SENEGENCE® EYECRÈME

Eye-area care, tested with clinical precision.

In an independent two-week home-use study, board-certified ophthalmologist examinations, visual-acuity testing, participant check-ins, and daily diaries supported use around the eye area - including among contact-lens wearers.

30 completed | 2 weeks | Ophthalmologist observed | Tested as SGF19112-03

30

participants completed the study

2 WEEKS

31 enrolled; women ages 19-69.

0 observed

test-article-related adverse effects

FINAL OPHTHALMOLOGIST EXAMINATION

Among 30 completers under the study conditions.

8

contact-lens wearers completed

INCLUDED IN FINAL ASSESSMENT

Nine enrolled; eight completed.

CLINICAL SAFETY-IN-USE EVIDENCE

Three complementary layers of observation supported the final safety conclusion.

01

Ophthalmologist examination

Baseline and two-week examination of upper and lower eyelids and lid margins, conjunctivae, visible corneal anomalies, slit-lamp findings, and the periorbital area.

02

Visual-acuity assessment

A trained evaluator measured visual acuity at baseline and after two weeks; no clinically relevant changes were found.

03

Participant monitoring

A one-week call-in and daily safety diaries captured observations during twice-daily home use.

Descriptive results

Safety evidence	Finding among 30 completers
Ophthalmologist examination	No test-article-related adverse effects observed
Visual acuity	No clinically relevant changes
One-week check-in	No problems reported
Daily safety diaries	No negative safety-related comments
Contact-lens subgroup	Eight wearers completed without observed test-article-related adverse effects

This safety study did not report inferential tests or p-values.

CLAIMS SUPPORTED BY THE ESSEX CONCLUSION

Ophthalmologist-Tested and **Safe for Contact Lens Wearers**, for the tested formula under the defined two-week conditions.

TECHNICAL STUDY RECORD

A signed Essex final report authenticates the safety-in-use conclusion.

INDEPENDENT LABORATORY Essex Testing Clinic, Inc.	PANEL / ENTRY 21663 / 46915
SPONSOR CODE S174	TESTED ARTICLE Eye Creme AGE Defense Formula SGF19112-03
DESIGN 2-week, single-blind home-use safety evaluation	POPULATION 31 enrolled; 30 completed; ages 19-69
USE Twice daily, morning and night	REPORT DATE 24 January 2022

INDEPENDENT CONCLUSION

The Essex report concluded that the submitted product was safe for use in the eye area and supported the statements “Ophthalmologist-Tested” and “Safe for Contact Lens Wearers.”

STUDY APPLICATION

Results support “Ophthalmologist-Tested” and “Safe for Contact Lens Wearers” for Eye Creme AGE Defense Formula SGF19112-03 under the reported two-week safety-in-use design.

INDEPENDENT LABORATORY EVIDENCE

Original source pages follow.

Original Essex pages follow, preserving the laboratory cover, study metadata, signed investigator approvals, Quality Assurance statement, methods, and aggregate safety findings while excluding participant-identifying tables and administrative forms.

LABORATORY **Essex Testing Clinic, Inc.**	PANEL / ENTRY **21663 / 46915**
REPORT DATE **24 January 2022**	AUTHENTICATION **Signed investigators + signed QA statement**

SOURCE AUTHENTICATION

The final source includes signed investigator approvals and a signed independent Quality Assurance statement.

Independent laboratory source pages are included in the complete PDF. Participant-identifying information has been removed where indicated; aggregate findings are unchanged.

ESSEX
TESTING CLINIC

FINAL REPORT

CLINICAL EVALUATION OF THE OPHTHALMOLOGIC SAFETY-IN-USE OF AN EYE CREAM

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

Sponsor

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

Sponsor Representative

Nikki Chew
Director, Research & Development

Clinical Testing Facility

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

Sponsor Code: S174
ETC Panel No.: 21663
ETC Entry No.: 46915

Date of Final Report

01.24.22

ETC Panel No.: 21663
ETC Entry No.: 46915

SIGNATURE PAGE

CLINICAL EVALUATION OF THE OPHTHALMOLOGIC SAFETY-IN-USE OF AN EYE CREAM

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

G. Argueta — 1/18/22

Gabriela Argueta
Project Manager
Study Director

Date

1.21.22

Toni F. Miller, PhD, DABT, BCFE
Scientific Director
Principal Investigator

Date

Lynda Ann Youngworth, MD — 1/18/22

Lynda Ann Youngworth, MD
Board-Certified Ophthalmologist
Medical Investigator

Date

Essex Testing Clinic, Inc.

QUALITY ASSURANCE STATEMENT

This study (ETC Panel No.: 21663; ETC Entry No.: 46915) was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects – Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

For purposes of this clinical study:

_X_	Informed Consent was obtained.
____	Informed Consent was not obtained.
_X_	An IRB review was not required.
____	An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This report is considered a true and accurate reflection of the testing methods and source data.

Sherri L Sayles 21 Jan 2022

Sherri L. Sayles, MS
Manager, Quality Assurance

Date

TABLE OF CONTENTS

CLINICAL EVALUATION OF THE OPHTHALMOLOGIC SAFETY-IN-USE OF AN EYE CREAM

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

1.0 OBJECTIVE

The objective of this study was to evaluate the ophthalmologic safety-in-use of an eye cream after 2 weeks of use by a panel of 30 female volunteers aged 18-69 years, approximately 25% of whom were to be contact lens wearers. Pre- and post-test eye examinations were performed by a Board-Certified Ophthalmologist to support the claims "Ophthalmologist-Tested" and "Safe for Contact Lens Wearers".

2.0 SPONSOR

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

2.1 Sponsor Representative

Nikki Chew
Director, Research & Development

3.0 CLINICAL INVESTIGATORS

Study Director:	Gabriela Argueta Project Manager
Study Coordinator:	Jackson Hinden
Principal Investigator:	Toni F. Miller, PhD, DABT, BCFE Scientific Director
Medical Investigator:	Lynda Ann Youngworth, MD Board-Certified Ophthalmologist

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 STUDY DATES

Start Date:	November 22, 2021
Finish Date:	December 6, 2021

6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

7.0 TEST MATERIALS

The test article used in this study was provided by:

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

It was received on October 21, 2021, and identified as follows:

ETC Entry No.	Qty Rec'd	Test Article ID	Physical Description
46915	35 Jars	SeneDerm Eye Creme AGE Defense Formula# SGF19112-03	Beige Semi-solid

8.0 TEST SUBJECTS

Approximately 35 female subjects, between 18 and 69 years of age and in general good health, were to be empanelled to ensure that at least 30 completed the study (approximately 25% of whom were to be contact lens wearers). All subjects were required to read, understand and sign a written Informed Consent Form (Appendix A) and completed a brief Medical History Form (Appendix B).

9.0 TEST PROCEDURE

The use test was conducted in accordance with the appended Study Protocol (Appendix C).

Prior to study enrollment, potential subjects completed a Medical History Form. The subjects who met the study criteria based on this review were given an ophthalmologic examination. Subjects who met the inclusion/exclusion criteria were empanelled. All enrolled subjects were examined by the Medical Investigator (a Board-Certified Ophthalmologist) prior to initiation of the study and at the end of a 2-week use period. The subjects were instructed to call the Clinic after 7 days of use and as necessary during the remainder of the study to document if any problems had occurred.

The examinations included: upper and lower eyelids and margins, conjunctivae, visible corneal anomalies, slit lamp examinations and a general examination of the periorbital area of the eyes. In addition, pre- and post-test visual acuity examinations were performed by a trained evaluator. All findings were recorded on individual subject Data Recording Forms (Appendix D). The type of contact lenses (hard, soft, extended wear, etc.) used by the subjects was recorded on the subject's Medical History Form. The prospective subjects were asked *not* to wear any eye makeup product during the first (qualifying) and final ophthalmologic examinations.

Enrolled subjects were issued the eye cream and instructed on the use of the product as pre-determined by the Testing Clinic and/or Sponsor for the period of 2 weeks. During this period, subjects were instructed not to use any other eye creams or introduce any new personal care products around the face/eye area during the course of the study. A Daily Diary Form (Appendix E) was given to each subject to record the date and time of application and to attest to the use of the product per instructions. Subjects returned the test article at the final visit.

INSTRUCTIONS: The following items must be included in this diary:

1. Date and times test article was used.
2. Any comments or observations you may have had while using the test article.

DIRECTIONS FOR USE:

1. Use twice a day, morning and night.
2. Apply on upper eyelid and under eye.
3. Record uses in diary.

10.0 RESULTS AND DISCUSSION

A total of 31 female subjects (ranging in age from 19 to 69 years and 9 of whom were contact lens wearers) were enrolled on November 22, 2021. Thirty (30/31) subjects completed the single-blind, home-use test on December 6, 2021. Subject No. 14 discontinued due to personal reasons unrelated to the conduct of the study. Subject demographics are presented in Table 1. Of the total subjects completing the study, 8 subjects were contact lens wearers, 7 wore glasses, and 15 had uncorrected vision.

Visual Acuity

Visual acuity examinations, made by a trained evaluator, were conducted at baseline (pre-test) and again after 2 weeks of test article use (post-use). There were no clinically relevant changes in the visual acuity of any test subject. The results are summarized in Table 2.

Ophthalmologist Examinations/Call-in Comments

All subjects called the clinic after 1 week of use. There were no problems reported at that time. There were no test article-related adverse effects observed by the examining Ophthalmologist at the 2-week post-use examination. These results are summarized in Table 3.

Daily Diary Comments

There were no negative safety-related diary comments made by any of the subjects who commented during the course of the study. All comments are listed in Table 4.

11.0 CONCLUSIONS

A single-blind, home-use test was conducted with 30 female subjects (27% of whom were contact lens wearers) who used Test Article: **SeneDerm Eye Creme AGE Defense Formula# SGF19112-03** twice daily for 2 weeks. Test Article: **SeneDerm Eye Creme AGE Defense Formula# SGF19112-03** was found to be safe for use in the eye area and the claims "Ophthalmologist-Tested" and "Safe for Contact Lens Wearers" are considered to be supported.

ESSEX
TESTING CLINIC

STUDY PROTOCOL

CLINICAL EVALUATION OF THE OPHTHALMOLOGIC SAFETY-IN-USE OF AN EYE CREAM

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

Sponsor

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

Sponsor Representative

Nikki Chew
Director, Research & Development

ETC Panel No.:
21663

November 16, 2021

799 Bloomfield Avenue · Verona, NJ 07044 · (973) 857-9541 · Fax # (973) 857-9662

STUDY PROTOCOL

CLINICAL EVALUATION OF THE OPHTHALMOLOGIC SAFETY-IN-USE OF AN EYE CREAM

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

1.0 OBJECTIVE

The objective of this study is to evaluate the safety-in-use of an eye cream after 2 weeks of use, with pre- and post-test eye examinations being performed by a Board-Certified Ophthalmologist to support the claims "Ophthalmologist-Tested" and "Safe for Contact Lens Wearers" by a panel of 30 female volunteers aged 18-69 years, approximately 25% of whom will be contact lens wearers.

2.0 SPONSOR

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

2.1 Sponsor Representative

Nikki Chew
Director, Research & Development

3.0 CLINICAL INVESTIGATORS

Medical Investigator: Lynda Youngworth, MD, Board-Certified Ophthalmologist
Principal Investigator: Toni F. Miller, PhD, DABT, BCFE, Scientific Director
Study Director: Gabriela Argueta, Project Manager
Study Coordinator: Jackson Hinden

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 ETC PANEL NUMBER

21663

6.0 STUDY DATES

Start: November 22, 2021
End: December 6, 2021

7.0 ETHICS

7.1 Ethical Conduct of the Study

This study will be conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

7.2 Subject Information and Consent

This study will be conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent will be obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent will be provided to each subject.

8.0 TEST MATERIAL

The test article will be supplied by the Sponsor in individual containers suitable for the study design. It will be identified as follows:

SeneDerm Eye Creme AGE Defense Formula# SGF19112-03

8.1 Storage

Upon receipt, test articles supplied will be logged in according to ETC's SOPs. They will be stored at room temperature and in a secure area. The test articles will be distributed only to subjects entered into the study, under the supervision of the Study Director/Principal Investigator, in accordance with the conditions specified in the protocol.

8.2 Packaging and Labeling (Coding)

The investigational materials will be packaged and labeled (coded) by the Study Sponsor in a manner consistent with the study design.

8.3 Disposition

Used test articles will be disposed of at the completion of testing, unless otherwise noted by the Study Sponsor. Unused test articles will be kept at the Testing Facility for 90 days after completion of testing. With the exception of a retained sample, the remaining portions will then be properly disposed of by the Testing Facility.

9.0 STUDY DESIGN

9.1 Subject Selection

Approximately 35 female subjects, between 18 and 69 years of age and in general good health, will be empanelled to ensure that at least 30 complete the study (approximately 25% of whom will be contact lens wearers). All subjects will be required to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

9.1.1 Inclusion Criteria

a. Females between the ages of 18 and 69 years, in general good health, who are able to read, understand, and sign an Informed Consent Form.
b. Women who will indicate their willingness to participate in the study, follow directions, and stay on the study for the entire 14 days.
c. Women who are free of any skin/eye condition or a history of skin/eye conditions that might interfere with the purpose, conduct or integrity of the study.
d. Women who are regular users of eye cream.

9.1.2 Exclusion Criteria

a. Any woman who does not meet the inclusion criteria.
b. Women who are pregnant, planning a pregnancy or nursing a child.
c. Women with a known sensitivity to skincare products.
d. Women using systemic or topical anti-inflammatory agents with the exception of OTC acetaminophen (eg, Tylenol), ibuprofen (eg, Advil), or aspirin for 5 days prior to the start of testing.
e. Women who cannot agree to not use systemic or topical anti-inflammatory agents, with the exception of OTC acetaminophen (eg, Tylenol), ibuprofen (eg, Advil) or aspirin during the course of the study.
f. Women who have participated in another clinical (face/eye) study within 14 days of study initiation.

9.0 STUDY DESIGN (CONT'D)

9.2 Test Procedure

Subjects will report to the Testing Facility with a freshly washed "clean face" (without wearing face/eye area cosmetics). All subjects will be examined by the Medical Investigator (a Board-Certified Ophthalmologist) on Day 1 of the study. The examinations will include: upper and lower eyelashes and margins, conjunctivae, visible corneal anomalies, slit lamp examinations and a general examination of the periorbital area of the eyes.

In addition, a pre-test visual acuity examination will be performed by a trained evaluator. All findings will be recorded on individual subject data forms. The type of contact lenses (hard, soft, extended wear, etc.) used by the subjects will also be recorded on the subject Medical History Forms.

Immediately after baseline evaluations, the subjects will be given the test article and daily diary with the following instructions:

INSTRUCTIONS: The following items must be included in this diary:

1. Date and time test article was used.
2. Any comments or observations you may have had while using the test article.

DIRECTIONS FOR USE:

1. Use twice a day, morning and night.
2. Apply on upper eyelid and under eye.
3. Record use in diary.

The subjects will also be instructed to call the Clinic after 7 days of use and as necessary during the remainder of the study to document if any problems have occurred and to review product use.

After 2 weeks of use, all subjects will return to the Clinic with the remaining test article and their diary. The Medical Investigator will re-examine each subject for any reactions to the contact area. In addition, a post-test visual acuity examination will be performed by a trained evaluator. Pre- and post-use examinations will be documented on the Data Form.

9.0 STUDY DESIGN (CONT'D)

9.3 Concomitant Usage of Eye/Face Products

All subjects must use only the eye cream provided during the course of the study. They may not use any other eye cream or introduce any new personal care products or cosmetics on the face or around the eye area during the course of the study.

9.4 Adverse Reactions

Any reported and/or observed adverse reactions will be promptly reported to the Principal/Medical Investigators. If deemed appropriate, the Sponsor will be notified. In any case, any adverse response/reaction related to the study will be noted in the individual's data form.

10.0 RECORD RETENTION

All records pertaining to this study will be retained by Essex Testing Clinic, Inc. for a period of not less than 2 years following the submission of the Final Report.

11.0 FINAL REPORT

Within 4-5 weeks following the conclusion of the study (approximately January 10, 2021), a Draft/Final Report will be submitted to the Sponsor citing experimental design, summarized data, clinical observations, subject demographics (age, sex, etc.), and any pertinent subjective comments (stinging, burning, itching, etc.) by the subjects and an evaluation of the test results from the aspect of efficacy. The report will also include a copy of the Study Protocol, Informed Consent Form, Medical History Form, Data sheets and Daily Diary.

12.0 ACCEPTANCE OF PROTOCOL

By signature below, it is represented that the protocol contains all necessary details for carrying out this study. This study will be conducted according to this protocol. Any modifications to this protocol must be approved by both the Sponsor and Essex Testing Clinic, Inc.

Toni F. Miller, PhD, DABT, BCFE
Scientific Director
Essex Testing Clinic, Inc.

11/17/21
Date

Nikki Chew
Director, Research & Development
SeneGence International

11/17/21
Date

Essex Testing Clinic, Inc._____