


On behalf of Vision Expo, we sincerely thank you for being with us this year.




Vision Expo Has Gone Green!

We have eliminated all paper session evaluation forms. Please be sure to complete your electronic session evaluations online when you login to request your CE letter for each course you attended! Your feedback is important to us as our Education Planning Committee considers content and speakers for future meetings to provide you with the best education possible.




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Financial Disclosures

- Consultant with LKC 
- Consultant with Adnexa Ocular Amniotic Membranes 
- Consultant with Sight Science 
- Member Board of Directors 

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Autologous Serum in Optometric Practice

Presenter: Ansel T. Johnson, O.D.

Bringing Tear Serum to the forefront of Dry Eye Therapy

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Course Objectives

- Understanding the composition and mechanism of action autologous serum
- Understanding indications and possible utilizations for autologous serum
- Understanding how to prescribe autologous serum
- Knowledge of other biologic options to autologous serum

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About Ansel T. Johnson, OD

- **Adjunct Professor:**
 - Midwestern Chicago College of Optometry (Externship site)
 - Kentucky College of Optometry – UPIKE (Externship site)
 - New England College of Optometry (Externship site)
 - Southern College of Optometry (Externship site)
- **Additional Clinical Externship Site**
 - UAB College of Optometry
- **Medical Director – United Eye Care Providers**
- **Founder, CEO – Healthy Living With A Vision Foundation**
 - (A 501c3 Organization)

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Replenishing The Eye's Moisture



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Autologous Serum Defined

- The cells or tissue given or used for treatment is from the same individual.
- First noted use is in a 1975 study testing to test the ability of a perfusion pump to keep chemically burned eyes moist
- First investigated for **ocular** use in 1984 by Robert Fox, Raymond Chan et al
 - Autologous serum used in patients that did not get relief or subjective improvement with available artificial tear supplements
 - Patients continued use without complications

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Autologous Serum Acquisition

- How is the serum acquired?
 - venipuncture
- Patient's blood is drawn at a lab, doctor's office or patient's home. No fasting is required.
- The blood draw is centrifuged separating blood into its various components.
- The serum to saline ratio may vary according to the prescribing doctor's assessment
- It is important to keep the eye drops away from light because some of its components (vitamin A) degrade quickly with light exposure



Source: <https://doi.org/10.1590/S0004-27492008000700010>

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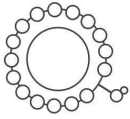
Autologous Serum Mechanism of Action

- "What is in your blood serum?"
 - Contains multiple growth factors, vitamins, proteins and other components that have been considered important for corneal and conjunctival integrity. Human serum has similar biochemical properties normally found in tears
 - **Epidermal growth factor(EGF)** – By promoting cell migration and proliferation EGF is a major stimuli for promotion of corneal wound healing.
 - **Transforming growth factor-β** – part of intricately balanced interactions between cells. Helps cooperative interactions that involve numerous cytokines engaged in corneal surface integrity.
 - **Fibronectin** - A structural extracellular protein that binds to collagen and cells. A major factor in corneal development.
 - **Cytokines** – regulate immune response
 - **Vitamin A** - deficiencies cause corneal scaring and opacifications Important in goblet cell health and integrity.

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Autologous Serum Mechanism of Action

- **Epidermal growth factor(EGF)** – By promoting cell migration and proliferation EGF is a major stimuli for promotion of corneal wound healing.
- Promoted for skin care and antiaging.



Growth Factor (EGF)



Source: Cell Biol Int. 1995 May;19(5):413-30. doi: 10.1006/cbir.1995.1086

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Autologous Serum Mechanism of Action

- **Transforming growth factor-β** – part of intricately balanced interactions between cells. Helps cooperative interactions that involve numerous cytokines engaged in corneal surface integrity.
- Transforming growth factor beta (TGF-β) is a multipotent growth factor affecting cell differentiation, proliferation, apoptosis and matrix production.

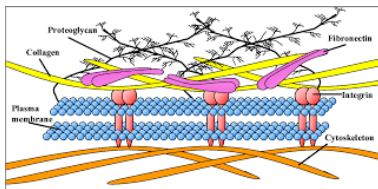


Source: <https://www.sciencedirect.com/topics/neuroscience/transforming-growth-factor-beta>

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Autologous Serum Mechanism of Action

- **Fibronectin** - A structural extracellular protein that binds to collagen and cells. A major factor in corneal development.
- **Fibronectin (FN)** is a ubiquitous extracellular matrix (ECM) glycoprotein that plays vital roles during tissue repair.

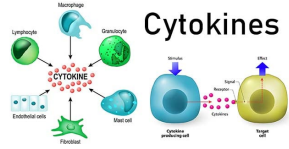


Source: <https://fibrogenesis.biomedcentral.com/articles/10.1186/1755-1536-4-21>

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Autologous Serum Mechanism of Action

- **Cytokines** – regulate immune response
- Cytokines are small proteins that are crucial in controlling the growth and activity of other immune system cells and blood cells. When released, they signal the immune system to do its job. Cytokines affect the growth of all blood cells and other cells that help the body's immune and inflammation responses.



Source: <https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cytokines.html#:~:text=Cytokines%20are%20small%20proteins%20that%20help%20the%20body%27s%20immune%20and%20inflammation%20response.>

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Autologous Serum Mechanism of Action

- **Vitamin A** - deficiencies cause corneal scarring and opacifications Important in goblet cell health and integrity.
- Involved in mediating the relationship between gut bacteria and the immune system
- A key for good vision, a healthy immune system, and cell growth.

PROPERTIES OF VITAMIN A

By Botanical-online.com

- *Vitamin A appears in the retina of the eye, and it's important for the vision health.*
- *To treat eye fatigue, glaucoma, night blindness, myopia, astigmatism, ...*
- *It strengthens the immune system.*
- *In animal fats: milk, cheese, eggs (yolk) ...*
- *The body can get vitamin A from beta-carotene: carrots, spinach, chard, mango, peach, ...*



Source: <https://www.botanical-online.com/vitamin-a-10benefits-for-your-health.html>

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Autologous Serum A Super Food for the Eyes

Provides for Homeostasis Within the Eye

- Homeostasis is the tendency toward a relatively stable equilibrium between interdependent elements on the ocular surface
- Maintained by physiological processes of tear production.
- Whatever the initial causes of dry eye, the subsequent chronic dryness of the [ocular surface](#) results in inflammatory reactions and destruction of the lacrimal glands and [conjunctival epithelium](#).
- Once dry eye disease has developed, inflammation is the key mechanism of dry eye disease causing ocular surface injury, as both the cause and consequence of cell damage. In practice

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Commercial Artificial Tear Products

- Drawbacks and limitations of commercial over the counter tear supplements:
 - Lack essential tear components such as growth factors, vitamins, and immunoglobulins.
 - Often contain preservatives, stabilizers, and other additives, which potentially induce toxic or allergic reactions



Autologous Blood Serum Eye Drop Solution Processing Using PALA™ Kits Dr. Gale H. Thorne Ph.D., P.A. Gale H. Thorne Jr., MBA Healthcare Management May 4, 2019

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Autologous Serum Indications

- A viable alternative for the most severe cases of dry eye and ocular surface disease.
- 1.5 million people in the US are estimated to live with severe dry eye not resolved with OTC or prescription eye drops.
- Conditions that can result in severe dry eye-related ocular surface disorders:
 - Sjögren's syndrome
 - Superior limbic keratoconjunctivitis
 - Graft-versus-host disease
 - Stevens-Johnson syndrome
 - Ocular cicatricial pemphigoid
 - Recurrent or persistent corneal erosions
 - Neurotrophic keratopathy
 - Mooren's ulcer
 - Aniridic keratopathy
 - Filtering blebs after trabeculectomy
 - Post-keratorefractive surgery

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Autologous Serum Indications

- Sjögren's syndrome
 - Rheumatoid arthritis patients that suffer with secondary Sjögren syndrome generally have the highest level of damage to the ocular surface with severe ocular complications and subsequent visual impairment.
 - Diagnostic tests:
 - SS-A (Ro) and SS-B (La) antibodies:
 - Antinuclear Antibody (ANA)
 - Rheumatoid Factor
 - Complete Blood Count (CBC)
 - Complete Metabolic Panel
 - Erythrocyte Sedimentation Rate (ESR)
 - C-Reactive Protein (CRP)
 - Immunoglobulins:
 - Serum Protein Electrophoresis and Serum Immunofixation
 - Complement Proteins

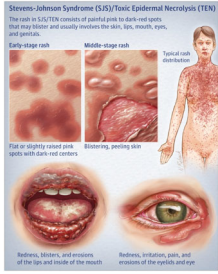


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Autologous Serum Indications

• Steven Johnson Syndrome

- much more likely to occur in people infected with the human immunodeficiency virus (HIV), with an estimated incidence of 1/1000.



Source: <https://www.ncbi.nlm.nih.gov/books/NBK459323/>
 Facebook, 19/2/20 - Steven-Johnson Syndrome/Toxic Epidermal Necrolysis - Derm Ed

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Autologous Serum Indications

• Superior limbic keratoconjunctivitis

- A chronic and recurrent eye disease which affects the superior bulbar conjunctiva and tarsal conjunctiva, as well as the superior limbic aspect of the cornea.

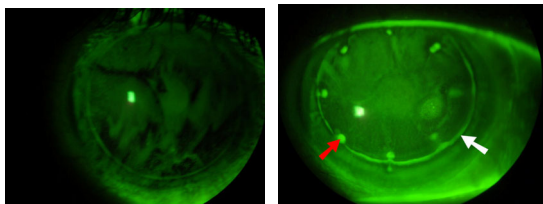


Source: <https://entokey.com/superior-limbic-keratoconjunctivitis-2/>

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Autologous Serum Indications

• Post-keratorefractive surgery (ie. Lasik)

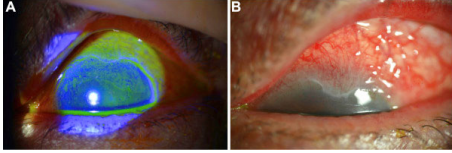


Source: https://www.lasikcomplications.com/case_reports.htm

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Autologous Serum Indications

- Graft-versus-host disease
 - Ocular involvement, either in an acute or chronic presentation, may range from mild to severe with accompanying vision loss present in 60-90 % of patient

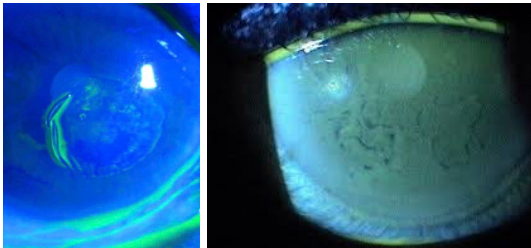


Source: Graft versus host disease: clinical evaluation, diagnosis and management EM Espana, S Shah, MR Santhiago, AD Singh Graefes Archive for Clinical and Experimental Ophthalmology, 2013

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Autologous Serum Indications

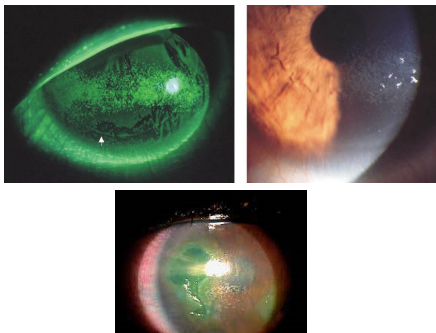
Recurrent or persistent corneal erosions



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Autologous Serum Indications

Neurotrophic keratopathy



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Autologous Serum Possible Risks & Complications

- **Concerns about bacterial or fungal contamination**
- Peripheral corneal infiltrate and ulcer
- Eyelid eczema
- Microbial keratitis in patients with an epithelial defect
- Increased discomfort or epitheliopathy
- Temporary bacterial conjunctivitis
- Scleral vasculitis and melting in RA patients
- Immune complex deposition with 100% serum

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Autologous Serum Possible Risks & Complications

- Blood is extracted from patient's vein with vacuum extraction tubes without anticoagulant. Subsequently, the tubes are left in vertical position at 22°C for about 2 hours to allow coagulation. After blood clot is formed, supernatant is centrifuged to separate the serum from the solid components. A bottle of serum eye drops with the desired concentration, adequately identified and preserved from light is given to the patient. It is important to keep the eye drops away from light because some of its components (vitamin A) degrade quickly with light exposure. M

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Autologous Serum Barriers to Treatment

Cost

- Lack of Insurance Coverage
- Complex processing methodology
- Proximity of dispensing lab for blood draw and preparation
- Necessity for freezer and refrigeration storage

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Most Popular Autologous Serum Brands



- Vital Tears approx. \$449 for a 3 month supply
 - Market leader source of Analogous serum, Needs sterile hoods for fabrication of vital tears.

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Most Popular Autologous Serum Brands



- NovoTears can be produced with 20%, 33% or 50% serum
- Can also choose NovoTears Plus: combines NovoTears with cyclosporine.
- 45 Days: \$100/month or \$150 total cost
- 90 Days: \$98/month or \$295 total cost
- 180 Days: \$75/month or \$495 total cost

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Most Popular Autologous Serum Brands



- Asepti Kits \$275 6-month supply
- Different and innovative packaging
- Sterile kits and inserts within a sterile production kit that is never exposed to the elements. No need for heavy duty equipment. Production time reduced to 90 min compared to several hours. Most times patients can receive their tears within 24 hours.

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Prescribing Autologous Serum

- A prescribed serum concentration generally ranges from 20% to 50%
- Eye drop application per day is prescribed at 2 to 6 times per day which gages amount of blood needed to draw. Various factors can help determine concentration.
- On average 60ml supplied at a time. Each vial is 5 ml estimate 4 drops per vial per day.
- Four drops per day is average dosage.
- Average concentration is 20% to 50% serum to saline. Hyaluronic acid may be used instead of saline.

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Biologic Options to Autologous Serum

- d-MAPPS(•derived-Multiple Allogeneic Proteins Paracrine Signaling (Branded name Regener-Eyes®)
 - a first in class, natural, sterile biologic ophthalmic solution that is preservative free
 - contains a large number of immunoregulatory factors
 - acellular however it contains proteins and cytokines in addition to the water, glucose, lactates and electrolytes, and placental-derived biomaterials
 - microRNAs (miRNAs)
 - Ocular conditions for utilization
 - Meibomian gland dysfunction
 - Dry Eye
 - Sjogren's Syndrome
 - Dosages and Prescribing

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Biologic Options to Autologous Serum

- Hydrated Amniotic Membranes
 - Composition
 - Applications and Procedures
- Dehydrated Amniotic Membranes
 - Composition
 - Applications and Procedures

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Biologic Options to Autologous Serum

- Cenegermin(Branded Oxervate)
 - Composition
 - Applications and Procedures
 - Utilized for recurrent corneal erosion

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Prescribing Autologous Serum for Asepti Kits

Patient Instructions:

- This will receive 12 (each) 5 ml, preservative free bottles of serum tears.
- 50ml of serum tears in an appropriate 6-month supply, 24 - 30 days supply.
- Also arrives with: 12ml of our own donor of serum tears.
- Keep unopened bottles well refrigerated during period of use.
- These eye bottles are needed keeping these not in use frozen.
- Use as directed per physician.

Please be aware of the following before arriving:

- Arrive at least 15 minutes before blood and process the serum.
- Please be well hydrated.
- Bring eye medication to transport serum tears.
- Cash is 247K Credit/Debit Card and most HSA/FSA accepted.
- No insurance accepted.

Call 708.963.1200 to Schedule Your Appointment

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Autologous Serum Lab Location Information

Vital Tears Information
<https://vitaltears.org/physicians>

NovoTears
<https://aiscaregroup.com/our-divisions/opthalmics/novotears-hcp/>

ARC Point Labs location
 • <https://www.arcpointlabs.com/locations-by-state/>

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Informed Consent

This document is a screenshot of an 'Informed Consent' form for eye drops. The header includes the logo for 'Vision Eye Care Associates' and contact information: 'Adult & Pediatric Comprehensive Eye Care, Optometric & Treatment of Eye Diseases & Eye Surgery & Management, 13812 L. Weston, Blue Bell, PA 15009, Office (717) 661-3552 • Fax (717) 661-1170, www.visioneye.com'. The text is organized into several sections: 'What are autologous serum eye drops?', 'What conditions do autologous serum eye drops treat?', 'How are autologous serum eye drops made?', 'How are autologous serum eye drops used?', 'What precautions need to be taken when using autologous serum eye drops?', and 'What questions need to be asked when using autologous serum eye drops?'. There are also sections for 'Patient Name', 'Date', and 'Patient Signature'.

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Questions




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