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Collection and Processing Specimens for Autologous Serum (AS) Tears

Principle

This procedure provides instructions for collection and processing of blood specimens for further manufacture into Autologous serum (AS) tears. Autologous serum (AS) tears or autologous serum eye drops (ASEDs) are customized drops made from a patient's own blood diluted in sterile saline or hyaluronic acid. Because serum is composed of a complex mix of growth factors, proteins, antioxidants and lipids, it is more akin to the components of human tears and may provide a more effective replacement than manufactured tears.

Scope

This procedure is intended for SCPMG Laboratory Systems staff who oversee or are responsible for collection, processing, and packing specimens from Kaiser Permanente Southern California Medical Centers, Medical Office Buildings, and/or other locations in which patient specimens are obtained for Autologous serum tears.

Policy

- Personnel who process, pack, and/or transport laboratory specimens shall have records for Universal (Standard) Precautions, PHI confidentiality in accordance with HIPAA guidelines.
 - Protected Health Information (PHI) shall not be attached to the outside of the transport container (tote).
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**Safety or
Special Safety
Precautions**

Refer to the safety manual for general safety requirements.

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Specimen collection

Follow the steps below when patient presents for collection	
Step	Action
1	Verify orders: Laboratory orders for autologous tears are ordered in Kaiser Permanente Health Connect (KPHC) <ul style="list-style-type: none"> • Autologous Serum Eyedrops 20% [227397] • Autologous Serum Eyedrops 40% [254504] • Autologous Serum Eyedrops 100% [254505] KPHC Order must be placed by physician or designee.
2	Specimen collection for autologous tear specimens is only performed at locally designated location (see appendix A) <ul style="list-style-type: none"> • Specimens are collected Monday-Friday from 7:30 am to 12:00 pm except where locally agreed upon arrangements with Ophthalmology Department are made.
3	Follow specimen collection skin preparation steps 1-5 prior to phlebotomy from the procedure for <i>Blood Culture – Skin Preparation and Specimen Collection</i> . <ul style="list-style-type: none"> • Use ChloroPrep® to cleanse the collection site. • Collect either 12 SST/GLD6 or 20 SST/GLD6 (depending on order placed) specimen tubes from patient, avoiding hemolysis. • All tubes must be full. • Cerner will print the required number of labels. • Complete Cerner resulting process for these orders. NOTE: Label should not cover expiration date or lot numbers on collection tube.
4	Send specimens with in a biohazard bag to main laboratory or other designated local location through pneumatic tube system (where available) for processing at the designated medical center laboratory.

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Specimen processing

Follow the steps below for specimen processing	
Step	Action
1	<p>Upon specimen receipt in designated laboratory</p> <ul style="list-style-type: none"> Verify test requested and obtain a copy of the “Order Details” from KPHC Chart Review. <p>NOTE: Order Details must be sent with samples to Vital Tears</p>
2	<p>Specimens must sit upright for 2-6 hours prior to centrifuge. (This allows for complete coagulation and clot retraction.)</p> <p>After appropriate elapsed time centrifuge specimen tubes for 15-20 minutes at approximately 3000 RPM.</p>
3	Place centrifuged collection tubes in a Vital Tears supplied “tube sleeve” and place sleeve in biohazard bag for shipping.

Specimen Send-Out

Follow the steps below for specimen send-out	
Step	Action
1	<p>Pack and Send specimens overnight using Vital Tears protocol for packing and shipping for processing into Autologous Serum Eye Drops.</p> <ul style="list-style-type: none"> Be sure to use the Vital Tears Transport Kit using Vital Tears supplied FedEx labeling. Remember to use Vital Tears supplied Kodiakooler gel packs for shipping. Do not use dry ice or freeze samples. <p>Refer to Attachment B</p>
2	<p>Specimens can be shipped Monday through Friday.</p> <ul style="list-style-type: none"> Vital Tears does receive specimens on Saturdays. (Local agreements may limit to fewer available shipping days)
3	<p>Package specimens for overnight shipment with copy of KPHC Order Details to:</p> <p>Vital Tears 10560 N. Ambassador Drive, Suite 210, Kansas City, Missouri, 64153.</p> <p>For Questions Call: 800-360-9592.</p> <ul style="list-style-type: none"> Ask for any Vital Tears Client Services Staff Member. <p>Website: www.vitaltears.org</p>

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Materials and supplies

Vital Tears Shipment Kit:

- - Sleeves
 - - Biohazard Ziploc bag
 - - Foam cooler and shipping box
 - - Foam spacers
 - - 2 Kodiakooler gel packs (require 48 hours to freeze solid)
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Attachments

Attachment A: Collection Sites for Autologous Serum Tears
Attachment B: Packing and Shipping Instructions

Controlled Documents

The following controlled documents support this procedure.

Regional Parent Document Reference Number: SCPMG-PPP-0366 Rev. 01

Reference
Blood Culture – Skin Preparation and Specimen Collection

Author(s)

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Collection and Processing Specimens for Autologous Serum (AS) Tears

ATTACHMENT A: Collection Sites for Autologous Serum Tears

Medical Area	Collection Location
Antelope Valley	Antelope Valley Medical Offices (AVMO)
Baldwin Park	Baldwin Park Medical Center - Laboratory
Downey	Downey Medical Center Laboratory
Fontana	Fontana Medical Center Lab
Kern County	Stockdale Lab
Los Angeles Medical Center	1515 Vermont
Los Angeles Medical Center	4700 Sunset
Los Angeles Medical Center	4900 Sunset
Los Angeles Medical Center	4950 Sunset
Ontario	Ontario Medical Center Laboratory
Orange County - Anaheim	Kraemer II MOB
Orange County - Irvine	Irvine Lab
Panorama City	Santa Clarita MOB 2 Lab
Panorama City	MO3 Lab at Panorama City

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Collection and Processing Specimens for Autologous Serum (AS) Tears

ATTACHMENT A: Collection Sites for Autologous Serum Tears

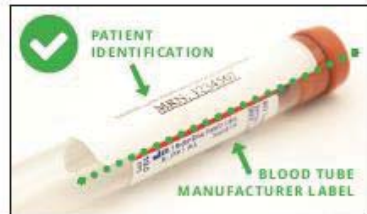
Riverside	Riverside Laboratory
Riverside	Murrieta MOB Laboratory
San Diego	Clairemont Mesa Medical Center
South Bay	Normandie North
West Los Angeles	West Los Angeles Laboratory
Woodland Hills	Woodland Hills Medical Center Lab

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ATTACHMENT B: Packing and Shipping Instructions

PRIOR TO SHIPPING, ENSURE THAT YOU:



Position your patient identification label on the tube so as **not to cover the lot number and expiration date** on the manufacturer's label.



Package the blood tubes into the sleeves then **seal them** in the biohazard Ziploc bag. Place a foam spacer **under and over** the bagged tubes. This entire unit goes into the bottom of the cooler.



Place 2 **FROZEN** Kodiakooler gel packs on top of the foam spacer before closing the cooler.



Place the **KPHC Detail Order** page on top of foam lid. Prepare the kit for shipping. Set up shipping for **overnight delivery**.

- ✔ If you **DO NOT** have a regularly established daily FedEx pickup time, please contact our Client Services Department at **(800) 360-9592** or **info@vitaltears.org** ASAP to schedule a FedEx pickup.
- ✔ If you **DO** have a regularly established daily FedEx pickup time, please ensure the necessary steps are taken to meet the pickup deadline.
- ✔ If a package is not picked up on time for overnight delivery, please **contact Vital Tears as soon as possible**.

Signature Manifest

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Vital Tears

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
Qiyamaa Portillo (K237031)	Assistant Director Operations	19 Feb 2020, 11:52:09 AM	Approved

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Janice Wolf (K119893)	Director Operations Area Lab	21 Feb 2020, 09:55:12 AM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Sony Wirio (A478893)	Pathologist, Medical Director	25 Feb 2020, 11:53:43 AM	Approved