded on the transport document. The carrier must inform the recipient of the blood plasma about any deviation from the defined temperature. In addition, the recipient should check the records for any discrepancies when the goods are inspected at each interface.

Data loggers should be used to record the temperatures within the cargo unit independently of the means of transport. The positions of the measuring points and the number of data loggers to be used is generally prescribed by the manufacturer, otherwise it can be determined by an independent expert. Multiple data loggers should be used within each cargo unit in order to ensure accurate data. The positions of the data loggers should be recorded in the transport document to facilitate subsequent checking of the measurements.

Transportation or storage at excessive temperatures causes the protein concentration to fall and may result in an increase in microorganisms and pathogens. If safety concerns prevent the plasma from being processed or transfused, it must be discarded.

TOXICITY/HEALTH HAZARDS

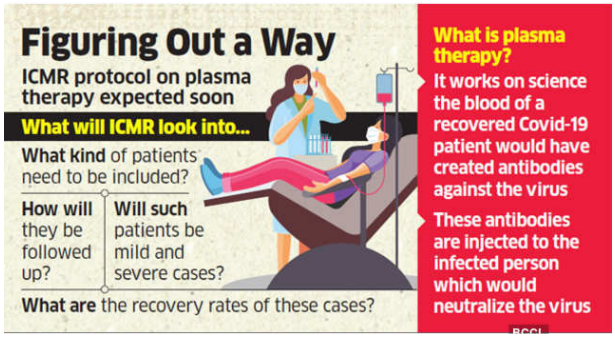
The welded edges of the plasma bags and the welded tubes of the plasma bottles are extremely sharp when frozen. These represent a risk of serious injury to staff handling the individual packs.

In the case of blood plasma that has not yet been screened for pathogens and been declared as negative, there is always a risk that it may contain life-threatening pathogens such as HIV or hepatitis. For this reason, those involved in obtaining the plasma should wear gloves and avoid any direct contact with the blood or blood plasma of the donor. If the plasma is frozen or freeze-dried, the risk of infection is reduced to a minimum, but cannot be eliminated.

If any leaks are detected in bottles or bags, they should immediately be discarded in order to protect the recipient and the staff. Furthermore, no attempt should be made to open plasma bottles and bags during transportation or storage because of the risk of infection (e.g. with HIV or hepatitis).

NOTE

India Health Ministry says there is not enough evidence to claim plasma therapy can be used for treatment of COVID-19.
Plasma therapy is not an approved treatment for COVID-19 and is only one of the several therapies which is being explored currently. The therapy is still at an experimental stage and the Indian Council for Medical Research (ICMR) is currently studying its efficacy.



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QUESTION OF THE MONTH

Insured is holding a Marine transit Open policy with INLAND TRANSIT (RAIL/ROAD/AIR) CLAUSE – A (all Risk) 2010.

A reefer truck load of food items (insured under this policy) is on its way from Gujarat to Chennai, Tamil Nadu. The LR date is 17th March 2020. The truck enroute to Chennai is not allowed to move onwards from Vijaywada in Andhra Pradesh on 20th March 2020. The cargo was temperature sensitive in nature, so to safe guard it against temperature excursion, the transporter stored it in a transporter's godown with necessary facilities by incurring additional expenses. There was a short circuit on 28th March 2020 and a fire broke in the godown where cargo was storage and damaged the cargo. The policy excludes storage which is not in ordinary course of transit.

Question? Is this loss due to fire admissible under the policy?

LAST MONTH'S QUESTION

Insured imported cargo on CIF Mumbai basis. The cover provided by supplier terminated upon discharge at Mumbai port. Client could not complete clearance formalities from the port owing to the impact of lockdown due to Corona Virus. Owing to some combustible cargo stored as co-mingled at the port warehouse on the 16th day after discharge of the cargo at Mumbai port warehouse, there was a fire at the port warehouse and cargo was damaged. Indian Insured has given All risk Cover for tail end transit to commence the Inland Transit risk from the Mumbai port, client had not opted to take a fire policy for the cargo lying at the Mumbai port warehouse.

Q. Cargo had not yet started its tail end transit. Does the cargo stand covered?

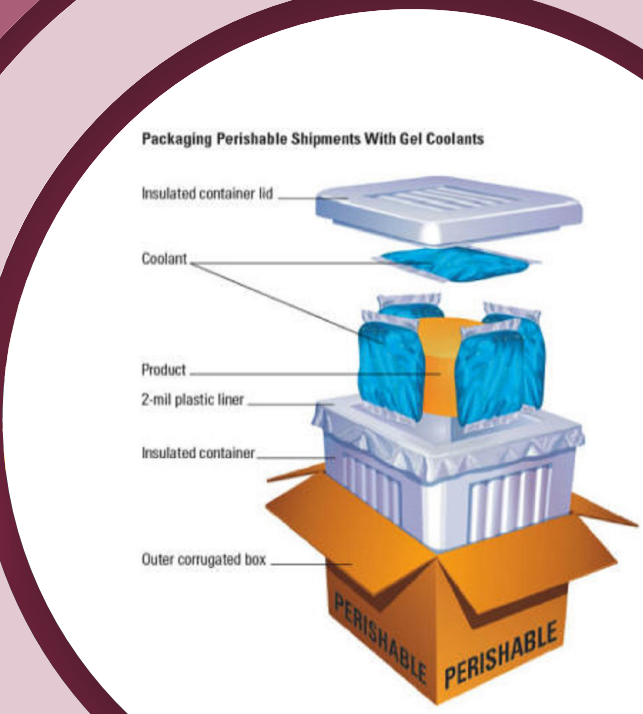
LAST MONTH'S ANSWER:

The cargo does not stands covered in Indian Insurer's policy as goods are damaged prior to commencement of Inland transit from Mumbai port.
Cargo would have been covered, had the insured promptly informed Indian insurer regarding the delay in clearance beyond their control and requested for extension of policy to cover storage of goods at port by paying adequate premium.

CORRECT ANSWERS SENT BY: (In order of replies received)

- MD MAAZ SHAIKH - Tata AIG General Insurance Co. Ltd., Parel, Mumbai
- VIJAYANAND V - Mahindra Insurance Brokers Ltd., Chennai
- BHARAT BHUSHAN - Optima Insurance Brokers Pvt Ltd., New Delhi

PLEASE SEND YOUR REPLIES/ANSWERS TO ADDRESSES GIVEN ON LAST PAGE OF THE MARINE NEWSLINK.



IF YOU HAVE ANY COMMENTS/ FEEDBACK PLEASE SEND IT TO

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