KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Standard Operating Procedure

Title: PRE - Autologous Serum Eyedrops - Specimen Collection and Processing		**Procedure Number** SFOSOP-0270 **Revision:** 5
Department: Clinical Lab Pre-Analytical **Area:** 1600 Owens Street SFO Mission Bay 2238 Geary Blvd SFO Clinical Lab 2425 Geary Blvd SFO Hospital Lab 4131 Geary Blvd French Campus Lab	***Approved & Released Standard Operating Procedure***	**Implementation Date:** 11/02/2017
Type of Document: General Lab		**Retention Period:** 10 - Year(s) **Review Period -** 340 **Days**

BACKGROUND:

The use of autologous serum, in eye drop form, is an effective ophthalmologic moisturizing treatment for clinical conditions affecting the ocular surface, when other treatment options do not prove effective. The product has biomechanical and biochemical properties similar to normal tears. They contain components such as fibronectin, vitamin A and growth factors that have an epitheliotrophic effect on the ocular surface epithelial cells.

POLICY:

Autologous serum eyedrops is a blood product derivative ordered by Corneal Surgeon Ophthalmologist Specialists. Patient preparation requires aseptic technique. Specimens must be collected and maintained in a closed system in the laboratory environment.

Autologous serum is only collected in specimen collection locations approved by the facility Laboratory Director. These locations must have equipment and materials to prepare and ship collected specimens fully frozen to the compounding pharmacy.

The designated lab locations for the **Kaiser San Francisco** are **2238 for collection and 2425 for processing and shipping.**

LABORATORY PROCEDURE:

RECEPTION:

1. For same day shipment, the patient must present to the *designated* laboratory by 10 am Monday – Thursday. If collected after 10 am, Monday – Thursday, processed specimens will be stored upright in the freezer for next day shipment. Do not collect specimens if the laboratory location isn't open for at least 3 more hours.

2. From KPHC, release AUTOLOGOUS SERUM EYEDROPS [227397] for the specimen collection. Alternatively, the request may be in the form of a Ophthalmology procedure form or a laboratory requisition.

3. The request must include the patient's full name, medical record number, patient's full address where the final product is to be shipped, the provider's name / identifier number and the request for autologous serum eyedrops to be sent to Avella Specialty Pharmacy in Phoenix,CA.

4. If not ordered in KPHC, in DOE, order RILIS mnemonic, ASED (AutoSerumEyeDps) to print 15 barcode labels. ASED is an "X test" and will auto-close out following order.

5. Verify patient identification using two patient identifiers, photo identification, and full name, as usual in the outpatient setting.

PHLEBOTOMY:

1. Validate patient identification using two patient identifiers, photo identification and full name, as usual in the outpatient setting, comparing patient's full name and MR# to the same on ***each*** specimen label and the requisition.

2. Prepare the venipuncture site for *aseptic* specimen collection in the same manner as preparing to collect a blood culture, with careful attention to timing of the scrub and dry time.

Materials:

1. Scrub solution: ChloraPrep One-Step 1.5 ml Frepp Applicator.
2. Tourniquet
3. A timing device to determine minimum scrub and drying time.
4. Place six 10cc or 8.5 cc plastic serum separator (SST) gel vacutainer tubes in a rack. Using isopropyl alcohol pads, scrub the vacutainer stopper tops, allowing the alcohol to dry before performing venipuncture.

Venipuncture Site Preparation Procedure:

1. Perform hand hygiene and don gloves as usual.
2. Determine which arm to use; apply tourniquet; identify venipuncture site, then release tourniquet.
3. Use of a *surgical* marker is the only acceptable method to mark a vein.

4. Open the ChloraPrep sterile blister pack. Remove the applicator using aseptic technique.
5. Squeeze the side handles together to break the ampoule. Discontinue squeezing once the solution flows into the foam head.
6. Place the applicator foam head onto the venipuncture site and press down once or twice to prime the applicator. Ensure the foam head is well saturated.
7. Apply the solution in a back and forth motion within a 3" area for a minimum of 30 seconds, timed by using a timing device. Discard the used applicator.
8. Allow the solution to dry for at least 30 seconds, using a timing device.
9. Do not touch the phlebotomy site once it has been cleaned. If the site is touched, repeat the arm scrub using a new ChloraPrep and dry time.
10. Do not cover the phlebotomy site prior to venipuncture. If the site is covered, repeat the arm scrub using a new ChloraPrep and dry time.
11. Proceed with phlebotomy without palpating anywhere in the scrubbed area. If phlebotomy is not performed within 5 minutes, repeat the scrub using a new ChloraPrep and dry time.

Specimen Collection:

1. Without palpating the site, perform venipuncture using a 21 gauge or larger needle (inner bore) and fill six10cc or eight 8.5cc SST vacutainer tubes. Do not use 23 or 25 gauge needles.
2. Verify each specimen label matches the patient name and MR#, as you are labeling the filled tubes.
3. Document your NUID, date and time of draw on the tube label. Document your NUID, date and time of draw on the requisition.
4. Place the collected tubes back in the rack. Hand off the filled rack with the requisition to the processor.

SPECIMEN PROCESSING:

1. Leave tubes in a rack in a vertical position at room temperature 22-30°C for a minimum of two and up to six hours to allow complete coagulation and clot retraction. Longer coagulation time is related to a larger effect of the autologous serum over the migration and differentiation of epithelial cells. Centrifuging the samples earlier than one hour can compromise the solution.
2. Specimens will remain at the collection site until after a minimum of two hours and the centrifuging. After that, the specimens will be transferred to the hospital lab.
3. Centrifuge a minimum of 15 minutes at standard speed to produce complete serum separation above a solid paraffin barrier in the SST gel tube.
4. **DO NOT OPEN THE TUBE FOR ANY REASON. The sample must be maintained in an unopened SST tube to ensure asepsis.**
5. Verify complete separation of cells and serum by gel barrier in the spun SST tube. If

serum and cells are not completely separated by a paraffin barrier, repeat centrifugation.

6. Once serum is completely separated above a solid paraffin barrier, immediately freeze intact SST tubes. Do NOT open, allow to freeze solid before preparing for shipment. Do NOT transfer or draw off the serum.

7. Causes for rejection are: hemolyzed, cloudy, thawed, and unspun specimens.

PREPARE SEND OUT TO AVELLA SPECIALTY PHARMACY

1. Package the fully frozen SST tubes on enough dry ice to ensure full contact with all tubes to remain fully frozen until delivery.
2. FedEx, packaging must be done in accordance to DOT regulations to ship overnight FROZEN to the pharmacy.
4. Include the physician's order with the specimens. The order must include the address the final frozen product will be shipped by the pharmacy (usually the patient's home address). The requesting Corneal Surgeon Ophthalmologist Specialist has also placed the order on Avella Specialty Pharmacy website.

Avella Specialty Pharmacy

ATTN: LAB

23620 North 20th Drive, Suite 12

Phoeniz, AZ 85085

Tel: 877-546-5779

(Choose 3 for representative and option 3 again for Ophthalmology)

Website: www.Avella.com

Ship Monday thur Thursday Only

LABORATORY DOCUMENTATION OF AUTOLOGOUS SERUM EYEDROPS

1. Retain a copy of the Autologous Serum Eyedrops order, to include specimen collection and shipping tracking documentation.

REFERENCES:

1. America Association of Blood Banks, Technical Manual, Fifteenth Edition, 2005.
2. *ChloraPrep One-Step 1.5 ml Frepp Applicators, El Paos, Texas. Medi-Flex, current version.*
3. Avella Specialty Pharmacy Autologous Serum Eyedrop Protocol for Lab.
4. LÓPEZ-GARCÍA, et. al., USE OF AUTOLOGOUS SERUM IN OPHTHALMIC PRACTICE *ARCH*

SOC ESP OFTALMOL 2007; 82: 9-20

5. UCSD Stem Cell Processing Lab, La Jolla, CA, Protocol for Autologous Serum Eyedrops, 2008.

Associated Documents:

External Documents

Cornea Location Codes autoserum v6 06.2017.doc

Associated Documents:

Document Name

Click to Open an Associated Document

Document Revision History:

Revision: 5	**Date Created:** 04/02/2013 **Date of Last Revision:** 11/02/2017	**Last Approval Date:** 11/02/2017

Document Author: LaWanda Young/CA/KAIPERM	**Document Manager:** Olga T Toler/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	4/3/13
2	Content	New address for Leiter's Pharmacy	7/24/14
3	Cornea Location list	Change SFO contact	10/16/14
4	Approver	Changed CLIA director to Eric Suba	8/16/16
5	Title, Reception,Phlebotomy, Reception and Send to	Title: Antologous Serum Eyedrops - Specimen and Processing. Change to Avella Specialty Pharmacy in Reception #3,Sent to#3&4, References #3. Tube collection Phlebotomy Materials #3 and Specimen collection #1 Deleted 2200 O'Farrell and added Mission Bay Lab	6/8/17
6	Specimen Processing	Added: "Specimen will remain at collection site for a minimum of two hours and after centrifuging. After that , the specimens will be transferred to hospital lab."	11/1/17
7	Specimen Processing	Causes for rejection	

Notification List:

Approvals:

First Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Nov 2, 2017 12:49:29 PM PDT - Approved by: Eric Suba/CA/KAIPERM

Document History Section