

PALA KIT*

Autologous Blood Serum Tears Convenience Kit



AseptiKits*

Patent No.:
US 10,555,872 B1
Other Patents Pending

Symbol Definitions

STERILE | R

Sterile by Radiation



Single Use

Latex Info

Not Manufactured With Natural Rubber Latex

STERILE | EO

Sterile by Ethylene Oxide

LOT

Lot Number



Storage Temperature



Attention, See Instructions For Use



Quantity



Use By



DEHP Free

REF

Reorder Number



Patent Information



Manufactured by



Manufactured for

PALA Convenience (PALA) Kit Contains:

1. PALA transport and disposal bag with an attachable Hazardous Waste Label.
2. PALA dose preparation (PREP) kit wrapped in a procedure towel comprising conventional 60 mL syringe, a second conventional syringe with female/female Luer adapter, a blood transfer barrel, four 10 mL sterile 0.9% NaCl prefilled syringes and gloves.
3. Sterilizing and Filling Transport (Sterile) Kit disposed within an insulated eye drop bottle pouch and providing a sealed bag, a stabilizing tray holding four Nemera eye drop bottles and associated caps and a sterilizing filter assembly comprising two 0.2 micron filters (a sterilizing filter with a portion disposed inside the bag, and another 0.2 micron filter proximally affixed thereto).

Instructions for Use

PALA Tears Kit Description

The PALA™ Kit is used for convenient production of autologous blood/serum eye drops. Contents of the PALA Sterile Kit are pre-sterilized and retained in a sterile state throughout eye drop bottle filling. All fluid entering the PALA sealed bag pass through a sterilizing grade, 0.2-micron filter. Parts of the PALA PREP kit are packaged clean.

Warnings

1. Follow institutional protocols and Universal Precautions when handling all patient fluids, medications, devices, needles, syringes, prefilled syringes, phlebotomy blood collection and transfer products, female/female adapters, alcohol, other cleaning agents, gloves, personal protective equipment (PPE) and other ancillary products that may be associated with use of this kit.
2. Inspect PALA Sterile Kit bag before using. Do not use if damaged.
3. Fully instruct patients relative to storage and use of autologous serum eye drops.
4. For single use only.

Cautions

1. Do not use PALA Sterile Kit bag near sharp objects.
2. Do not apply excessive force while injecting fluids through the syringe filter.
3. Proximal filters can become clogged making syringe dispensing difficult.
4. Air locks which can also obstruct bottle filling are best eliminated by priming.
5. The sterile filter will continue to sterilize if the proximal filter is removed and not replaced, however, if the sterile filter becomes clogged, bottle filling will be obstructed.
6. Assure that bottle caps are securely affixed and locked to eye drop bottles before opening bag.
7. Always follow institutional protocols relative to

patient and caregiver safety.

8. Do not attempt to disconnect pre-assembled components unless so instructed.
9. Thoroughly mix autologous blood serum and saline solution.
10. Assure that eye drops are appropriately refrigerated in an insulated transport bag prior to release for patient use.
11. Process autologous blood serum shortly after blood collection.
12. Instruct patient how to properly prime eye dropper before each use.

Instructions Regarding Freezer Packs

Upon receipt of the product, immediately remove freezer packs and store in freezer. Do not use freezer packs that are not frozen.

Blood Collection and Processing Instructions for Use (Phlebotomy supplies not included)

1. Collect a prescribed volume of blood using "mottled red top with inert separator and clot activator gel" blood collection tubes (also known as "Tiger tubes" or equivalent and attach appropriate labeling).
2. Wait at least 30 minutes for the blood to coagulate before centrifuging.
3. Centrifuge all blood collection tubes per institutional protocol.
4. Deliver blood collection tubes to processing site.

Tears Production Instructions for Use

5. Unwrap PREP Kit supplies.
6. Review the dosing chart to determine volumes of saline and blood serum.
7. Access the phlebotomy fluid transfer barrel and 60 mL syringe without female/female Luer adapter attached.
8. Fully insert a centrifuged blood collection tube into the phlebotomy barrel.
9. Invert the barrel/blood collection tube assembly and hold it at a 45-degree angle such that the clear blood serum is at the bottom of the blood collection tube. Do not shake or rock tube.
10. Draw the serum into the 60 mL syringe being careful to avoid drawing any red blood cells into the syringe. Repeat with each blood collection tube until prescribed volume of serum is collected.
11. Using the syringe with an attached female/female Luer adapter, draw the prescribed volume of 0.9% NaCl saline provided in prefilled syringes. (See dosing chart)
12. Remove the last 10 mL prefilled saline syringe from the female/female Luer adapter.
13. Attach the 60 mL syringe containing the autologous blood serum to the syringe with the female/female Luer adapter.
14. Dispense the contents of the syringes back and forth from syringe to syringe at least five (5) times to assure thorough mixing of the serum and saline solution.
15. Detach the filled syringe from the

female/female Luer adapter.

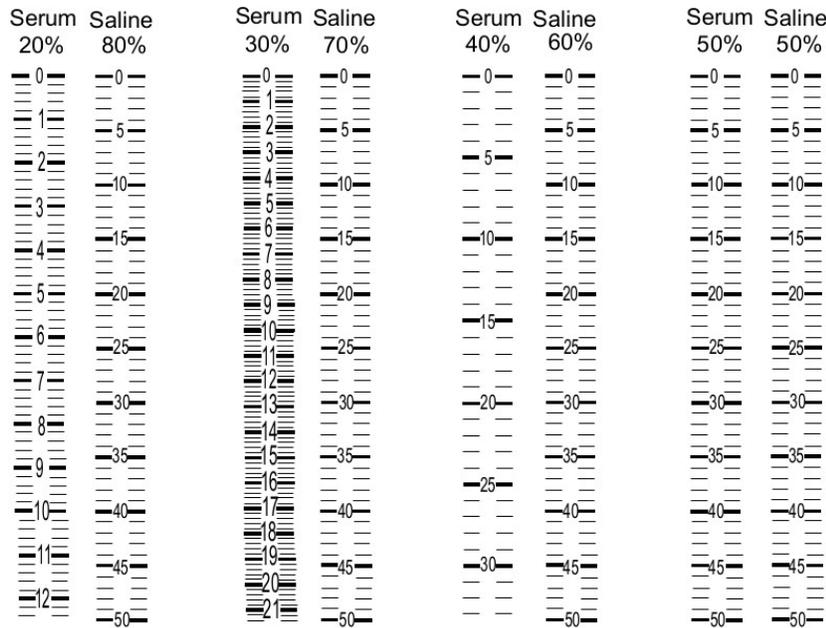
16. Remove the PALA Sterile Kit from the insulated pouch.
17. Center the tray directly under the 0.2 micron filter and tent the bag above it as shown in Figure 1.
18. Remove filter cap from the proximal filter and attach the filled syringe thereto.
19. Prime filter assembly by pointing dispensing end upright and dispensing liquid from the attached syringe in the same manner a syringe is primed.
20. Maximum volume of each vial is 10mL. Deliver solution into each eye drop bottle being careful to ensure the delivery nozzle is positioned within each bottle opening. If syringe dispensing becomes too difficult, remove the proximal filter.
21. From the outside of the PALA Sterile Kit, place a cap on a each vial and tighten until the cap locks in place.
22. After securely capping all bottles, perform bubble test to assure filter integrity. Open the PALA Sterile Kit package and remove the tray containing the closed eye drop bottles.
23. Turn each cap once more to assure each cap is locked.
24. Label each eye drop bottle following institutional protocols.
25. Insert bottles and one (1) provided frozen freezer pack into the insulated bag. Doses can be frozen in the eye drop bottles.
26. Close bag, seal and deliver to patient.
27. Provide patient instructions relative to storage, use, warnings and cautions.
28. Properly dispose of all products per institutional protocol. After applying BIOHAZARD WASTE LABEL, PALA Kit zipper bag may be used for disposal.

Figure 1



PALA Serum to Saline Volume Reference

The combined maximum volume of the eye drop bottles is 40mL. All measurement indicia are in mL.



Volume of saline of an acquired volume of serum can be calculated as follows:

$$\text{mLsaline} = \text{mLserum} * \frac{100 - \% \text{serum}}{\% \text{serum}}$$

Prescription Volume Quick Chart

Percent Serum	Serum (mL)	Saline (mL)	8.5mL Tubes Needed
10%	4	36	2
15%	6	34	3
20%	8	32	4
25%	10	30	5
30%	12	28	5
35%	14	26	6
40%	16	24	7
45%	18	22	7
50%	20	20	8
55%	22	18	9
60%	24	16	9
65%	26	14	10
70%	28	12	11
75%	30	10	11
80%	32	8	12
85%	34	6	13
90%	36	4	13
95%	38	2	14
100%	40	0	15

*Chart based on use of 8.5mL serum separator tubes

*Chart overestimates number of serum separator tubes needed, as it is preferable to have extra serum rather than not enough.

*Normal serum yield is approximately 3mL-3.5mL serum per 8.5mL blood tube. Serum yield varies patient to patient.