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Welcome to AMA Laboratories

With more than 30 years of experience the AMA family of laboratories are independent testing facilities that perform clinical research and specialize in safety and efficacy testing. We are a trusted resource for formulators of cosmetics, cosmeceuticals, OTC drugs, personal care and household care products, active ingredient and raw material suppliers as well as manufacturers of medical devices, automotive, textile, marine and other related industries.

We also perform specialized testing, including Matched Scientific Photography™ paired with PhotoGrammetrix® and PolyChrommetrix® 3D modeling to really help products stand out.

Location and staffing
AMA’s campus is in New City, N.Y., about 30 miles north of New York City, in a modern 70,000-square-foot office and laboratory facility. Our laboratory staff of more than 60 brings a collaborative approach to testing and measurement challenges with expertise in disciplines such as Biology, Chemistry, Medicine, Nursing, Pharmacology, Cell Biology, Microbiology, Toxicology, Mathematics, Engineering and Physics. We develop and conduct clinical trials from recruitment through sophisticated laboratory testing and analysis. Our advanced imaging department delivers a full complement of services in support of customer marketing, claims substantiation and scientific measurements.

In addition to staff physicians, AMA engages Board Certified professionals on a consulting basis depending on a client’s specific needs. Areas of expertise may include, but are not limited to: Dermatology, Ophthalmology, Psychology, Podiatry, Internal Medicine, Hematology, Dentistry, Pediatrics, Plastic Surgery and Gynecology.

Affiliations
The company and many of its employees maintain continuing memberships or relationships with these organizations:

- The International Society of Bioengineering and the Skin (ISBS)
- The Society of Cosmetic Chemists (SCC)
- American Academy of Dermatology (AAD)
- Personal Care Products Council (PCPC)
- The International Cosmetic Manufacturers and Distributors Association (ICMAD)
- In-Cosmetics
- The New York Academy of Sciences
- American Public Health Association (APHA)

Certifications
AMA Laboratories is registered with and consequently inspected on a regular basis by the U.S. Food and Drug Administration (FDA). AMA’s Quality Management System is ISO 9001 certified.

Quality policy
AMA Laboratories, Inc. conducts clinical research specializing in safety and efficacy testing in a timely and efficient manner meeting or exceeding customer-specified requirements and adhering to regulatory and industry standards for high quality.

AMA Laboratories fully complies with and seeks continual improvement of its ISO 9001 Quality Management System.

AMA follows Good Laboratory Practices (GLP) and Good Clinical Laboratory Practices (GCLP) as described in the Code of Federal Regulations (CFR) 21 where applicable, as well as Good Automated Laboratory Practices (GALP) as defined by EPA Article 2185.
Services

Procedures and methodology
Whenever possible, tests are performed by official methods derived from approved regulatory and government procedures and formal monographs as well as published methodology.

Custom Analyses can be performed and new methods developed to satisfy specific testing needs on request. We develop unique, individually tailored protocols to accommodate almost any test requirements, utilizing specialized panelist bases including but not limited to age, skin conditions, ethnicity, and gender.

Test results
At the conclusion of testing, a signed and dated Final Report describing all results together with any related photography/imaging and analysis is submitted. Raw data is always available on site or in duplicate for your records. Special arrangements can be made to receive interim results if necessary.

Images suited for commercial reproduction taken directly from scientific studies can help conserve marketing costs. Our Graphic Arts Department will assist with preparing and formatting images, from miniature to poster and billboard sizes, for print or digital media.

Confidentiality
Client confidentiality is our highest priority at AMA. The company is always willing to review and sign specialized mutual NDAs (Non-Disclosure Agreements) and targeted confidentiality agreements as well.

Sample submission
Detailed written instructions must accompany all samples. Perishable products should be packed in dry ice and shipped during the early part of the week. If necessary, AMA will advise you on the quantity of material needed to meet specific testing requirements. Generally, a minimum of 120 grams is required; Repeat Insult Patch Testing (RIPT) and Photoallergy Studies require 400 gram samples. Sample submission forms can be downloaded directly from the AMA website and sent in with your product (www.amalabs.com/customer-support/sample-submission-form), and they can also be requested to be sent directly by email.

Sample preparation
Because the matrix of many products varies considerably, special sample preparation and compositing may be required. In such instances, the fee is typically $75 per sample. An additional charge will be assessed only for samples requiring excessive extraction, heating, formulating or other procedures.

Sample retention policy
Unless advised otherwise we retain samples for the following time periods:

- Perishables – 2 months beyond study completion
- Non-perishables – 3 months beyond study completion, or up to 3 years if the sample is known to be in support of a government application

Note: Requests to return samples must be received prior to study commencement.

Rush analysis
AMA will accommodate special emergency situations whenever possible and in most cases at no additional charge. Rush notification must be communicated in advance.
A TRADITION OF TESTING

For over 30 years, AMA Laboratories, Inc. has pioneered the field of Cosmetic Testing. We clinically validate your innovation with our proven technology.

Specializing In:

- SPF Testing, all Global Methods (results in 1 week)
- In-Vivo & In-Vitro Measurements
- Product Efficacy Studies
- RIPT for Hypoallergenic Claims
- Infrared Protection Factor, IRPF™
- Moisturization & Skin Hydration
- Antiperspirant & Deodorant Efficacy
- Matched Scientific Photography, MSP™
- PhotoGrammetrix Analysis, PhGx®
- PolyChrommetrix 3D Modeling, PcMx™
- Instrumental Claim Support
- Hair & Nail Care Studies
- Color Persistence Evaluations
SPF (Sun Protection Factor)

Testing to support your products’ label claims

AMA specializes in SPF testing to determine the relative Sun Protection Factor for product labeling requirements: Static, Water Resistant, UVA and UVB testing that complies with global regulatory agencies.

Our fully compliant SPF testing uses single-port solar simulators to ensure the highest level in exposure accuracy. We perform tests to the following worldwide standards:

- FDA 2011 21 CFR Parts 201 and 310 – Labeling and Effective Testing; Sunscreen Drug Products for Over-the-Counter Human Use – Food and Drug Administration (U.S.)
  - Static
  - Water Resistant 40 Minute/Water Resistant 80 Minute (Water Resistant Testing includes Static determination)
- ISO 24444 – Cosmetics - Sun protection test methods - In vivo determination of the Sun Protection Factor (SPF)
  - Current method provides for Static determination only
- International Sun Protection Factor; International Global Harmonization Method (SPF) [CTFA-SA, COLIPA, JCIA, PCPC]
  - Static
  - Water Resistant 40 Minute/Very Water Resistant 80 Minute (Water and Very Water Resistant Testing include Static determination)
- AS/NZS 2604:2012 - Australian/New Zealand Standard
  - Static
  - Water Resistant 40 Minute, Water Resistant 80 Minute, 2-hour, 3-hour, 4-hour (Water Resistant Testing includes Static determination)
- UVA Protection Efficacy
  - ISO 24442 - Cosmetics-Sun Protection Test Methods – In-Vivo Determination of sunscreen UVA Protection
  - JCIA Method - Japan Cosmetics Industry Association (PA, PFA, PPD)

All solar simulators and detectors are calibrated three times annually by two independent certification facilities to all NIST traceable standards.

To support Broad Spectrum claims, it is economically advisable to conduct the In-Vitro Investigation (Critical Wavelength) prior to In-Vivo testing.

Many companies still prefer to test according to previously published sunscreen methods and monographs in order to more intensively investigate the efficacy of their products. AMA has maintained a repertoire of such tests:

- Sweat Resistant or Sweat Proof, Wash-on Products, and Abrasion (Towel) Resistant;
- 4-, 6-, and 8-Hour Studies
- Salt Water Immersion (Ocean Simulation)
- Chlorine Water Immersion (Pool Simulation)
- Exercise Programs (Sports Claims)
- Towelettes
- Sprays (Pump and Aerosol)
- Post-Insult SPF (Heat, Wind and Sand)

We offer discounts for combination testing. Complimentary “screening panels” are always available which can drastically reduce the cost of testing a new product by completely bypassing the need for uneconomical and time-consuming In-Vitro SPF studies.

We can provide test methodologies to assist in qualifying for the Skin Cancer Foundation’s Seal of Recommendation for sun protection products. For more information please refer to the Foundation’s web site: www.SkinCancer.org.
UVA/UVB In-Vitro Testing – Broad Spectrum Claim

In-Vitro test
Used to determine the combined level of UVA/UVB protection of sunscreen products.

Methods
- FDA 2011 21 CFR Parts 201 and 310 - Labeling and Effective Testing; Sunscreen Drug Products for Over-the-Counter Human Use – Food and Drug Administration (U.S.) Critical Wavelength – Necessary for Broad Spectrum claims
- International Standard ISO 24443 - Determination of sunscreen UVA Photoprotection In-Vitro
- COLIPA - “COLIPA In-Vitro UV Protection Method” - In-Vitro method for the determination of the UVA Protection Factor and Critical Wavelength values of sunscreen products, 2011
- The Boots Star Rating - “Measurement of UVA:UVB Ratios According to the Boots Star Rating System - 2011 revision”
- AS/NZS 2604:2012 - “Australian/New Zealand Standard; Sunscreen Products – Evaluation and Classification”
Infrared Testing

AMA’s infrared protection testing at the in-vivo and in-vitro level

Infrared radiation (IR) was long considered harmless; however, it is now identified as a major contributor to photo-damage and photo-aging.¹ To meet the growing demand for IR protection, AMA developed a new method for evaluating the Infrared Protection Factor (IRPF™) of topical skin care/sun care products. It represents a fully validated, unbiased independent test.*

The In-Vitro method is fully validated against In-Vivo results, all patterned after current ISO and FDA regulatory standards. A final In-Vitro and/or In-Vivo report is issued at the conclusion of the study, signed and dated by all relevant staff scientists, defining the product’s ability to reduce the visible effects of IR.

State-of-the-art spectroradiometric equipment used in testing the material is fully customized and calibrated to National Institute of Standards and Technology (NIST) traceable standards. All In-Vitro results can be further verified visually and instrumentally in two test subjects and against the In-Vivo data for an additional fee. The formal test protocol is available upon request for a fee, fully applicable to a study being placed with AMA.

More about our tests

In-Vitro testing designates infrared protection capabilities via an in-house generated factor. This factor is based on in-vivo SPF values and interpolates percentage protection as a function of the transmission values of a film obtained during spectroradiometric measurements. We perform spectroradiometric measurements over the range of 700-1440nm (IRA), as well as the full spectrum up to -2500nm (IR). Sample reports are available.

In-Vivo testing addresses the immediate, visible biological response of skin exposed to infrared radiation (before any permanent damage may occur).¹ The visible response (erythema) is acquired and evaluated using our Matched Scientific Photo Analysis (PhotoGrammetrix®).

*Notice: This test method has not been reviewed nor is in any way authorized by ISO (International Standards Organization), the FDA (U. S. Food and Drug Administration) or any other global regulatory agency. The test report provides no warranties or guarantees for labeling and/or claim substantiation either implied or expressed.

¹ http://www.happi.com/contents/view_sunsceen-filter/2012-04-30/sun-protection-should-protect-from-ira-damage/
http://www.csheb.org/PDF/2nd/Peter%20R%20Boyce.pdf
In-use Testing

Equipment and capabilities

Highly sophisticated dermal evaluation devices extend the laboratory’s capabilities for human biophysical measurements. These include such computerized instruments as:

Skin moisturization (hydration)

- **Electroconductivity via Novameter**
  Nova® Dermal Phase Meter, Model DPM 9003 (NOVA Technology Corp., Gloucester, Mass.) is used to obtain measurements of skin surface impedance to determine electroconductivity of the treatment sites. This meter provides a relative measure of the retained water content of the skin as a function of the skin’s dielectric value. Skin impedance is recorded automatically when equilibrium is achieved.

- **Capacitance via Corneometer®**
  The Corneometer® (Courage and Khazaka Electronic GmbH, Köln, Germany) provides a method to reproducibly and accurately determine the hydration level of the skin surface. Analysis of moisture retention capacity of the skin is based on the dielectric constant of water and measured in the superficial layers of the stratum corneum (as deep as 10-20 µm to ensure that the measurement is not influenced by capillary blood vessels).

Transepidermal Water Loss (TEWL) via DermaLab Evaporimeter - Skin barrier protection

Transepidermal Water Loss (TEWL), the low level of moisture that constantly transpires through the skin, is measured with a computerized Evaporimeter using the DermaLab System (cyberDERM, Inc. Cortex Technology, Penn.). A built-in A/D (analog-to-digital) converter streams data for analysis. A reduction in TEWL generally indicates proportionately high film (barrier) integrity and/or wound closure in wound healing studies.

Surface Evaluation of Living Skin (SELS) via Visioscan® - Wrinkle reduction, skin smoothness, roughness, and scaling

Visioscan® (Courage + Khazaka Electronic GmbH) takes a direct image of the living skin non-invasively. The Visioscan software automatically calculates skin smoothness, skin roughness, scaliness and wrinkle parameters by creating a mathematical interpretation of skin surface topography. The measuring head contains a CCD-camera and two halogen lamps to evenly illuminate the measuring field on the skin. In the image, grey level distribution corresponds to different phenomena. (White pixels represent desquamation on the skin; dark pixels represent lines and wrinkles, etc.)

Skin elasticity via Cutometer®

A Cutometer® (Courage + Khazaka Electronic GmbH) is used to measure skin firmness and elasticity based on a suction method. Resistance of skin drawn into the probe by negative pressure (firmness) and its ability to return to its original position (elasticity) are displayed as curves. From these curves measurement parameters for viscoelastic properties of skin are calculated.
Skin sebum content via Sebumeter SM 810 PC

A Sebumeter SM 810 PC (Courage + Khazaka Electronic GmbH) is used to obtain skin sebum measurements (skin surface lipids). To accomplish this, a special-purpose film within the cartridge measuring head is applied for 30 seconds to the relevant skin area. The cartridge is then inserted into the Sebumeter SM 810 PC to determine variations in film transparency, spectrophotometrically. The instrument presents the result as µg/cm².

Skin color evaluation via Minolta Chromameter and IMS SmartProbe

This evaluation method is ideal for skin lightening/whitening/brightening studies as well as tan accelerator evaluations and erythema suppression (counter irritation, anti-inflammatory). Instrument color measurements corroborate visual analyses. They are performed using a Minolta Chromameter or the equivalent (SmartProbe 400, IMS Inc). The Minolta CR-200 Chromameter interfaced with a DP-100 Color Computer System (Minolta CR-200) detects subtle changes in color by a 3D profile of hue, value and chroma. These characteristics are then translated into Munsell color coordinates (L*, a*, b*). Any increase in the L* values indicate lightening of the skin color. The a* values represent relative red-to-green changes, and b* values represent relative blue-to-yellow changes.

Skin scaliness/surface debris via D-SQUAME skin sampling discs

Adhesive discs take the trial-and-error out of sampling cells of the superficial stratum corneum (top layer of skin). These crystal clear polymer discs provide the required rigidity and adhesion to uniformly sample a fixed area of skin surface. The discs give optimum visibility of adhering skin cells and allow staining by many histological preparations.

Itch relief testing via WEST-itch™ Esthesiometer

The Weinstein Enhanced Sensory Test™ (WEST) is used to evaluate the effectiveness of itch relief treatments. It enables In-Vivo evaluation of antipruritics on mild itch such as dry-skin, winter itch, insect bites or fiber-induced itch. The WEST-itch™ esthesiometer induces a controlled, reliable itch stimulus, and In-Vivo itch intensity is rated by test subject using a continuous ten-point scale.

Skin reflectance via The Skin-Glossymeter GL 200

Gloss measurement is important in the efficacy testing of skin care, hair care and decorative cosmetics (lipsticks, make-up, etc.). The Skin-Glossymeter GL 200 (Courage + Khazaka Electronic GmbH) assesses the gloss of the skin surface by measuring reflectance. The probe measures both the portion of directly reflected light mirrored from the surface, which is related to the gloss, and the scattered portion. This is important because skin not only varies in structure and brightness, but also in color. With Diffuse Scattering Correction (DSC), these variations are taken into account and almost eliminated, making it easy to accurately compare gloss measurements across different skin types.

- Matched Scientific Photography™/digital imaging – claims substantiation
- Scientific video production
- Survey studies
- Self-assessment
- Subjective/objective questionnaires developed to meet specific claims
- Licensed cosmetologists
Safety Testing and Hypoallergenic Claims

RIPT, Dermatologist, Ophthalmologist Testing, etc.
AMA provides a range of laboratory procedures specifically designed to evaluate the safety of products that contact the body.

RIPT (Repeat Insult Patch Test) for “Hypoallergenic” claim support
AMA offers a standard 6-week RIPT to determine irritation and sensitization potential. Specialty 24- and 48-hour combination single-application patch tests are available as well as cumulative irritation patch tests designed to evaluate the primary irritation potential of test materials.

RIPT (Repeat Insult Patch Test) data is derived from In-Vivo sample testing on panels of 50, 100, and up to 200 subjects to develop valuable information related to contact irritation and sensitization.

Patch test
• 24-hour patch test
• 48-hour patch test
• Cumulative Irritation 21-day examination

Upon request, physicians can perform tests to support product claims. This includes Dermatologist- and Pediatrician-Tested Claims as well as for other specialties such as plastic surgery, ophthalmology and gynecology.

Human comedogenicity
Testing to establish the propensity of a topical formulation or ingredient to induce formation of sebum plugs (comedones/blackheads) in sebaceous glands. Visual and microscopic observations are carried out to determine the ratio of comedones to follicles present in the treated area before and after a series of occlusive or semi-occlusive product applications.

Phototoxicity
Testing to investigate the potential of a topically applied product to cause skin irritation when exposed to UV radiation. This study is recommended for products intended for extended skin contact in sunlight (outdoors).

Photomaximization (photoallergy maximization test)
The potential of topically applied products to develop irritation and/or sensitization in the presence of UV light used to simulate natural sunlight. For example, baby products, dry-skin and sensitive-skin care, geriatric and all-day moisturizers, etc.

AMA can also provide the testing required to apply for the Skin Cancer Foundation’s “Seal of Recommendation” for sun protection products. For more information please refer to their web site: www.SkinCancer.org

Ophthalmologist tested – Exaggerated use studies
Physician-supervised, exaggerated-use studies designed for contact lenses and other eye-area products, including 28-day use; 50% contact lens wearers.

Facial sting/discomfort studies
Qualified panelists screened for relative sensitivity to commercial products to support “No Sting” and “Non-Irritating” claims.

Eye irritation/sting studies
Panelists can be instructed to report back the level of sting and irritation as a product comes in contact with the eye or the sensitive eye area to help support “No Tear” type claims.

Eye irritation studies can also be completed with our proprietary PhotoGrammetrix® technique.
Antiperspirant/Deodorant/Sweat-Resistance Studies
Temperature-and Humidity-controlled Environmental Chamber

Antiperspirants, sweat studies, water-resistant mascara and make up

Stability Environments, Inc. (SEI)
Model: Vaiisala HM141/HMP46
Controlled Environment Walk-In-Chamber

Capable of accurately reproducing a range of atmospheric conditions for studies involving perspiration: Antiperspirant, Deodorant, Sweat Resistance, Facial Sting, Durable Leave-on Cosmetics (e.g. 4-, 8-, 12- and 24-hour claims). SPF concepts can be developed to meet client specifications.

<table>
<thead>
<tr>
<th>Chamber Specifications</th>
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<tbody>
<tr>
<td>Calibrations</td>
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<tr>
<td>2X annually</td>
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</table>
Photography/Digital Imaging/Claims Substantiation

AMA’s cutting-edge photography / digital imaging studio

To complement our state-of-the-art testing facility, AMA offers unsurpassed photography and digital imaging services capable of helping a product stand out in an ever-changing and increasingly competitive global marketplace. Offering high-resolution still images in the form of Matched Scientific Photography™, AMA has effectively been able to revolutionize before and after photos and provide unbiased, repeatable, and quantified results from one timepoint to the next.

Video production

Our Media department specializes in producing corporate promotional videos, and we can quickly move from concept to final web videos or ready-for-TV infomercials in full HD.

The AMA difference

When pairing Matched Scientific Photography™ with our full high range videography studio or our 3D PolyChrommetrix® modeling it is possible to create a truly one-of-a-kind presentation package that will help to promote the most cutting-edge products from both a clinical and an advertising perspective.

At AMA we bring marketing and claim substantiation together and strive to streamline the process for our clients to the full extent of our capabilities. Our teams of graphic artists and video editors work to completely custom tailor presentation packages into whatever format you deem necessary; please inquire.
Matched Scientific Photography™ with PhotoGrammetrix® Analysis

At the vanguard of visual claim support

Our Matched Scientific Photography™ technique offers a fully controlled method to help ensure that the only major variables over the course of a given efficacy study are time and the effect of the product or treatment regimen itself. Our method documents panelists’ facial expressions and any special locational information.

Variables controlled and monitored at each session throughout the duration of the study include:

- Camera and lighting equipment position and angle
- Lighting temperature and intensity
- All camera and sensor-related settings
- Room temperature and humidity

Before a photo shoot begins, panelists are given time to acclimate to the ambient conditions of the studio. This minimizes any lingering effects from the weather or external environment. During a session, a subject’s physical position is electronically monitored; the subject receives instant feedback to closely maintain position along the X, Y, and Z axis to achieve the most accurate imaging possible.

Analysis

PhotoGrammetrix® is a powerful tool for analyzing the captured visual data. It isolates key variables of interest and presents them in an easy-to-understand and highly controlled format.

Visit our photo gallery at
http://www.amalabs.com/work/sample-studies/
ACNE REDUCTION

<table>
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<tr>
<th>Baseline</th>
<th>Day 3</th>
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Hair Frizz Reduction

Acne Treatments
3D Print and Design Studio

Bringing the effects of your products into the next dimension

With our novel 3D printing system it is now not only possible to see the before-and-after efficacy of your product but to add a fully tactile sensory experience via 3D replication of individual treatment sites. Maximize the visibility of your product during sales calls, at trade shows, and in display stands by demonstrating the effects with our fully controlled 3D imaging and printing system, PolyChrommetrix®.

With PolyChrommetrix® it is possible to allow your prospective clients to immerse themselves fully into the realm of your products’ efficacy in a hands-on and truly sensational manner. Run your fingers down fine lines and wrinkles and feel them as they disappear . . . Or better yet stand back and let your customers do the same as you watch the amazement wash over their faces.

*Feel the difference with AMA 3D Printing and PolyChrommetrix®.*
Testing Overview

Skin care
• Elasticity, tensile strength
• Anti-peeling
• Anti-aging
• Tanning efficacy
• Skin lightening/whitening/brightening
• Moisturization
• Skin firmness
• Sebum content
• Tan accelerator
• Dry skin and lips
• Antiperspirant
• Age spot/melasma reduction
• Acne
• Eczema
• Psoriasis
• Wrinkle reduction/superficial fine lines
• Under-eye swelling/dark circles

Hair care treatment studies
• Half head test
• Shampoo and conditioner efficacy
• Color persistence, hair dye and tints
• Gloss, tensile strength, comb-through
• Thinning hair studies
• Hair shaft diameter
• Anagen/telogen ratios
• Hair counting analysis
• Gravimetric pull analysis
• Anti-dandruff/seborrhea

Special studies
• Nail product evaluation
• Foot care treatment product panels
• American Podiatric Medical Association – Seal of Acceptance or Seal of Approval assistance available
• Baby product evaluation
• Tooth whitener studies
• Tear free type claims
• American Dental Association – Seal of Acceptance assistance available
• Osteoarthritis
• Rheumatoid arthritis
• Arthritis Foundation – Ease of Use Commendation Logo assistance
• Skin Cancer Foundation – Seal of Recommendation assistance

FDA Registered
ISO 9001 Certified
GLP/GCP Compliant
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