

PALA 12 KIT

Autologous Blood Serum Tears Convenience Kit



AseptiKits*

Patent No.:
US 10,555,872 B1
US 10,800,556 B2
US 10,940,087
US 11,312,605



Other Patents Pending

Symbol Definitions

STERILE | **R**

Sterile by Radiation



Single Use



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

Indications for Use: For use when preparing autologous serum eye drops as prescribed by a qualified practitioner.

PALA 12 Convenience (PALA) Kit Contains:

1. PALA 12 transport and disposal bag with an attachable Hazardous Waste Label.
2. PALA 12 dose preparation (PREP) kit wrapped in a procedure towel comprising conventional 60 mL syringe, a second conventional syringe with female/female Luer adapter, a conventional 30 mL syringe, a blood transfer barrel, 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 12 eye drop bottles, a plate holding 12 eye drop 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 and releasibly affixed thereto).

Instructions for Use

PALA 12 Tears Kit Description

The PALA™ 12 Kit is used for convenient production of autologous blood/serum eye drops. Contents of the PALA 12 Sterile Kit are pre-sterilized and retained in a sterile state throughout eye drop bottle filling by all fluid entering the PALA 12 bag being delivered through at least one of the sterilizing grade filters. Parts of the PALA 12 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 12 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 12 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.
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.

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. Follow institutional protocols for coagulation wait time before centrifuging. BD recommends 30 minute blood clotting time before centrifuging. BD recommends that serum separator tubes should be centrifuged no longer than 2 hours after collection.
3. Centrifuge all blood collection tubes per institutional protocol.
4. Deliver blood collection tubes to processing site.

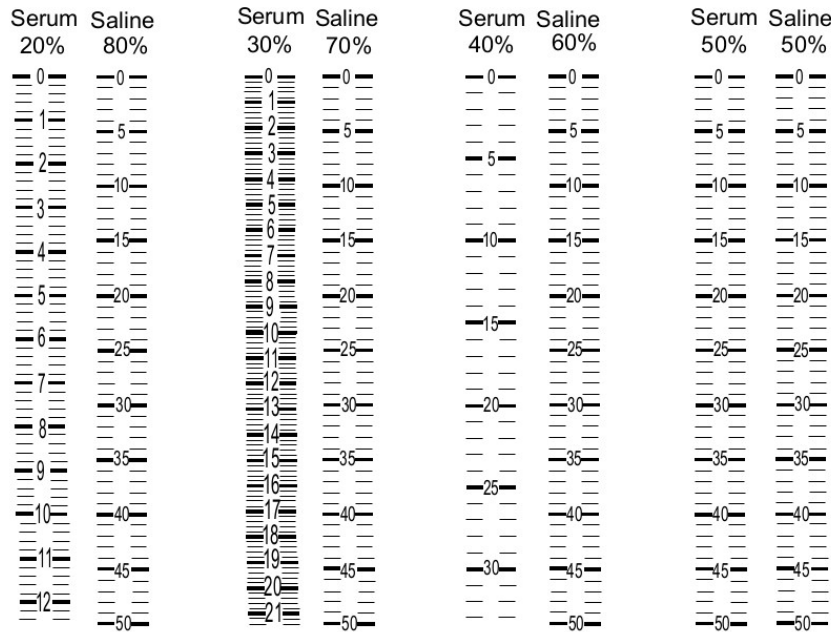
Tears Production Instructions for Use

5. Unwrap PREP 12 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 about 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 and measure the serum to meet the prescribed volume and serum concentration into the 60 mL syringe being careful to avoid drawing red blood cells into the syringe.
11. Using the syringe with an attached female/female Luer adapter, draw the prescribed volume of 0.9% NaCl saline. (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. For easier dispensing of the serum tears solution through filters a conventional 30 mL syringe is provided as an option for use in place of the conventional 60 mL syringe. The female/female Luer adapter can be used for multiple transfers of tears solution from the larger capacity 60 mL syringe.
16. Remove the PALA 12 Sterile Kit from the insulated pouch.
17. Center the tray directly under the 0.2 micron filter assembly and tent the bag above it.
18. Remove filter cap from the proximal filter and attach the filled syringe thereto.
19. **IMPORTANT** 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 5 mL. 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. When using the smaller 30 mL syringe, refill as necessary.
21. From the outside of the PALA Sterile Kit, grip the cap plate and place it on top of the bottles, aligning the caps with the bottles. (Note: The plate is easily displaced with proper techniques. Refer to AseptiKits' PALA 12 training video.)
22. Push caps downward onto the corresponding bottles, centering and aligning each cap.
23. Grip the filter assembly and push the nozzle into the top of the ratchet.
24. Using the ratchet, twist each cap onto the corresponding bottle as shown in Figure 1.
25. After securely capping all bottles, perform bubble test to assure filter integrity. Open the PALA 12 Sterile Kit package and remove the tray containing the closed eye drop bottles.
26. Turn each cap once more to assure each cap is tight.
27. Label following institutional protocols.
28. Insert bottles and one (1) provided frozen freezer pack into the insulated bag. Doses can be frozen in the eye drop bottles.
29. Close bag, seal and deliver to patient.
30. Provide patient instructions relative to storage, use, warnings and cautions.
31. Show patient how to properly open a bottle by holding each white cap while twisting the blue cap counter clockwise.
32. The enclosed BIO-HAZARD WASTE LABEL may be used to aid in proper disposal. Properly dispose of all products per institutional protocol.

PALA 12 Serum to Saline Volume Reference Chart

The combined maximum volume of the eye drop bottles is 60mL. All measurement indicia are in mL.



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

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

PALA 12 Prescription Volume Quick Chart

Percent Serum	Serum (mL)	Saline (mL)	8.5mL Tubes Needed
20%	12	48	5
25%	15	45	6
30%	18	42	7
35%	21	39	8
40%	24	36	9
45%	27	33	10
50%	30	30	11
55%	33	27	12
60%	36	24	13
65%	39	21	14
70%	42	18	15
75%	45	15	16
80%	48	12	17
85%	51	9	18
90%	54	6	19
95%	57	3	20
100%	60	0	21

*PALA 12 Prescription Volume Chart based on use of 8.5mL serum separator tubes

*PALA 12 Prescription Volume Chart overestimates by one the 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.