# Clinical Product Testing

## Dermatologically Controlled Patch Test Report

| | |
|---|---|
| **Client/Sponsor** | Upgrad'd Labs |
| **Client Address** | Unit E2 Churcham Business Park, Churcham, Gloucestershire, GL28AX |
| **Co-ordinator** | - |
| **Co-ordinator Address** | - |
| **Contact** | harriet.blackmore@upgradd.co.uk |
| **Investigational Product** | SYCL 4 |
| **Batch Reference** | |
| **ADSL Reference** | 22975 |
| **Study Centre** | Advanced Development & Safety Laboratories Limited<br>Unit 18 Yalberton Tor Industrial Estate, Paignton, Devon TQ4 7QN, UK |
| **No. Samples** | 1 |
| **Study Start Date** | 3/3/2025 |
| **Study Contact** | Hannah Folland |
| **Dermatological Oversite** | Dr Alice Walker (Dermatologist - GMC 7088381) |




**Advanced Development & Safety Laboratories Limited**
Units 9,17 & 18 Yalberton Tor Industrial Estate, Alders Way, Devon TQ4 7QN, United Kingdom
T: +44 (0) 1803 520 048 F: +44 (0) 1803 520 910 E: enquiries@adslaboratories.com

**Study Results and Observations**
This report is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study. The reported results relate exclusively to the tested sample and was performed at the stated study centre.

**Quality Assurance & Overview**
This study was conducted at the stated study centre with relevant company and individual qualification including;

**Company**
- Accreditation according to ISO 9001:2015
- Accreditation according to ISO 17025:2017

**Competent Employees**
- BSc (Hons) App. Chem CSci, CChem FRSC, PhD
- Fellow of the Royal Society Of Chemistry and a "Chartered" Chemist and Scientist
- Members of The Society Of Cosmetic Scientists
- Members of the British Toxicology Society
- Members of Society of Dermatology
- Members of International Society of Dermoscopy
- Members of European Academy of Dermatology & Venereology (EADV)
- Members on the Editorial board of the journal Dermatopathology

**Other Declarations**
I declare that the following report constitutes an accurate account of the procedures adopted and the results obtained in the performance of this study. The study was performed in accordance with the principles of *Good Clinical Research Practice* and in consideration of the *Declaration of Helsinki* relating to ethical principles for research involving human subjects.

| | |
|---|---|
| **Service Category:** | A shared 96-hour Human patch test in 30 healthy male and female subjects, to investigate the skin irritation potential of test articles and two standard controls following application under occlusion. |
| **Study Design:** | Single-blind, within-subject comparison. |
| **Test Articles:** | • Client Supplied Investigational Product (IP)<br>• Laboratory Supplied Negative Control (NC) (Deionised Water)<br>• Laboratory Supplied Positive Control (PC) (SLS 0.3%) |
| **Dosage Regime:** | Every 24 hours / 4 applications |
| **Application:** | Rinse-off test articles are diluted to 8% in deionised water prior to use. Leave-on products are applied as is. The patches consisted of occlusive Finn Chamber on Scanpor 8mm tape to which Webril (Kendall Corporation) disks, approximately 2.5cm in diameter were fixed along the midline, mainly upper back (or upper arms when upper back was not suitable). |
| **Assessment:** | All of the sites were graded by the same qualified assessor on all days according to the European Society of Contact Dermatitis guidelines for diagnostic patch testing, published in July 2015. Illumination of the sites was by a 60 watt pearl bulb, approximately 30 cm from the site. Scoring of any skin reactions after the first, second, third and fourth dressing removal were recorded according to the evaluation scale. |
| **Duration of Treatment:** | 5 days |
| **Number of Subjects:** | 30 |
| **Type of Subjects:** | Healthy consenting volunteers, of either sex, aged at least 18 years old and according to the Ethical Considerations and Exclusion Criteria. |

**Synopsis**

- Characteristics of the included Panel
- Mean Daily Irritation Score (MDIS) of Investigational Product (IP)
- Mean Daily Irritation Score (MDIS) of Negative Control (NC)
- Mean Daily Irritation Score (MDIS) of Positive Control (PC)
- Statistical Comparisons
- Mean Irritation Index (MII)
- Conclusion

**Disclaimer**

- Study Control
- Principle Objective
- General Principles
- Ethical Considerations
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**Study Protocol**

- Application of IP / NC / PC
- Patch Chamber Removal
- Evaluation Scale

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- Profile Plot of PC vs IP
- Investigational Product (IP) Grading Evaluation
- Negative Control (NC) Grading Evaluation
- Positive Control (PC) Grading Evaluation

## Synopsis

### Characteristics of the included Panel

| | |
|---|---|
| **Number of Subjects** | 30 |
| **Number of Exclusions** | 0 |
| **Number of Withdrawals** | 0 |
| **Number of Valid Cases** | 30 |
| **Age Range** | 18 - 69 |
| **Female Subjects** | 23 |
| **Male Subjects** | 7 |
| **Fitzpatrick Assessment Range** | 6 - 25 |
| **Skin Types** | Sensitive |

### Mean Daily Irritation Score (MDIS) of Investigational Product (IP)

*MDIS is calculated by adding up the evaluation grades recorded for the subjects within the Panel then dividing the total by the number of subjects. A mean value is returned.*

| Time | Valid | Missing | MDIS | Median | STDEV | Min | Max |
|---|---|---|---|---|---|---|---|
| IP-24 | 30 | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| IP-48 | 30 | 0 | 0.07 | 0.00 | 0.37 | 0.00 | 2.00 |
| IP-72 | 30 | 0 | 0.10 | 0.00 | 0.40 | 0.00 | 2.00 |
| IP-96 | 30 | 0 | 0.20 | 0.00 | 0.66 | 0.00 | 3.00 |

### Mean Daily Irritation Score (MDIS) of Negative Control (NC)

*MDIS is calculated by adding up the evaluation grades recorded for the subjects within the Panel then dividing the total by the number of subjects. A mean value is returned.*

| Time | Valid | Missing | MDIS | Median | STDEV | Min | Max |
|---|---|---|---|---|---|---|---|
| NC-24 | 30 | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| NC-48 | 30 | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| NC-72 | 30 | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| NC-96 | 30 | 0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

**Mean Daily Irritation Score (MDIS) of Positive Control (PC)**

*MDIS is calculated by adding up the evaluation grades recorded for the subjects within the Panel then dividing the total by the number of subjects. A mean value is returned.*

| Time | Valid | Missing | MDIS | Median | STDEV | Min | Max |
|---|---|---|---|---|---|---|---|
| NC-24 | 30 | 0 | 0.07 | 0.00 | 0.37 | 0.00 | 2.00 |
| NC-48 | 30 | 0 | 0.23 | 0.00 | 0.57 | 0.00 | 2.00 |
| NC-72 | 30 | 0 | 0.57 | 0.00 | 0.68 | 0.00 | 2.00 |
| NC-96 | 30 | 0 | 0.63 | 1.00 | 0.67 | 0.00 | 2.00 |

**Statistical Comparisons**

An overview of results confirms…

- Skin reactions to PC significantly higher than NC at 5% level of significance as all p-values are smaller than 0.05.
- Skin reactions to PC significantly higher than IP at 5% level of significance as all p-values are smaller than 0.05.

**Mean Irritation Index (MII)**

*MII is calculated by adding up the MDIS for each of the time periods and then dividing by the total number of time periods. A mean value is returned.*

| Product | Mean Irritation Index (MII) | Cumulative Irritation Potential* |
|---|---|---|
| Investigational Product (IP) | 0.09 | *Not Irritating* |
| Negative Control (NC) | 0.00 | *Not Irritating* |
| Positive Control (PC) | 0.38 | *Mildly Irritating* |

**< 0.30 = Not Irritating; MII < 0.75 = Mildly Irritating; MII < 1.50 = Moderately Irritating; MII > 1.50 = Strongly Irritating*

**Conclusion**

Single application under occlusive patch of the Investigational Product (IP) under the control of a dermatologist induced no reaction of irritation and has a very good skin compatibility. The following claims are substantiated for the Investigational Product (IP):

- Dermatologically tested
- Dermatologically approved
- Clinically tested
- Safe for skin
- Suitable for sensitive skin

**Disclaimer**

As per COLIPA guidelines the test was performed under the assumption that the Client is responsible for providing ADSL with clear and truthful information concerning any ingredient within the Investigational Product with potential toxicological relevance. On this basis a general assessment of the toxicological information concerning the product was preliminarily undertaken and ethical implications as to its use during the present study considered.

**Study Control**

**Principle Objective**

This Patch Test was conducted in order to assess the potential of the Investigational Product (IP) to induce contact sensitization in the skin of healthy volunteers. The study aims to provide a better knowledge of the skin safety of the Investigational Product (IP) under controlled conditions.

**General Principles**

- Products are tested pure or diluted depending on product type and intended use. In most cases are tested pure. The rinsing products are diluted at 8% unless otherwise specified and depending on the kind of product. The hydrophilic products are diluted in demineralized water while lipophilic products are diluted in mineral oil.
- Powders are placed in the small area of the device for occlusive application and a drop of demineralized water or mineral oil is added to facilitate the homogeneous dispersion on the application surface and to ensure a good contact with the skin.
- Solid materials are reduced into small pieces of dimensions suitable to be applicable onto the test discs of the occlusive device.
- The observation of the effects caused by the application of the test substance is performed c. 15 minutes after the patch removal. Clinical analysis is performed according to a scale proportional to the severity of irritation for each of the considered irritation phenomena (erythema, desquamation, edema, vesicles).

**Ethical Considerations**

This study has been performed in accordance with the principles of *Good Clinical Research Practice* and in consideration of the of the *Helsinki Declaration* (Helsinki Declaration 64th WMA General Assembly, Fortaleza, Brazil, October 2013) relating to ethical principles for research involving human subjects. It has followed the “Guidelines for the Assessment of Skin Tolerance of Potentially irritant Cosmetic ingredients", COLIPA, 1997.

- Subjects were recruited according to the specified recruitment criteria of inclusion and exclusion
- Subjects were informed about the purpose and type of study, the possible risks, and provided written consent
- Information concerning the toxicological profile of the product were obtained prior to the study
- Precautions were taken to avoid excessive skin reactions or adverse effects
- Security measures have been prepared in case of adverse reactions & emergency contact information provided

Furthermore, subject data is held according to the requirement of General Data Protection Regulation (GDPR).

**Exclusion Criteria**

- Pregnant women
- Subjects with excessive blemishes, marks, scars, sunburns on the test site(s) which could interfere with scoring
- Forms of medication which may affect skin response
- Signs of pre-existing skin irritation on test site(s)
- Participation in simultaneous studies which that might interfere with the test evaluation
- Minors

During the study the following withdrawal criteria were applied:

- Subjects who did not follow the requested conditions
- Subjects who suffered any illness or accident or developed any condition which could affect the outcome of the study
- Subjects who no longer wish to participate in the study

Subjects were asked to refrain from exposure to UV rays and to avoid getting the patches wet and asked to provide information concerning the use of any drug, with particular reference to anti-inflammatory drugs, steroids and antihistamines.

**Study Protocol**

**Application of IP / NC / PC**

The area of skin designated for patch testing was cleaned with demineralized water and towel dried. The patch was applied to the cleaned area.

**Patch Chamber Removal**

At the applicable time intervals the patch was removed and residue was wiped away. c. 15 minutes after removal of the patch the application area was carefully examined by the competent study monitor to evaluate skin reactions and grade accordingly with values ranging from 0 to 3 to express differences in observable reactions.

**Evaluation Scale**

| | |
|---|---|
| **ERYTHEMA**<br>*Superficial reddening of the skin as a result of irritation causing dilatation of the blood capillaries* | |
| None | **0** |
| Light erythema, hardly noticeable | **1** |
| Moderate and uniform redness | **2** |
| Severe and uniform redness | **3** |
| **OEDEMA**<br>*A buildup of fluid in the body which causes the affected tissue to become swollen* | |
| None | **0** |
| Slight (edges of area well defined by definite raising) | **1** |
| Moderate (raised approximately 1 mm) | **2** |
| Severe (raised more than 1 mm / extending beyond the area of exposure) | **3** |
| **DRYNESS/DESQUAMATION**<br>*Skin peeling / shedding of the outermost membrane or layer of skin* | |
| None | **0** |
| Dryness with light desquamation (smooth skin) | **1** |
| Moderate desquamation | **2** |
| Severe desquamation | **3** |
| **VESICLES**<br>*Small, fluid-filled sacs that can appear on the skin* | |
| None | **0** |
| Very small vesicles (barely visible) | **1** |
| Clearly visible, small vesicles (well-defined contours) | **2** |
| Large, well-defined vesicles | **3** |

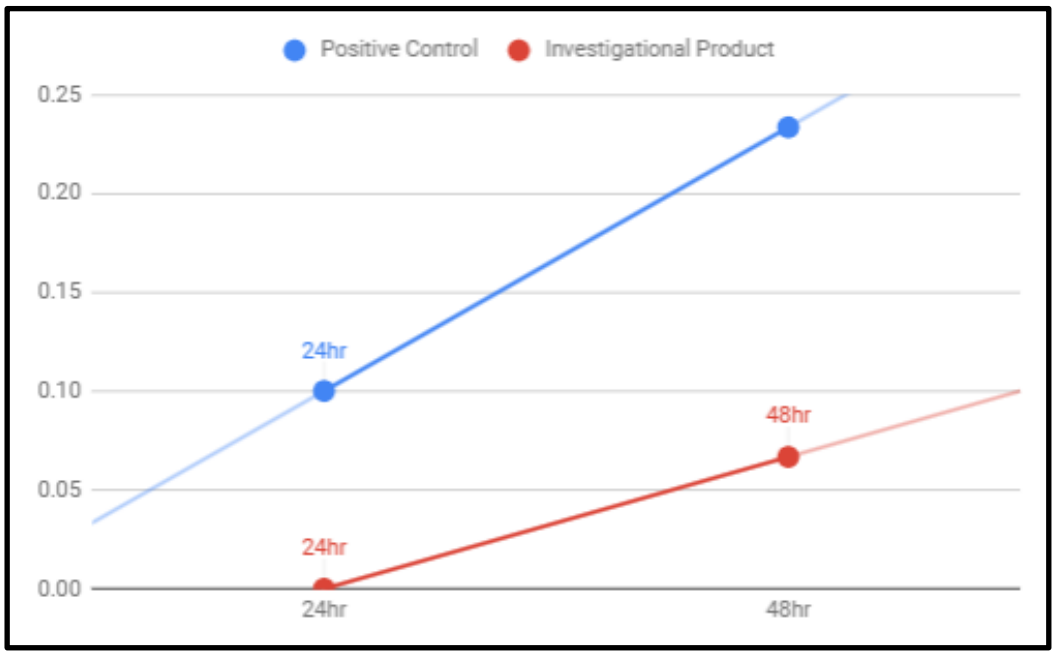
**Data Control and General Data Protection Regulation**

Subject data is held according to the requirement of General Data Protection Regulation (GDPR) with the data being archived electronically by Advanced Development & Safety Laboratories Limited. Residual sample of the Investigational Product (IP) is kept for c. 1 month unless otherwise specified.

The information concerning the subjects required as part of undertaking the testing was confidentially treated and any photos are taken in a manner as to deem the subject non-recognizable. Identifiable personal information of subjects is not communicated with third parties. As part of reporting the results from Patch Tests & User Evaluations we anonymise data so we are able to share study information with Clients for the purposes of meeting the relevant regulation. Due to the fact that personal data is rendered anonymous and any external publication does not relate to an identified or identifiable natural person, the principles of data protection will not apply.

## Tables

### Profile Plot of PC vs IP



## Investigational Product (IP) Grading Evaluation

| | 24hr ERYTHEMA Grade | 24hr OEDEMA Grade | 24hr DRYNESS/DESQUAMATION Grade | 24hr VESICLES Grade | 24hr Combined Evaluation | 48hr ERYTHEMA Grade | 48hr OEDEMA Grade | 48hr DRYNESS/DESQUAMATION Grade | 48hr VESICLES Grade | 48hr Combined Evaluation | 72hr ERYTHEMA Grade | 72 hr OEDEMA Grade | 72hr DRYNESS/DESQUAMATION Grade | 72hr VESICLES Grade | 72hr Combined Evaluation | 96hr ERYTHEMA Grade | 96 hr OEDEMA Grade | 72hr DRYNESS/DESQUAMATION Grade | 96hr VESICLES Grade | 96hr Combined Evaluation | Comments | Gender |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | | Female |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Tape reaction (mc | Male |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | | Female |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | Tape reaction (mil | Male |
| 12 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 1 | 3 | | Female |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Male |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | Female |
| 30 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| DCIS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| MDIS | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.07 | 0.00 | 0.00 | 0.00 | 0.07 | 0.10 | 0.00 | 0.00 | 0.00 | 0.10 | 0.17 | 0.00 | 0.00 | 0.03 | 0.20 | | |
| Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | |
| STDEV | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.37 | 0.00 | 0.00 | 0.00 | 0.37 | 0.40 | 0.00 | 0.00 | 0.00 | 0.40 | 0.53 | 0.00 | 0.00 | 0.18 | 0.66 | | |
| Min | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | | |
| Max | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 1.00 | 3.00 | | |

## Negative Control (NC) Grading Evaluation

| Subject No. | 24hr ERYTHEMA Grade | 24hr OEDEMA Grade | 24hr DRYNESS/DESQUAMATION Grade | 24hr VESICLES Grade | 24hr Combined Evaluation | 48hr ERYTHEMA Grade | 48hr OEDEMA Grade | 48hr DRYNESS/DESQUAMATION Grade | 48hr VESICLES Grade | 48hr Combined Evaluation | 72hr ERYTHEMA Grade | 72hr OEDEMA Grade | 72hr DRYNESS/DESQUAMATION Grade | 72hr VESICLES Grade | 72hr Combined Evaluation | 96hr ERYTHEMA Grade | 96hr OEDEMA Grade | 96hr DRYNESS/DESQUAMATION Grade | 96hr VESICLES Grade | 96hr Combined Evaluation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 2 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 3 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 4 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 5 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 6 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 7 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 8 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 9 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 10 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 11 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 12 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 13 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 14 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 15 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 16 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 17 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 18 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 19 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 20 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 21 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 22 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 23 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 24 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 25 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 26 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 27 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 28 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 29 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| 30 | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** | 0 | 0 | 0 | 0 | **0** |
| **IDIS** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **MDIS** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Median** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **STDEV** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Min** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Max** | 0.00 | 0.00 | 0.00 | 0.00 | **0.00** | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

**Positive Control (PC) Grading Evaluation**

| | 24hr ERYTHEMA Grade | 24hr OEDEMA Grade | 24hr DRYNESS/DESQUAMATION Grade | 24hr VESICLES Grade | 24hr Combined Evaluation | 48hr ERYTHEMA Grade | 48hr OEDEMA Grade | 48hr DRYNESS/DESQUAMATION Grade | 48hr VESICLES Grade | 48hr Combined Evaluation | 72hr ERYTHEMA Grade | 72 hr OEDEMA Grade | 72hr DRYNESS/DESQUAMATION Grade | 72hr VESICLES Grade | 72hr Combined Evaluation | 96hr ERYTHEMA Grade | 96 hr OEDEMA Grade | 72hr DRYNESS/DESQUAMATION Grade | 96hr VESICLES Grade | 96hr Combined Evaluation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 1 |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 2 |
| 9 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 2 |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 11 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 1 |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 17 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 19 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 20 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 1 |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 22 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 26 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| 28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 30 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |
| DCIS | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| MDIS | 0.07 | 0.00 | 0.00 | 0.00 | 0.07 | 0.23 | 0.00 | 0.00 | 0.00 | 0.23 | 0.57 | 0.00 | 0.00 | 0.00 | 0.57 | 0.63 | 0.00 | 0.00 | 0.00 | 0.63 |
| Median | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 1.00 | 0.00 | 0.00 | 0.00 | 1.00 |
| STDEV | 0.37 | 0.00 | 0.00 | 0.00 | 0.37 | 0.57 | 0.00 | 0.00 | 0.00 | 0.57 | 0.68 | 0.00 | 0.00 | 0.00 | 0.68 | 0.67 | 0.00 | 0.00 | 0.00 | 0.67 |
| Min | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Max | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 | 0.00 | 0.00 | 0.00 | 2.00 |