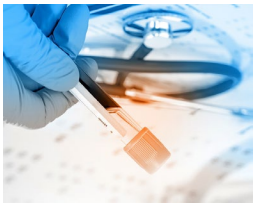
# AUTOLOGOUS BLOOD SERUM EYE DROPS
# Information Sheet

## *AUTOLOGOUS SAME DAY EYE DROPS*
## *Now offered by Secure Health Partners in Colorado.*

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



*An estimated 1.5 million people in the U.S. suffer from severe dry eye disorders that are not resolved using off-the-shelf or prescription eye drops, e.g. Restasis or Xiidra.*

Autologous blood serum for eye care was first discovered when used as one of the fluids in a 1975 study testing the ability of a perfusion pump to keep chemically burned eyes moist (Brennan, 2016). Due to more recent research and recognized patient needs, there has been a resurgence in interest of autologous blood serum eye drops (Anitua, Muruzabal, Tayebba, Riestra, Perez, Merayo-Llove and Oriva, 2015).

None of the commercially available artificial tear preparations include essential tear components such as epidermal growth factor, hepatocyte growth factor, fibronectin, neurotrophic growth factor, and vitamin A – all of which have been shown to play important roles in the maintenance of a healthy ocular surface epithelial milieu. Autologous serum (“AS”) eye drops contain these essential factors and are beneficial in the treatment of ocular surface diseases such as persistent epithelial defects (PED), superior limbic keratoconjunctivitis, keratoconjunctivitis sicca, and neurotrophic keratopathy (Community Pharmacy, 2018).

A number of practical issues have prevented clinicians from processing patient blood serum on a broad scale. These included access to a laminar flow hood, high processing costs and worries over a wide variety of potential contamination issues. Preparers must also follow government regulations relative to the handling of biologic fluids under a laminar flow hood (Allen, 2016).

# AUTOLOGOUS BLOOD SERUM EYE DROPS
# Information Sheet

While autologous serum drops help many patients, they are not readily available (Hasson, 2012).

Contamination issues include sterility of the blood sample caused by a lack of sterility at the blood collection site and breaks in aseptic technique during preparation. In fact, “Bacterial contamination is a potential risk in the production and use of serum eye drops. Sterile manufacturing conditions, beginning with thorough skin disinfection, are of the utmost importance. It is preferable that further processing is performed in a closed system.” (Geerling, MacLenan and Hartwig, 2004).

Today, while there are an increasing number of compounding pharmacies which process autologous blood serum, there continues to be a shortage of such for processing ABSEDs (Lipner, 2017). Also, today such processing has been too expensive for most patients.

Due to high preparation costs, insurance companies generally do not cover autologous blood serum eye drops (“ABSEDs”) (Bedinghous, Fogoros, 2018).

## PALA™ Kit Description

The term “PALA” stands for Portable Aseptic Level Assurance. The patents pending, PALA™ Kit (“PALA Kit”) by AseptiKits, LLC, comprises a sterile, closed system processing bag with integral .2-micron syringe filter and all of the mixing/transfer supplies needed for processing centrifuged autologous blood. A proprietary tray helps secure each eye drop bottle in an upright position to avoid spillage. All filling and capping of each eye drop bottle is completed from the exterior of the bag thereby maintaining product sterility throughout each procedure.

The kit is designed to enable clinicians to process and provide blood serum in a normal saline solution of various prescribed concentrations. The .2-micron syringe filter produces eye drops having a sterility assurance level (“SAL”) of 10-6 in virtually any environment outside of a laminar flow hood. Given the need to refrigerate the eye drops after processing (Hassan, 2012), a set of freezer packs and an insulated pouch are also provided. This means that ABSEDs can be processed in a doctor’s office, lab, pharmacy or any place where qualified medical personnel are available.

The kit was created using off-the-shelf proved components and meets all requirements pertaining to a “convenience kit” under FDA guidelines. The product is assembled by a contract manufacturer under an existing FDA 510(k) for procedure kits.

# AUTOLOGOUS BLOOD SERUM EYE DROPS
# Information Sheet

The PALA kit enables clinicians to provide ABSEDs in any environment where there is access to a phlebotomist, blood drawing supplies and a centrifuge.

## Summary and Conclusions

Severe dry eye disorders afflict over 1.5 million patients per year. It has been known for decades that such disorders are readily treated using autologous blood serum and saline to provide eye drops. Unfortunately, many ABSED processing barriers, including high costs and concerns about contamination, prevented patients from having access to ABSEDs and receiving relief.

The PALA Kit provides a closed system ABSED processing kit that solves contamination issues through use of an integral .2-micron syringe filter and sterile bag, while making processing of ABSEDs easy and simple in virtually any environment outside of a laminar flow hood. A proprietary tray helps keep the eye drop bottles in an upright position and facilitates securing the bottles while enabling capping of the bottles from the exterior of the bag. The kit is designed for use in doctor offices, labs and pharmacies. Processing the blood is fast, simple and easy while avoiding issues associated with processing such drops under a laminar flow hood.

## References Allen, L.

(2016). Autologous serum 20% in Sodium Chloride Ophthalmic Solution. U.S. Pharmacist. 2016;41(6)40-41. Retrieved from https://www.uspharmacist.com/article/autologous-serum-20-in-sodium-chloride-ophthalmic-solution Anitua, E., Muruzabal, F., Tayebba, A., Riestra, A., Perez, V., Merayo-Lloves, J. (2015). Autologous serum and plasma rich in growth factors in ophthalmology: preclinical and clinical studies. Acta Ophthalmologica. April 2, 2015. Retrieved from https://onlinelibrary.wiley.com/doi/full/10.1111/aos.12710 Bedinghous, T., Fogoros, N. (2018). Will Autologous Serum Eye Drops Work for Me? Eye Health: Dry Eye Syndrome. September 11, 2018. Retrieved from https://www.verywellhealth.com/autologous-serum□eye-drops-3422030 Brennan, K. (2016). Thicker than Water: The benefits and limitation of this unique therapy. Review of Ophthalmology. November 2016. Retrieved from https://www.reviewofophthalmology.com/article/thicker-than-water-autologous-serum Community Pharmacy (2018). Retrieved from www.communitypharmacy.com/autologous_serum_eye_drops.html Geerling, G., MacLennan, S., Hartwig, D. (2004). Autologous serum eye drops for ocular surface

disorders. British Journal of Ophthalmology. 2004;88:1467-1474. Retrieved from https://bjo.bmj.com/content/88/11/1467 Hassan, M. (2012). Autologous serum eye drops reduce ocular surface disease symptoms: Downsides include risk of bacterial infection and the need to refrigerate drops. Primary Care Optometry News. October 2012. Retrieved from https://www.healio.com/optometry/cornea-external-disease/news/print/primary-care-optometry news/%7B3e8ebb26-ec2f-415c-bda7-4a37a3a2f7d8%7D/autologous-serum-eye-drops-reduce-ocular surface-disease-symptoms Lipner, M. (2017). Pharmaceutical focus: Getting to the dry truth. Ophthalmology News. December 2017. Retrieved from https://www.eyeworld.org/getting-dry-truth.