Records processed under FOIA Request 2013-6291; Released 10/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 1996

Mr. Gary L. Hein
President
Lincoln Diagnostics, Incorporated
Hickory Point Road Box 1128
Decatur, Illinois 62525

Re: K961918
Trade Name: Multi-Test II
Regulatory Class: Unclassified
Product Code: LDH
Dated: May 16, 1996
Received: May 17, 1996

Dear Mr. Hein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Acting Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

K961918

510(k) Number (if known): K961918

Device Name: Multi-Test II

Indications For Use:

The sole indication for Multi-Test II is for the percutaneous administration of diagnostic allergenic extracts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cricenti
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K961918

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

510(K) ROUTE SLIP

510(k) NUMBER K961918 PANEL HO DIVISION DDIG BRANCH

TRADE NAME MULTI-TEST II

COMMON NAME DISPOSABLE SKIN TEST APPLICATOR

PRODUCT CODE ___

APPLICANT LINCOLN DIAGNOSTICS, INC.
SHORT NAME LINCDIAG
CONTACT GARY L HENI
DIVISION
ADDRESS HICKORY POINT RD BOX 1128
DECATUR, IL 62525
PHONE NO. (217) 877-2531 FAX NO. (___) ___-____

MANUFACTURER LINCOLN DIAGNOSTICS, INC. REGISTRATION NO. 1450391

DATE ON SUBMISSION 16-MAY-96 DATE DUE TO 510(K) STAFF 31-JUL-96

DATE RECEIVED IN ODE 17-MAY-96 DATE DECISION DUE 15-AUG-96

DECISION __ DECISION DATE _____

Is this 510(k) identified as a Class III device ____YES ✓ NO

un
GW

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: August 6, 1996

From: Reviewer(s) - Name(s) Vicki Hibbard

Subject: 510(k) Number K961918

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Is substantially equivalent to marketed devices.
- ☐ Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☐ Requires more data.
- ☐ Accepted for review 5/23/96 (date)
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☑NO
Is this device subject to the Tracking Regulation?	☐YES	☑NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☑NO
Is this a prescription device?	☑YES	☐NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☑Enclosed
(required for originals received 3-14-95 and after)

☐A 510(k) summary OR ☑A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 80 LDH Unclassified

Additional Product Code(s) with panel (optional):

Review: Patricia Cicerone acting (Branch Chief) CDRH (Branch Code) 8-7-96 (Date)

Final Review: Susan Runner for (Division Director) 8/7/96 (Date)

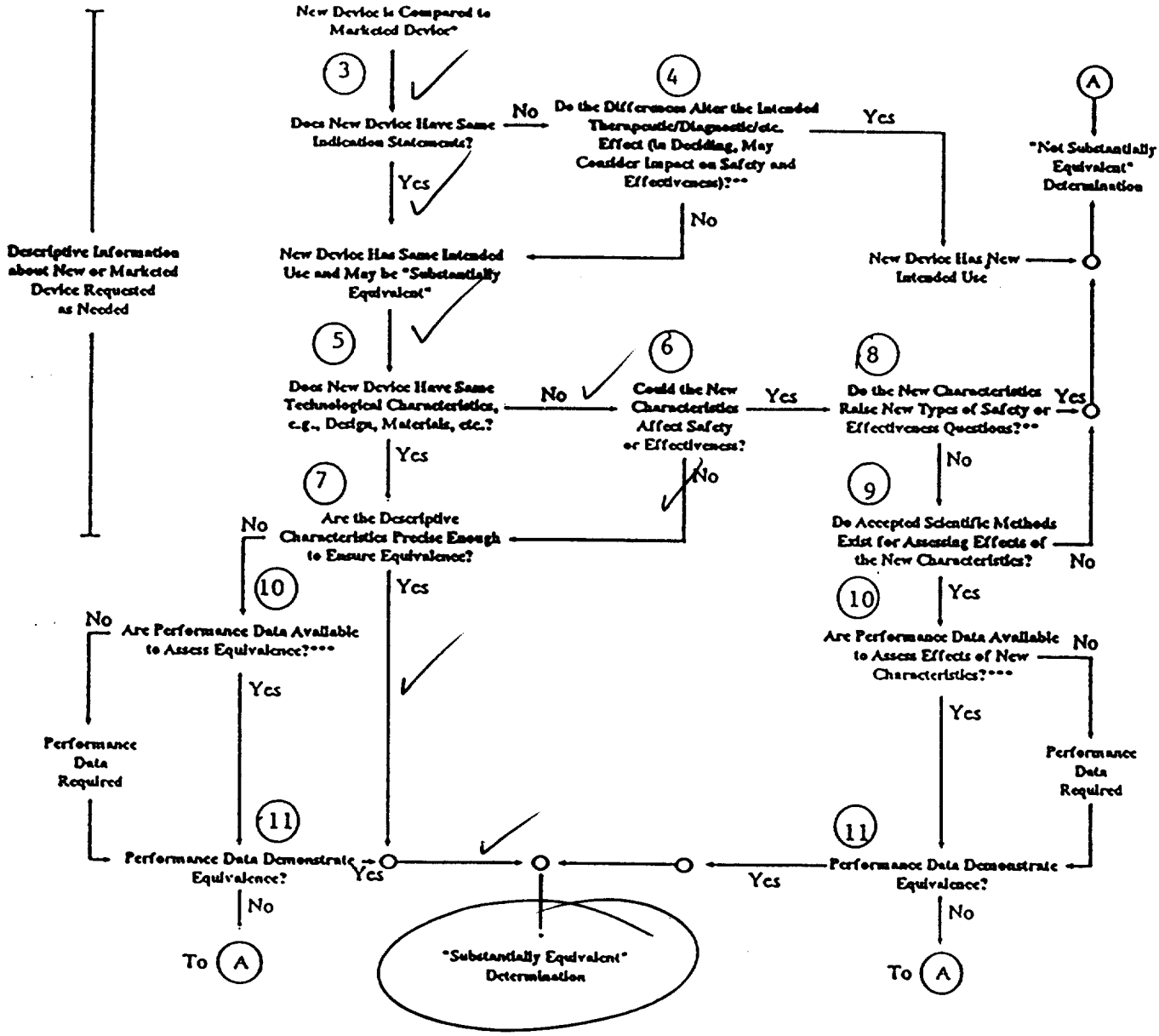
S

Revised: 1-2-96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K961918

Reviewer: Viola Hibbard

Division/Branch: DDIGD/GHDB

Device Name: Multi-Test II

Product To Which Compared (510(K) Number If Known): Multi-Test by Lincoln Diagnostics, Inc., (k760699).

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is Device Subject To 510(k)?	✓		If **NO** = Stop
3. Same Indication Statement?	✓		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?		✓	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

See SE memo dated 8/6/96

7

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

MEMO TO THE RECORD
510(K) REVIEW

K961918

DATE: 8/06/96
FROM: Viola Hibbard

OFFICE: HFZ-480
DIVISION:DDIGD/GHDB

COMPANY NAME: LINCOLN *Diagnostics*, INC.
DEVICE NAME: Multi-Test II

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The Multi-Test II device consists of acrylic plastic (Atohaas VM647). It is a "T-bar" shaped device with eight arms (four on each side of the handle). At the end of each arm is a test head with nine protruding test points. They will label each of the test heads one through eight. They design the testing heads to fit into the correct well of the Dipwell Tray to load the antigen from each well in the tray.

The Multi-Test II Dipwell Tray with Lid consists of Acrylic Plastic Atohaas SG-7. The tray will hold up to three testing applicator devices (total of 24 wells for antigens). They label each set of eight wells one through eight to correspond with the test applicator as described above.

The devices are separate ones that they will assemble, package and shipped as separate products and not as a kit. The two devices are sterilized and packaged by different methods as outlined in Section 3., C to follow.

The Multi-Test device is not preloaded with antigens and is not accompanied by any antigens.

2. INTENDED USE:

The Multi-Test device is used to administer allergenic extracts in the diagnosis of an allergy.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: No
B. Implant (short-term or long-term): No

8

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

C. Is the device sterile? Yes
Method: Ethylene Oxide/Multi-Test II Device
Gamma Radiation/Dipwell Tray w/Lid
Gamma Dose: 25 to 40 kilograys
Validation Method: AAMI Guidelines
SAL: 10-6*
Packaging: Multi-Test II device - styrene tray sealed with heat seal coated 1073B Tyvek.
Dipwell Tray with Lid - polyethylene/Tyvek breather bag
*I spoke by telephone with Mr. Mowen at Lincoln Diagnostics. In the addendum I of the document, the SAL was written as 10 to the 6th. This is an error. The correct SAL will be as noted above.

D. Is the device for single use? Yes
E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes

F. Is the device for home use or portable? No
G. Does the device contain drug or biological product as a component? No

H. Is this device a kit? No
I. Software-driven: No
J. Electrically Operated: No
K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): No

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Multi-Test by Lincoln Diagnostics, Inc., (k760699).
M. The submission provides comparative specifications.

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The device is similar in intended use as many other marketed devices. It functions in a like or similar manner in that the device is used to prick and/or abrade the superficial epidermis for introducing skin test allergens. The acrylic plastic material used for this device is also used in most other marketed devices for this intended use.

Similar to the predicate, the instructions for use are clearly outlined. With the written instructions, the sponsor will provide pictures to enhance the labeling. Appropriate cautions are added to the instructions for use.

The original Multi-Test device and the Multi-Test II differ in the manner in which the allergenic extracts are loaded on the points.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

The predicate design was different because of the loading procedure. The difference is in the test head which had a circular plastic head. This circular component was removed because the loading of antigens will now be done by inserting the device into the wells of the tray. The user will fill the wells of the tray with selected antigens.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? No
If not, does the submission include a certification that such information will be made available to interested persons upon request? Yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 LDH

Classification should be based on:

880.none Class: Unclassified

Viola Hibbard 8/6/96
Viola Hibbard

10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14 K961918 14

D. R. MOWEN
Vice President

LINCOLN
Diagnostics, INC.
P. O. BOX 1128 • DECATUR, ILLINOIS 62525 • PHONE (217) 877-2531 • 1-800-537-1336

May 23, 1996

Food and Drug Administration
CDRH
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: Multi-Test II
510(k) Notification
No. K961918

Attention: Viola Hibbard

Dear Miss Hibbard:

Enclosed are two copies of the completed Indications For Use form requested by Ms. Linh Tran to be included with our 510(k) submission referenced above.

Sincerely,

D. R. Mowen
D. R. MOWEN
Vice President

DRM:sy
Enclosures

RECEIVED
24 MAY 96 10 08
FDA/CDRH/OCE/DMC

11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-0291, Released 10/15/14

510(k) Number (if known): K961918

Device Name: Multi-Test II

Indications For Use:

The sole indication for Multi-Test II is for the percutaneous administration of diagnostic allergenic extracts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Checklist for Premarket Notifications [510(k)s]

Device Trade Name: Multi-Test II	K#: 961918
Submitter Name: Lincoln Diagnostics, Inc	
Date Received: 5/17/96 90 Day Due Date: 8/15/96	

Review Tier (circle one): 1 (2) 3

Question	Yes	No
A. Is the product a device?	✓	
B. Is the device exempt from 510(k)?		✓
C. Expedited Review Status: Requested by sponsor,		✓
or identified by PILOT Division		
Granted by Pilot Division?		
D. Has this device been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		✓
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Decision: ACCEPT ✓ REFUSE TO ACCEPT _____

Administrative Reviewer Signature: L. Lieu Date: MAY 22 1996

Supervisory Signature: Nels Hibbard Date: 5/23/96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Multi-Test II K961918

Submitter Name: Lincoln Diagnostics, Inc.

General Content of a 510(k)	MISSING INFORMATION
1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address. COMMENT:	
2.* Safe Medical Device Act of 1990 Requirements: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement COMMENT: see attached	(d)
3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device. COMMENT:	
4.* Description of Device (or modification): diagrams, engineering drawings, or photographs. COMMENT:	
5.* Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT:	

14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6.	Biocompatibility Data: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT:	
7.	Sterilization Information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8.	Software Validation & Verification: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9.	Information Recommended in FDA Guidance: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10.	Kit Information: see attachment if this device is a kit. COMMENT:	

Records processed under FOIA Request 2013-6291; Released 10/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 17, 1996

LINCOLN DIAGNOSTICS, INC.
HICKORY POINT RD BOX 1128
DECATUR, IL 62525
ATTN: GARY L. HENI

510(k) Number: K961918
Received: 17-MAY-96
Product: MULTI-TEST II

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14 K961918

LINCOLN Diagnostics, INC.

GARY L. HEIN
President

P. O. BOX 1128 • DECATUR, ILLINOIS 62525 • PHONE (217) 877-2531 • 1-800-537-1336

May 16, 1996

Food and Drug Administration
CDRH
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: Multi-Test II
510(k) Notification

RECEIVED
17 May 96 09:03
FDA/CDRH/OD/DMC

Attention: Viola Hibbard

Dear Miss Hibbard:

Your prompt response to Don Mowen's April 17, 1996 letter and your helpful comments are appreciated.

When we began development of Multi-Test II, it was our belief that a 510(k) submission on it would not be necessary because it constitutes only slight modifications to the original Multi-Test device covered by K760699. These modifications do not affect either safety or effectiveness as defined by 21 CFR 807.81.

What prompted Don Mowen to write the F.D.A. on April 17, 1996 was an April 12 phone call from F.D.A.'s Byron Tart who stated that he had received an inquiry about the status of a 510(k) covering our Multi-Test II device. It is our belief that only a competitor would raise this issue.

After carefully considering your comments, we prepared a 510(k) covering Multi-Test II and are enclosing the original and two copies. The Multi-Test II device and the Multi-Test II Dipwell Tray with Lid will not be provided as a kit. Even though the Dipwell Tray with Lid is used to load the points of the Multi-Test II device, the two components will not be packaged, assembled, or shipped as a kit. All applicable data that would be required for a 510(k) for either is, however, included in our accompanying 510(k) notification. Because the above referenced components do not constitute a kit, we do not consider suggestions for submitting information on a kit applicable.

We want to thank you for your help and let you know that any assistance you can give us in gaining prompt review will be greatly appreciated, particularly in light of the fact that delay resulted because we did not feel that a 510(k) was needed.

If you have any questions or comments, please call me or Don Mowen at (800) 537-1336.

Sincerely,

Gary L. Hein

GARY L. HEIN
President

GLH:sy
Enclosures

17

HD
uc

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

LINCOLN
Diagnostics, INC.

GARY L. HEIN
President

P. O. BOX 1128 • DECATUR, ILLINOIS 62525 • PHONE (217) 877-2531 • 1-800-537-1336

May 16, 1996

Food and Drug Administration
CDRH
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Reference: Multi-Test II
510(k) Notification

Attention: Viola Hibbard

This is to notify the Food and Drug Administration of our intent to introduce into Interstate Commerce for commercial distribution the following device:

(a) Proprietary Name: Multi-Test II
Common Name: Disposable Skin Test Applicator
Classification Name; System, Delivery, Allergen and Vaccine

(b) Establishment Registration Number: 1450391

(c) Classification: HHS Publication FDA91-4246 indicates this device category for review by the General Hospital Section, but no class is shown. Therefore, we do not believe that this device or category has been classified.

(d) Performance Standards: None established

(e) Labels, Labeling/Advertisements: See attached Multi-Test II labeling identified as Exhibits A, B & C. Also see the attached engineering drawings identified as Exhibit D. Advertising and promotional materials have not yet been developed, but claims will not exceed those for labeled use.

(f) Equivalence: Multi-Test II is equivalent or similar to the following devices:

(1) Multi-Test by Lincoln Diagnostics, Inc. See attached labeling identified as Exhibit E. Also see attached comparative photographs of the Multi-Test and the Multi-Test II devices identified as Exhibit D-1.

(2) Mono-Vacc by Lincoln Laboratories, Inc. See attached labeling identified as Exhibit F.

(3) DermaPIK by Greer Laboratories, Inc. See attached labeling identified as Exhibit G.

(4) The bifurcated needle by Allergy Laboratories of Ohio. See attached labeling identified as Exhibit H.

18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(5) Morrow Brown needle by Aller/Guard. See attached labeling identified as Exhibit I.

(6) Duotip-Test by Lincoln Diagnostics, Inc. See attached labeling identified as Exhibit J.

(7) Quintest by Bayer Corporation. See attached labeling identified as Exhibit K.

See the attached Device Comparison Table identified as Exhibit L.

The Mono-Vacc device, referenced as an equivalent, was introduced in 1960 for use in administering smallpox vaccine and allergenic extracts by private practicing physicians, at hospitals and at teaching institutions. Millions of subjects were vaccinated or skin tested with this device and it was widely used at military installations throughout the United States and overseas. In 1971 smallpox vaccination was discontinued, but use of the Mono-Vacc applicator for allergy skin testing continued.

In 1966, the Mono-Vacc device was modified and a soft plastic tube filled with tuberculin was placed around the points. The Tuberculin, Old, Mono-Vacc Test, licensed and regulated by the Center For Biologics Evaluation and Research, enjoys widespread use in the United States and abroad.

The Multi-Test device, initially marketed in 1977, is a further modification of the Mono-Vacc device consisting of eight Mono-Vacc like heads mounted to one handle. Multi-Test allows for the simultaneous administration of eight skin tests while only one test at a time could be done with Mono-Vacc. In the mid-1970's the National Cancer Institute became interested in the Multi-Test device and funded its development for use in a standardized reproducible system for assessing delayed hypersensitivity to a battery of preloaded ubiquitous antigens. The resulting Multi-Test CMI system, widely used for the measurement of delayed hypersensitivity in the assessment of cell mediated immune function, is licensed and regulated by the Center For Biologics Evaluation And Research. A distinction must be made between Multi-Test CMI and the Multi-Test device used to administer allergenic extracts. The Multi-Test device used in the diagnosis of allergy is not preloaded with antigens and is not accompanied by any antigens. Those using the product select whatever allergens they deem appropriate for use with the Multi-Test device on a given patient.

The Multi-Test II device is a slightly revised version of the original Multi-Test unit. The revisions in no way affect the safety or effectiveness of the device as confirmed by the following:

(1) The nine points and the circular platform from which the points project are identical on both devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(2) The acrylic plastic (Atohaas VM647) used to injection mold the devices is identical.

(3) The packaging materials and production methods for the two devices are identical.

(4) The method of sterilization (ethelyne oxide) and sterility testing of the two devices are identical.

(5) The method of application of the test to the skin is identical for both devices.

(6) The size of the reactions and method of grading reactions are identical for both devices.

The original Multi-Test device and the Multi-Test II device differ only in the manner in which the allergenic extracts are loaded on the points. The original Multi-Test device is loaded by placing the unit in a specially designed loading holder with the points upright and transferring allergenic extracts from vials to the points with standard droppers or Dip 'N Touch dispensers. The Multi-Test II device is loaded by placing the unit in a specially designed acrylic plastic tray containing "wells" with different allergenic extracts in each well. Each well is numbered, as is each test location on the device. The handle of the Multi-Test II device has a unique feature that prevents the user from placing the unit in the tray in a reverse position, thereby assuring that the numbers of the device locations always coincide with the numbers on the wells of the tray.

All manufacturing procedures are in conformance with current Good Manufacturing Practice For Medical Device Regulations. Packaged devices are sterilized by ethylene oxide in a validated cycle by (b)(4) (b)(4) contractors (b)(4) contractors . t Sterility testing, as well as bioburden, ethylene oxide residuals, bacteriostasis-fungistasis and other supportive testing are performed by (b)(4) (b)(4) contractors at the same location. Shipments and marking of shipments are handled in accordance with Food and Drug Administration regulations.

The Multi-Test Dipwell Tray with Lid is provided for the loading of allergens on test points. Multi-Test Dipwell Trays with Lids are molded from Atohaas SG-7 gamma resistant acrylic plastic. See Exhibit M. Because of its gamma resistance, this acrylic material is used in many medical applications. The lidded trays are packaged in Perfecseal® Breather Bags constructed from 4 mil. LLDPE film and 1073B Tyvek. See Exhibit N. The breather bags are manufactured and certified by (b)(4) contractors (b)(4) contractors Packaged lidded trays are gamma radiation sterilized by (b)(4) contractors (b)(4) contractors at a high dose of (b) (4) kilograys utilizing (b) (b) Bacillus pumilus spore strips contained within (b) lidded trays. (b) (4) trays and (b) spore strips

20

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

are tested for sterility by [redacted] (b)(4) copyrighted material
For information regarding the use of the Dipwell Tray, see the attached labeling identified as Exhibit A.

(g) There are no adverse effects on the safety or effectiveness of the device. The acrylic material used to produce the Multi-Test device is utilized to administer about fifteen million skin tests annually. Multi-Test, introduced in 1977, is routinely and widely employed by leading medical schools and practicing allergists. More than twenty studies have been conducted in which negative controls, as well as positive reactions, have been evaluated. Reprints of representative studies and "Multi-Test - Excerpts From Published Data" are included and identified as Exhibits O1 through O5.

(h) See attached 510(k) statement.

(i) Not applicable.

(j) All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

Sincerely,

Gary L. Hein

GARY L. HEIN
President

GLH:sy
Enclosures

NOTE: Please see Addendum I, following page, for response to Sterility Review Guidelines.

21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

ADDENDUM I

Reference: Multi-Test II
510(k) Notification

Response To 510(k) Sterility Review Guidelines

The following information is provided in keeping with Sterility Review Guidelines and is presented in the same numerical order as the issues are cited by F.D.A.:

- The sterilization method for the Multi-Test II device is 100% ethylene oxide in a cycle validated in accordance with AAMI Guidelines. The sterilization method for the Multi-Test II Dipwell Tray with Lid is (b)(4) copyrighted material [redacted] high dose of (b) (4) [redacted] kilograys utilizing (b)(4) [redacted] strips packaged within the lidded tray.

- The sterility assurance level (SAL) is 10^6 for both, the Multi-Test II device and the Multi-Test II Dipwell Tray with Lid.

- The Multi-Test II device is packaged in a styrene tray sealed with heat seal coated (b) (4) [redacted]. This is the same packaging that has been utilized for the predicate Multi-Test device since 1977. The Multi-Test II Dipwell Tray with Lid is packaged in a polyethylene/Tyvek breather bag certified by the manufacturer. (b)(4) [redacted] (b)(4) [redacted]. Both types of packaging are widely utilized in the medical device industry and have been shown to be highly efficient in producing and maintaining product sterility.

- The levels of ethylene oxide residues for the Multi-Test II device are expected to be in the same range as those for the equivalent Multi-Test device. These levels at time of release to inventory have been determined to be; ethylene oxide - (b [redacted], ethylene chlorhydrin (b)(4) copyrighted material [redacted] ethylene glycol ([redacted] (4) [redacted]. These levels are well below the levels cited in Part 221 of the proposed rules. The ETO residue levels for the Multi-Test II device will be determined as soon as ETO processed devices are available. We assure that the levels will be within the applicable guidelines.

- The function of the Multi-Test II device is only to penetrate the superficial epidermal layer of the skin and therefore does not require pyrogen testing. The device is not labeled as non-pyrogenic nor are any of the other devices for which equivalence is claimed.

- The radiation dose for the Multi-Test II Dipwell Tray with Lid is (b)(4) to (b)(4) kilograys which is considered to be an effective high level sterilizing dose.

22

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as President of Lincoln Diagnostics, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Gary L. Hein

Gary L. Hein

May 16, 1996

Number Not Yet Assigned
(Premarket Notification (510(k)) Number)

23

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

PREMARKET NOTIFICATION
510(k) STATEMENT
(As Required By 21 CFR 807.93)

I certify that, in my capacity as President of Lincoln Diagnostics, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Gary L. Hein

Gary L. Hein

May 16, 1996

Number Not Yet Assigned

Premarket Notification (510(k)) Number)

24

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT A

MULTI-TEST® II

MULTI-TEST II is a sterile, disposable, multiple test head applicator used to administer skin test substances. When used to apply allergenic extracts it provides a quick, convenient, and standardized procedure. Before employing allergenic extracts with MULTI-TEST II or any testing device, the user should be completely familiar with the information contained in the package insert accompanying the extracts.

The MULTI-TEST II system for applying diagnostic allergenic extracts consists of these components:

1. The sterile disposable applicator. See Figure 1.

2. The Dipwell Tray and its protective lid. See Figure 2.

DIRECTIONS FOR USE

Loading MULTI-TEST II With Allergenic Extracts

1. Remove each sterile MULTI-TEST II device from its container by grasping the sealed label at the blue dot and pulling it off. See Figure 3.

2. Place MULTI-TEST II applicator into the Dipwell Tray containing extracts and control solutions. See Figure 4. The test heads of the device are numbered 1 through 8. The wells of the Dipwell Tray are also numbered 1 through 8. Each time a new MULTI-TEST II device is placed into its Dipwell Tray, test head No. 1 goes into well No. 1, test head No. 2 into well No. 2 and likewise for all test heads and well positions, numbers 1 through 8. This occurs each time because MULTI-TEST II will fit into the Dipwell Tray in only the correct position. **See Dipwell Tray package insert for complete instructions on its use with MULTI-TEST II.**

Administration of Allergenic Extracts With MULTI-TEST II

With the points of all eight test heads properly loaded, MULTI-TEST II is used as follows:

1. Select only testing sites that will permit sufficient surface area and sufficient subcutaneous tissue to allow adequate penetration of all points on all eight test heads. The preferred sites are the volar surfaces of each arm and the back. Skin of the posterior thighs may be used if necessary. Avoid hairy areas whenever possible since the reactions are more difficult to interpret in these areas. Cleanse sites with alcohol, ether, or acetone and allow to dry.

25

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

2. Point "T-bar" end of MULTI-TEST II toward a constant reference point such as the head of the subject being tested and press loaded unit into the skin with sufficient pressure to prick the skin and allow adequate penetration of points. Pointing "T-bar" toward a constant reference point greatly reduces any possibility of incorrectly identifying the extract (or control) applied at each test site. See Figure 5. **With proper pressure, a distinct puncture pattern from the points will be observed at each test site.** If the skin is taut, less pressure is required to gain proper penetration of points. With proper pressure, bleeding rarely occurs. In some cases the contour of the testing area may be such that slight "rocking" of the MULTI-TEST II unit will be required to gain adequate and uniform penetration of points from all test heads. For example, particular attention must be given to proper penetration of points on test heads No. 4 and No. 5 when the volar surface of the forearm is used, because these two test heads will be closest to the wrist over an area where the contour of the forearm narrows. A "feel" for using MULTI-TEST II properly is gained quickly after just a few applications. It is desirable to visually check each test site to be sure that adequate point penetration has been achieved.

3. Make an identification mark such as A, B, C on the skin at the "T-bar" end of the testing device. Results are then read in a clockwise manner, starting at test site No. 1 that will always be in the one o'clock position. If, for example, three test batteries are used, battery A is read from test site 1 through 8, battery B from test site 1 through 8, and battery C likewise. As pointed out earlier, this procedure provides a high degree of accuracy in relating test extracts (or controls) to test site results.

4. Discard MULTI-TEST II after one use. DO NOT REUSE. Discard in accordance with all local, state and federal regulations.

READING AND RECORDING MULTI-TEST II RESULTS

Because patients differ in their resonse to mechanical and chemical stimulation of the skin, interpretations of skin test results are most reliable when positive (histamine) and negative (glycerosaline) controls are used. It is preferred that testing be conducted so that positive and negative controls are applied at the same time and in the same general location as the diagnostic extracts. The response to histamine (1mg./ml.) is considered a 3+ reaction, while the response to glycerosaline is considered negative. The diagnostic extract test sites are graded against the positive and negative control sites. Reading of positive control results **is conducted 15 minutes following administration,** while reading of results from the negative controls and diagnostic extracts **is done 15 to 20 minutes after their administration.** However, positive reactions to diagnostic extracts can occur up to 30 minutes following administration. It should be noted that the use of histamine as a positive control also provides information as to whether or not the patient's ability to react adequately to diagnostic extracts is being impaired by use of drug products or other causes.

Typical reactions from the MULTI-TEST II technique are as follows:

Negative — No wheal or a wheal no larger in size than that produced at the negative control site. Erythema absent or area of erythema no larger than area of erythema occurring at the negative control site.

26

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

It should be noted that all scratch and prick type instruments do, on some patients, cause a wheal or erythema, or both, at the negative control site. Wheals may range in size from a barely detectable 1-2mm. to a well defined 5mm. Area of erythema may range from a faint 1-2mm. to a clearly defined 10mm. or larger. THEREFORE, READING ALL TEST RESULTS AGAINST THE NEGATIVE CONTROL IS IMPERATIVE.

1 + Wheal may or may not be present. If present, wheal must be as large or larger than negative control. Area of erythema significantly larger than area of erythema at negative control site.

2 + Wheal 5mm. to 7mm. and area of erythema usually larger than 10mm.

3 + Wheal 7mm. to 10mm. and area of erythema usually larger than 20mm. Slight pseudopodia and itching may occur.

4 + Any reaction with a wheal larger than 10mm. or pronounced pseudopodia. Area of erythema may or may not be larger than that of a 3+ reaction. Pseudopodia and itching are likely to occur. Record actual size.

NOTE: The above information is not absolute, but serves as a guide to reading MULTI-TEST reactions. Readings should always be made against positive and negative controls. Almost all adults exhibit 7 to 10 mm. wheals (3+) from properly administered histamine (1mg./ml.) unless their ability to react is impaired by use of drug products or other causes. Unimpaired histamine reactions in young children will often not exceed 6mm. wheals. Histamine wheal reactions less than 7mm. should not be considered 3+. Reactions comparable to those from negative controls are negative regardless of size.

A POSITIVE SKIN TEST REACTION TO ANY ALLERGENIC EXTRACT MUST BE INTERPRETED IN LIGHT OF THE PATIENT'S HISTORY OF SYMPTOMS, TIME OF THE YEAR, KNOWN EXPOSURES, AND EATING HABITS. SKIN TEST RESULTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFULLY COMPILED ALLERGIC HISTORY. THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

Recording of results should be done on forms provided by suppliers of allergenic extracts, on forms designed to meet the specific needs of individual practices, or on convenient MULTI-TEST II recording forms supplied by Lincoln Diagnostics.

CAUTION: The sterility of MULTI-TEST II is guaranteed only when the seal of the individual unit container is unbroken. The plastic MULTI-TEST II unit will not withstand heat sterilization or exposure to alcohol, ether, or acetone. Attempts to resterilize can result in transmisssion of blood-borne diseases. Repeated use of a single device may result in inaccurate test results.

CAUTION: All cautions and precautions contained in the package insert for allergenic extracts must be observed.

27

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT A

CAUTION: All cautions and precautions contained in the package insert for histamine phosphate must be observed.

CAUTION: Federal Law restricts this device to use by or on the order of a physician.

HOW SUPPLIED: MULTI-TEST II, Box of 6 sterile applicators, Stock No. MH-6 II.

MULTI-TEST II Dipwell Tray and Lid, package of one sterile tray and lid, Stock No. MHDW-1.

28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT A

Photograph Of Device

Figure 1

Photograph Of Dipwell Tray And Accompanying Lid

Figure 2

Photograph Showing Removal Of Device From Its Container

Figure 3

Photograph Showing Device Being Inserted Into Dipwell Tray

Figure 4

Photograph Of Device Being Used With T-Bar Pointed Toward Patient's Head

Figure 5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT A

MULTI-TEST® II

DIPWELL® TRAY

The Dipwell Tray, shown in Figure 1, is employed with the MULTI-TEST II device. It consists of 24 wells arranged in three sets of 8 each, with each set being identified by letters A, B, C and beyond. Individual skin test solutions are placed in their designated wells for use with MULTI-TEST II and for refrigerated storage. During storage, a specially designed lid fits tightly over the wells. See Figure 2. Detailed instructions for administering skin test solutions with MULTI-TEST II are included in a package insert contained in each package of MULTI-TEST II.

DIRECTIONS FOR USE

Employing the Dipwell Tray for loading MULTI-TEST II points and for refrigerated storage of skin test solutions provides a quick and convenient system for skin testing when these steps are followed:

1. Remove the sterile tray and its lid carefully from the package, keeping the lid over the wells until they are ready to be filled with skin test solutions. Immediately prior to filling, identify each set of 8 wells on the etched, rectangular area with letters A, B and C as shown in Figure 3. If more than one tray is employed, additional sets of 8 wells each are labeled D, E, F and beyond.

2. Individual test solutions are placed into individual wells so that each well contains the test solution that corresponds with that test solution's well location number shown on a recording form. For example, well A1 could contain negative control, glycerosaline, while A8 could contain positive control, histamine. Wells A2 through A7 would contain allergenic extracts. This approach is used for wells B1 through B8, C1 through C8 and beyond.

3. Dispense the desired amount of each skin test solution into its properly identified and numbered well. A sterile 1cc. tuberculin syringe, **with its needle removed**, can be used conveniently to withdraw extract and control solutions from their containers and to transfer the test solutions to their respective Dipwell Tray wells. A separate sterile syringe is used for each test solution. Each well must contain enough volume, at all times, to allow complete submersion of MULTI-TEST II points in the test solution. One cc. of solution provides more than one hundred skin tests with MULTI-TEST II.

4. Remove each sterile MULTI-TEST II device from its container by grasping the sealed label at the blue dot and pulling it off. See Figure 4. Place the points of each MULTI-TEST II device into the tray wells by aligning the concave portion of the "T-bar" with a tray guidepost. Then lower the handle of the device between the two guide panels, allowing each test head to enter its respective well. See Figure 5. The test head number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

on the device will always enter the matching well number of the tray because MULTI-TEST II will fit into the tray in only the correct position. It cannot be inserted incorrectly.

5. Select test site areas on the arms or back at which test batteries A, B, C and beyond will be applied. Cleanse testing sites with an appropriate disinfectant solution and apply skin tests as directed in the MULTI-TEST II package insert.

ADDITIONAL INFORMATION

The Dipwell Tray and its lid are designed so that when the wells are covered by the lid for refrigerated storage, additional covered Dipwell Trays can be stacked, one on top of the other, to conserve refrigeration space. The stacked trays can be conveniently transferred from the refrigerator to areas where skin testing is conducted. When separating stacked trays, care must be taken not to pick up the lid from the underlying tray. When in use, the bottom side of the Dipwell Tray fits over the top of its own lid.

The Dipwell Tray is designed so that its lid can be placed over a tray while MULTI-TEST II units are in the wells. This procedure provides much greater test solution protection than the common practice of placing extracts on the skin with a dropper and then pricking or scratching through each drop.

CAUTION: Sterility is guaranteed only when the package seal is unbroken.

CAUTION: All cautions and precautions contained in package inserts for allergenic extracts and control solutions must be observed.

SUPPLIED: One package consisting of a sterile Dipwell Tray and lid. Stock No. MHDW-1.

LINCOLN DIAGNOSTICS, INC.
Decatur, Illinois 62525

Printed in U.S.A. May 1996

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT A

Photograph Of The
Dipwell Tray

Figure 1

Photograph Of The
Dipwell Tray With
Lid On

Figure 2

Photograph Of Dipwell Tray
Showing Identifying
Letters A, B and C
For Each Set Of Wells

Figure 3

Photograph Showing
Removal Of The
Multi-Test II Device
From Its Container

Figure 4

Photograph Showing The
Proper Method Of
Placing Testing Device
Into Dipwell Tray

Figure 5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT B

INDIVIDUAL CONTAINER LABELING

STERILE DISPOSABLE

Multi-Test® II

(MULTIPLE SKIN TEST APPLICATOR)

DIRECTIONS: SEE PACKAGE INSERT.

CAUTION: DISCARD AFTER USE. DO NOT REUSE. STERILITY ASSURED UNLESS PACKAGE HAS BEEN DAMAGED OR OPENED.

LINCOLN DIAGNOSTICS, INC.
DECATUR, ILLINOIS 62525

33

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT C

UNIT CARTON LABELING

MAIN PANEL COPY

6 Sterile Disposable No. MH-6II

Multi-Test® II

(MULTIPLE SKIN TEST APPLICATOR)

DIRECTIONS: SEE PACKAGE INSERT. DISCARD AFTER USE. DO NOT REUSE. CAUTION: Federal Law restricts this device to use by or on the order of a physician.

LINCOLN DIAGNOSTICS, INC., DECATUR, ILLINOIS 62525, U.S.A.

END PANEL COPY

Multi-Test® II

6 STERILE
APPLICATORS

LINCOLN DIAGNOSTICS, INC

34

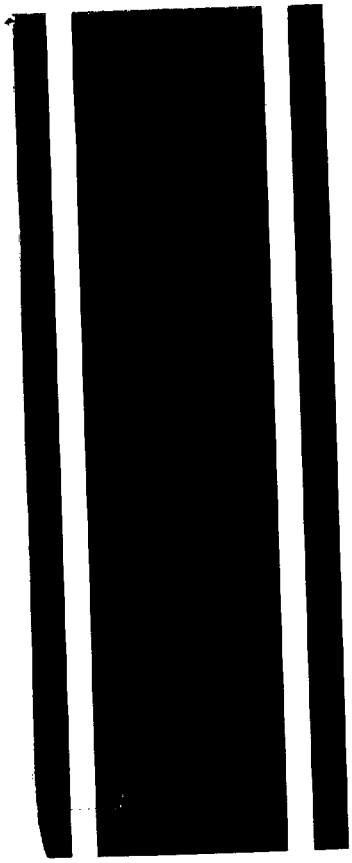
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT C

UNIT CARTON LABELING

LID COPY



Multi-Test® II

CONTROL NO.

35

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT C-1

UNIT PACKAGE LABELING

1 Sterile No. MHDW-1

MULTI-TEST II DIPWELL TRAY WITH LID

For Use With Multi-Test II Devices

DIRECTIONS: See Enclosed Package Insert

CAUTION: Sterile Until Opened

LINCOLN DIAGNOSTICS, INC.

DECATUR, ILLINOIS 62525 USA

LOT NO.

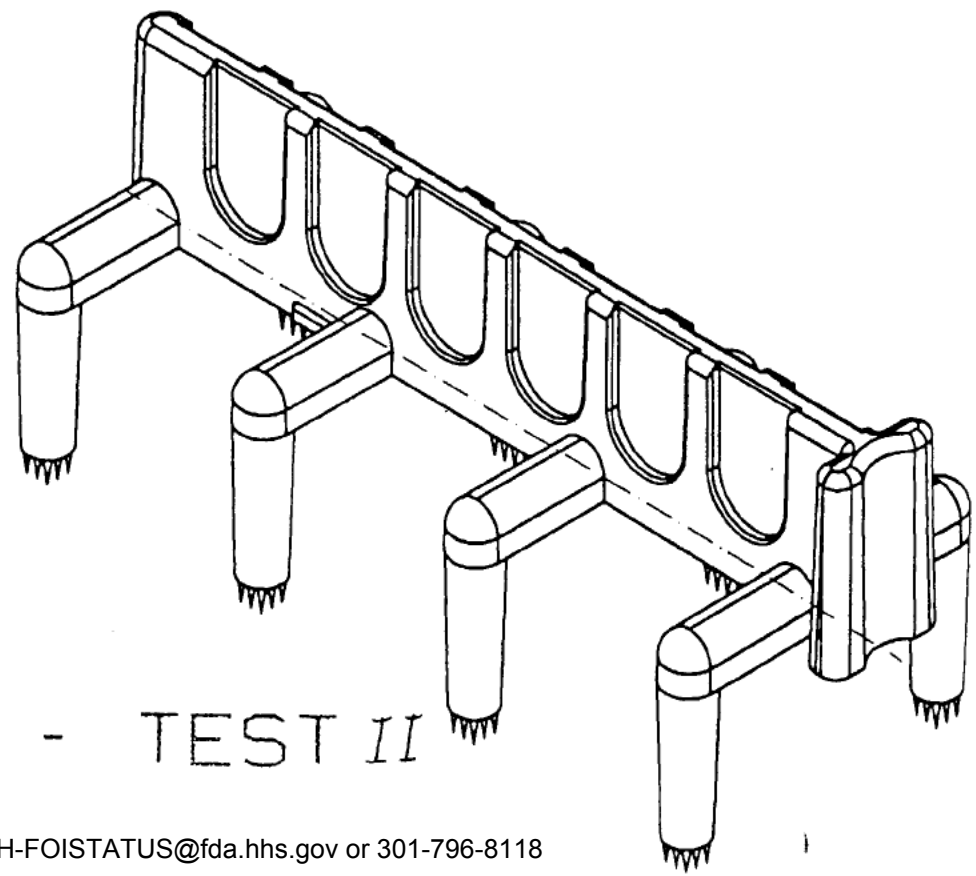
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

EXHIBIT D

(b) (4)

[redacted]

SECTION A - A



MULTI - TEST II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(2)

.125 HIGH CHARACTERS
RAISED .010/.012

EXHIBIT D

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291, Released 10/15/14

EXHIBIT D

(b)(4) Engineering Drawings

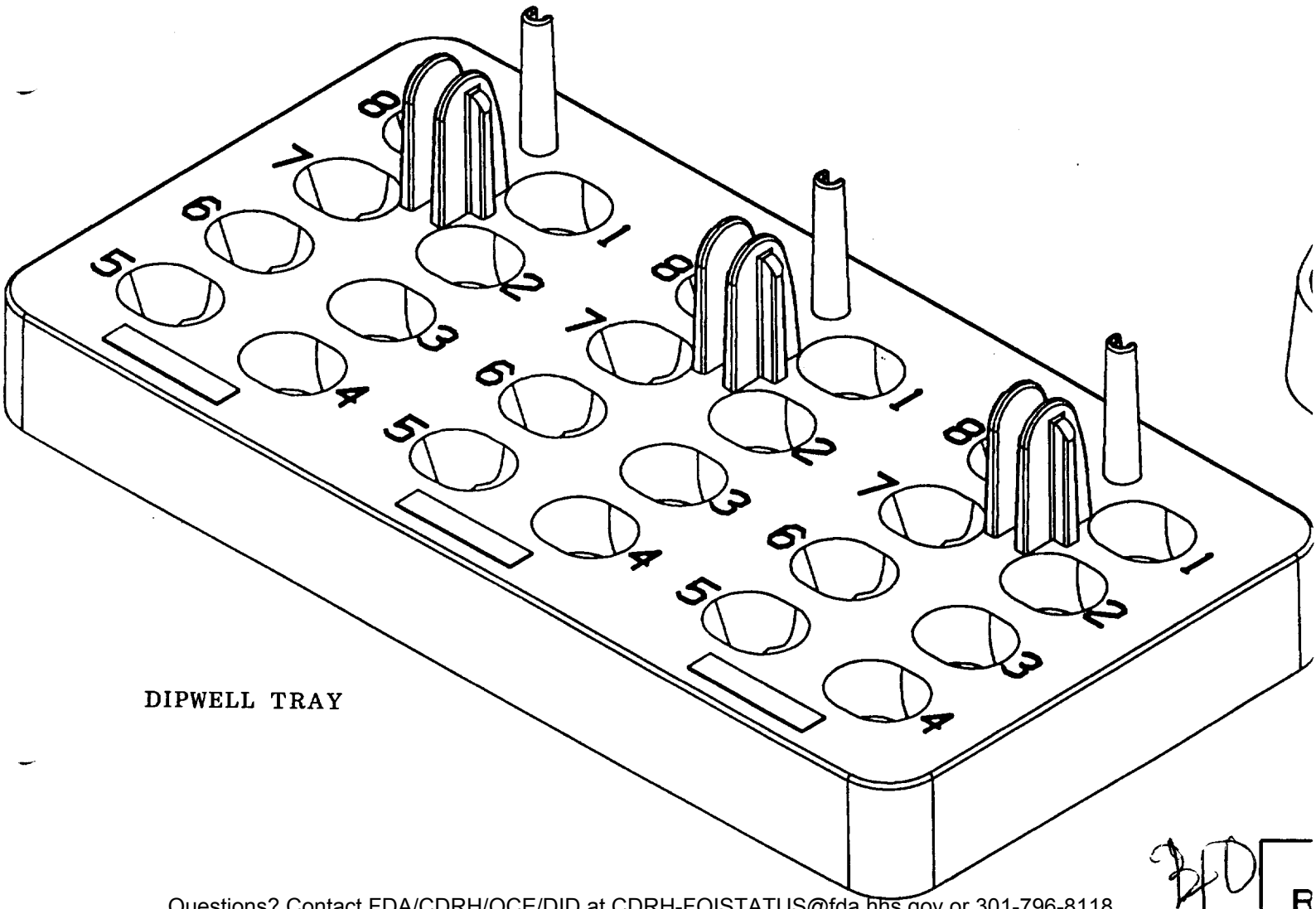
[redacted]

(b)(4)

[redacted]

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT D

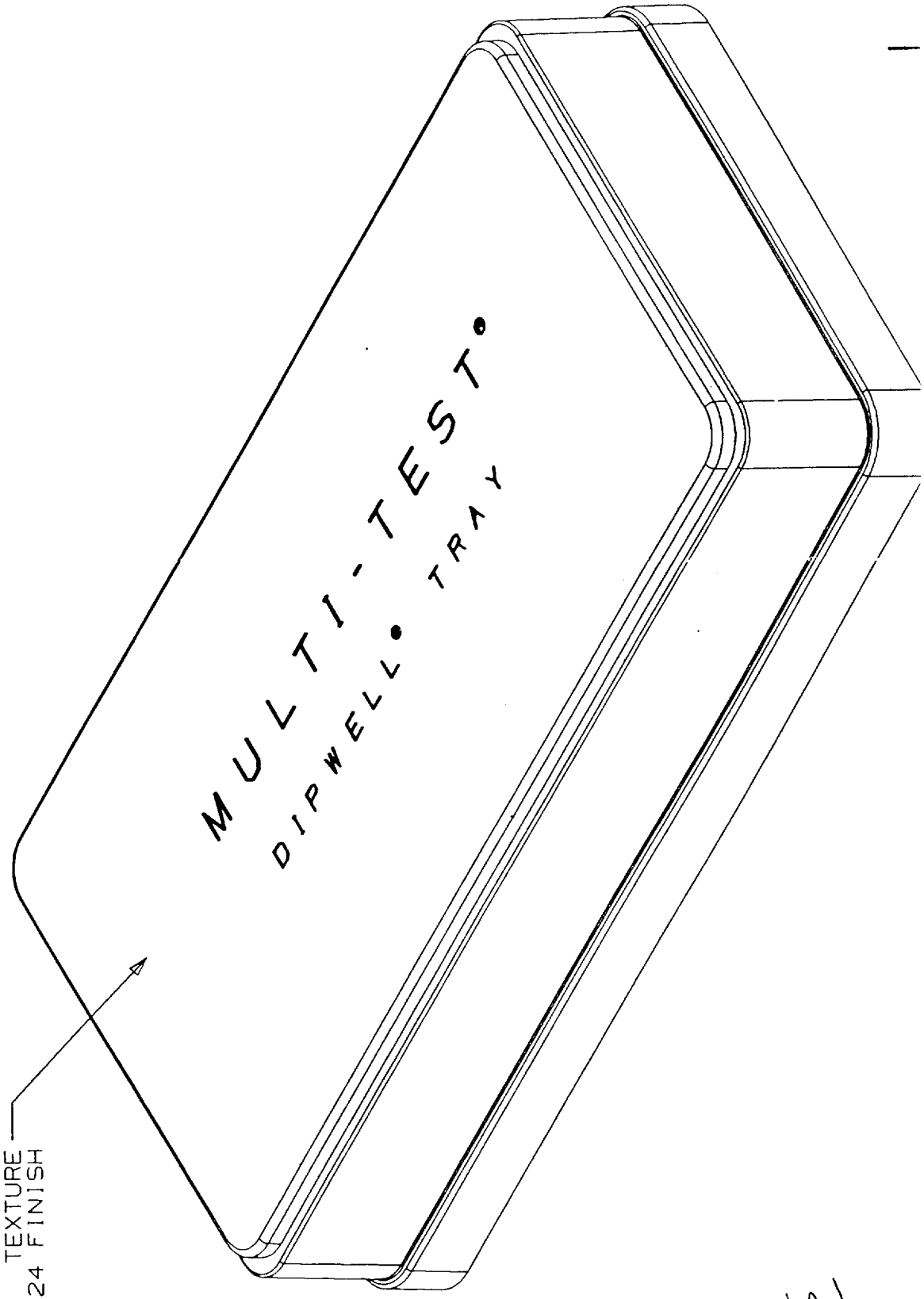


DIPWELL TRAY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT D

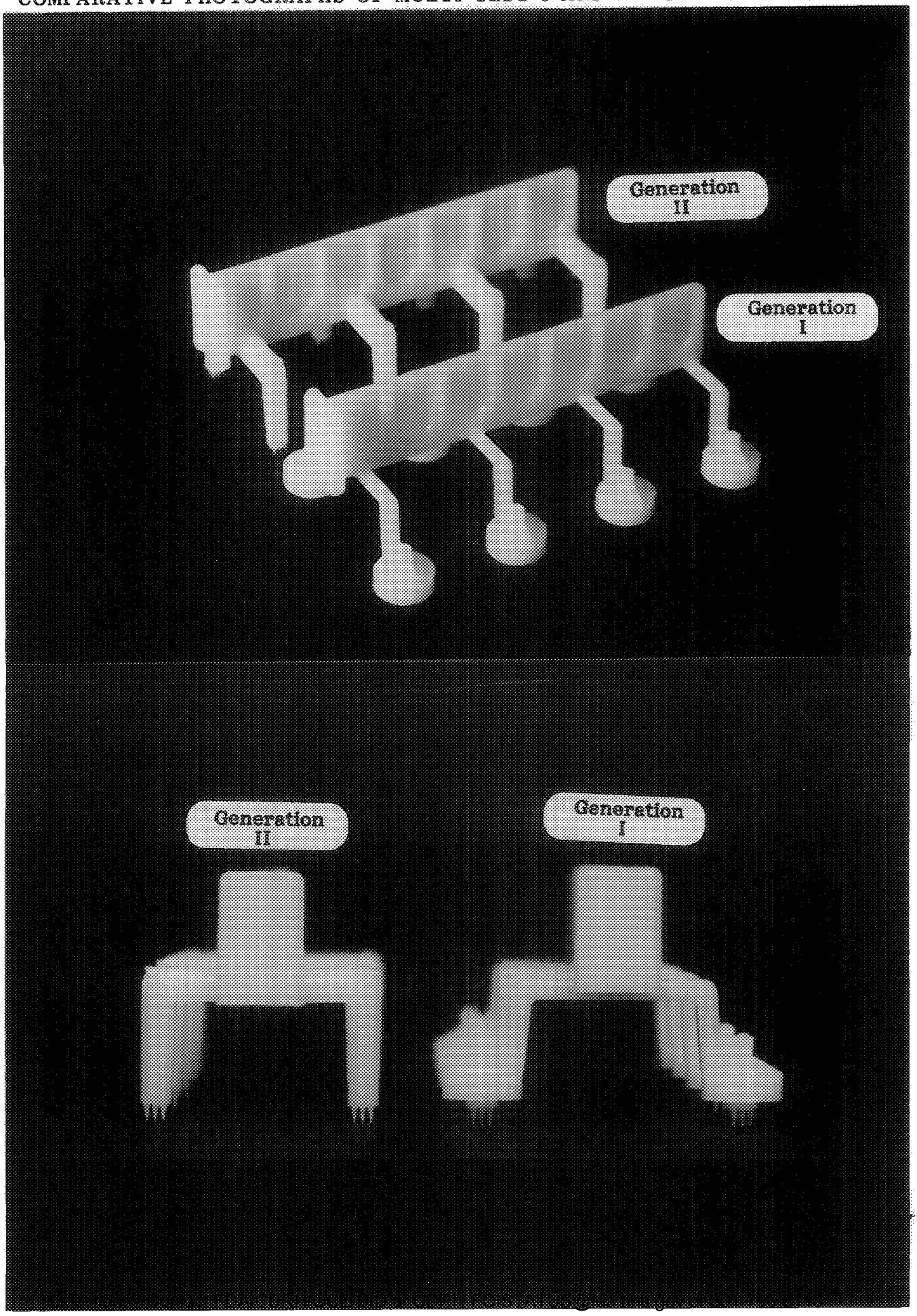


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT D-1

COMPARATIVE PHOTOGRAPHS OF MULTI-TEST I AND MULTI-TEST II DEVICES



Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT E

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

MULTI-TEST®

MULTI-TEST is a sterile, disposable, multiple test head applicator used to administer skin test substances. When used to apply allergenic extracts it provides a quick, convenient, and standardized procedure. Before employing allergenic extracts with MULTI-TEST or any testing device, the user should be completely familiar with the information contained in the package insert accompanying the extracts.

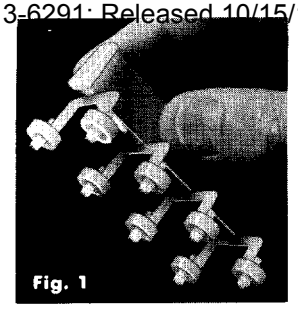
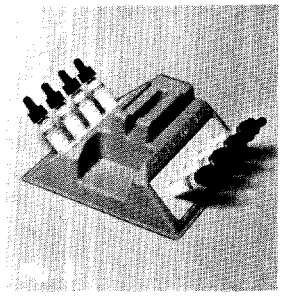


Fig. 1

The MULTI-TEST system for applying diagnostic allergenic extracts consists of these components:

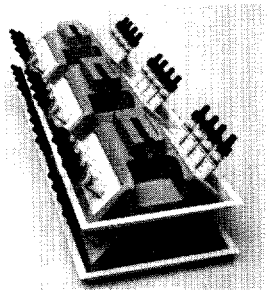
1. The sterile disposable applicator. See Figure 1.
2. A specially designed loading holder into which eight vials of diagnostic allergenic extracts (and controls) are placed. See Figure 2.
3. A tray constructed to hold three loading holders. The trays are designed to stack one above the other, minimizing space requirements. See Figure 3. The number of loading holders and trays employed is determined by the number of diagnostic extracts and controls administered to each patient. Further details related to loading holders and trays appear in this package insert under the heading "Additional Information."



DIRECTIONS FOR USE

Loading MULTI-TEST With Allergenic Extracts

1. Grasp container cover at point identified by blue dot and peel back cover. Remove sterile MULTI-TEST applicator from container. See Figure 4.
2. Place MULTI-TEST applicator in specially designed loading holder with points upright as shown in Figure 5. The test heads of the device are numbered 1 through 8. The wells on the loading holder into which the dropper vials of allergenic extracts are inserted are also numbered 1 through 8. Each time a new MULTI-TEST unit is placed into the loading holder, test head No. 1 lines up with dropper vial position No. 1, test head No. 2 with dropper vial position No. 2, and likewise for all test heads and dropper vial positions, numbers 1 through 8. This occurs each time because MULTI-TEST fits into the loading holder in only one position. When using three loading holders in a tray as shown in Figure 6, place the first



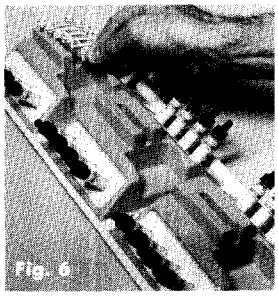


Fig. 6

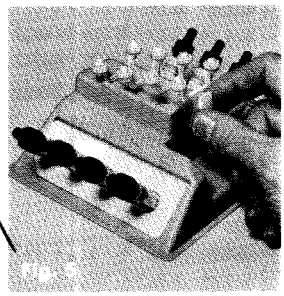


Fig. 5

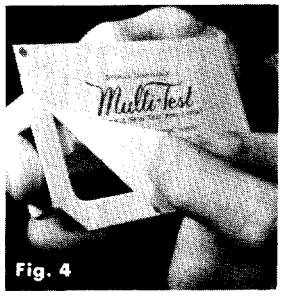


Fig. 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

MULTI-TEST unit in the loading holder furthest from you, the second in the center loading holder, and the third in the loading holder closest to you. **Reverse this order** when removing loaded MULTI-TEST units for application. This procedure prevents inadvertent contact between the user's hand and the test heads.

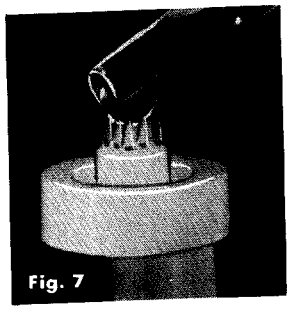


Fig. 7

3. While holding tip of dropper just slightly away from tips of points, slowly and gently squeeze dropper bulb until **drop barely begins to form.** NEVER USE FREE FALLING DROP OR FULL DROP.
4. Touch **forming drop** to tips of points allowing capillarity to pull extract onto test head points. See Figure 7. As **forming drop** is loaded onto points, partially release pressure on dropper bulb **before full drop is formed at dropper tip or is expelled.** A full drop will overload the test head points. Overloading the points will cause the testing substance to run down the sides of the points and away from the tips.

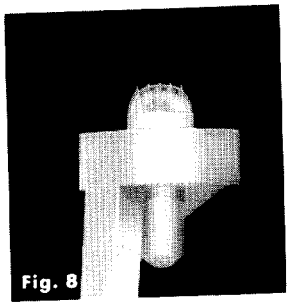


Fig. 8

5. Be sure that testing material "wells up" to the tips of all nine points, providing a sufficient "load." It may be necessary at times to use a very light "painting" stroke with extract formed at the dropper tip to spread it uniformly across the tips of all nine points. Figure 8 illustrates a proper "load." Practice is required to develop a good loading technique.

NOTE: It is convenient to load several MULTI-TEST units at one time for successive application. The preferred method of loading MULTI-TEST points is the Dip 'N Touch dispenser shown in Figure 8a. Dip 'N Touch information is available on request. Avoid creating air bubbles in extract during loading.

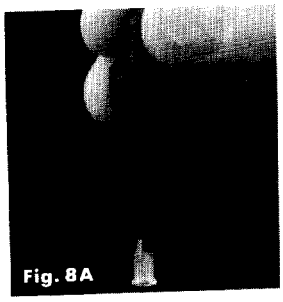


Fig. 8A

Administration of Allergenic Extracts With MULTI-TEST

With the points of all eight test heads properly loaded, MULTI-TEST is used as follows:

1. Select only testing sites that will permit sufficient surface area and sufficient subcutaneous tissue to allow adequate penetration of all points on all eight test heads. The preferred sites are the volar surfaces of each arm and the back. Skin of the

HS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

posterior thighs may be used if necessary. Avoid hairy areas whenever possible since the reactions are more difficult to interpret in these areas. Cleanse sites with alcohol, ether, or acetone and allow to dry.

2. Point "T-bar" end of MULTI-TEST toward a constant reference point such as the head of the subject being tested and press loaded unit into the skin with sufficient pressure to prick the skin and allow adequate penetration of points. Pointing "T-bar" toward a constant reference point greatly reduces any possibility of incorrectly identifying the extract (or control) applied at each test site. See Figure 9. **With proper pressure, the puncture pattern of the points will be observed at each test site, along with an imprint of the circular platform of each test head.** If the skin is taut, less pressure is required to gain proper penetration of points. With proper pressure, bleeding rarely occurs. In some cases the contour of the testing area may be such that slight "rocking" of the MULTI-TEST unit will be required to gain adequate and uniform penetration of points from all test heads. For example, particular attention must be given to proper penetration of points on test heads No. 4 and No. 5 when the volar surface of the forearm is used, because these two test heads will be closest to the wrist over an area where the contour of the forearm narrows. A "feel" for using MULTI-TEST properly is gained quickly after just a few applications. It is desirable to visually check each test site to be sure that adequate point penetration has been achieved.

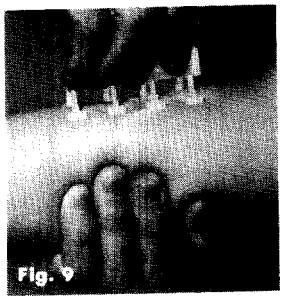


Fig. 9

3. Make an identification mark such as A, B, C on the skin at the "T-bar" end of the testing device. Results are then read in a clockwise manner, starting at test site No. 1 that will always be in the 1:00 o'clock position. If, for example, three test batteries are used, battery A is read from test site 1 through 8, battery B from test site 1 through 8, and battery C likewise. As pointed out earlier, this procedure provides a high degree of accuracy in relating test extracts (or controls) to test site results.

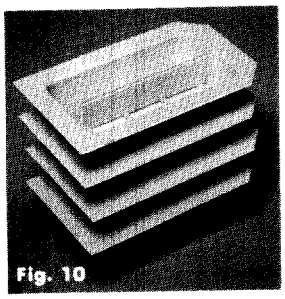


Fig. 10

4. Discard MULTI-TEST after use. DO NOT REUSE. An efficient way to utilize minimum space in disposing of MULTI-TEST units is shown in Figure 10. The used testing devices are placed into the containers from which they were removed, and the containers are then stacked for disposal as shown in Figure 10. The stacked containers can be placed back into the MULTI-TEST box so that box and used devices can be discarded at the same time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

READING AND RECORDING MULTI-TEST RESULTS

Because patients differ in their response to mechanical and chemical stimulation of the skin, interpretations of skin test results are most reliable when positive (histamine) and negative (glycerin) controls are used. It is preferred that testing be conducted so that positive and negative controls are applied at the same time and in the same general location as the diagnostic extracts. The response to histamine (1:1000) is considered a 3 + reaction, while the response to glycerin (50% concentration) is considered negative. The diagnostic extract test sites can be graded against the positive and negative control sites. Reading of positive control results **is conducted 8 to 10 minutes following administration,** while reading of results from the negative controls and diagnostic extracts **is done 15 to 20 minutes after their administration.** However, positive reactions to diagnostic extracts can occur up to 30 minutes following administration. It should be noted that the use of histamine (1:1000) as a positive control also provides information as to whether or not the patient's ability to react adequately to diagnostic extracts is being impaired by use of drug products or other causes.

Typical reactions from the MULTI-TEST technique are as follows:

Negative No wheal or a wheal no larger in size than that produced at the negative control site. Erythema absent or area of erythema no larger than area of erythema occurring at the negative control site. It should be noted that all scratch and prick type instruments do, on some patients, cause a wheal or erythema, or both, at the negative control site. Wheals may range in size from a barely detectable 1-2mm. to a well defined 5mm. Area of erythema may range from a faint 1-2mm. to a clearly defined 10mm. or larger. THEREFORE, READING ALL TEST RESULTS AGAINST THE NEGATIVE CONTROL IS IMPERATIVE.

1 + Wheal may or may not be present. If present, wheal must be as large or larger than negative control. Area of erythema significantly larger than area of erythema at negative control site.

2 + Wheal 5mm. to 7mm. and area of erythema usually larger than 10mm.

3 + Wheal 7mm. to 10mm. and area of erythema usually larger than 20mm. Slight pseudopodia and itching may occur.

4 + Any reaction with a wheal larger than 10 mm. or pronounced pseudopodia. Area of erythema may or may not be larger than that of a 3+ reaction. Pseudopodia and itching are likely to occur. Record actual size.

NOTE: The above information is not absolute, but serves as a guide to reading MULTI-TEST reactions. Readings should always be made against positive and negative controls. Almost all adults exhibit 7 to 10 mm. wheals (3+) from properly administered histamine (1:1000) unless their ability to react is impaired by use of drug products or other causes. Unimpaired histamine reactions in young children will

47

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

sometimes not exceed 6 mm. wheals. Histamine wheal reactions less than 7 mm. should not be considered 3+. Reactions comparable to those from negative controls are negative regardless of size.

A POSITIVE SKIN TEST REACTION TO ANY ALLERGENIC EXTRACT MUST BE INTERPRETED IN LIGHT OF THE PATIENT'S HISTORY OF SYMPTOMS, TIME OF THE YEAR, KNOWN EXPOSURES, AND EATING HABITS. SKIN TEST RESULTS ARE IN NO WAY A SUBSTITUTE FOR A CAREFULLY COMPILED ALLERGIC HISTORY. THEY SERVE AS ADDITIONAL INFORMATION TO AID IN IDENTIFYING CAUSATIVE ALLERGENS IN PATIENTS WITH ALLERGIC DISORDERS.

Recording of results should be done on forms provided by suppliers of allergenic extracts, on forms designed to meet the specific needs of individual practices, or on convenient MULTI-TEST recording forms supplied by Lincoln Diagnostics.

ADDITIONAL INFORMATION

When using the MULTI-TEST system of applying allergenic extracts, the user will find the following information helpful:

1. Each loading holder will accommodate eight dropper vials of testing material. Therefore, the user, in determining how many loading holders will be needed, must divide the number of extracts (and controls) used on each patient in a routine testing procedure by eight.

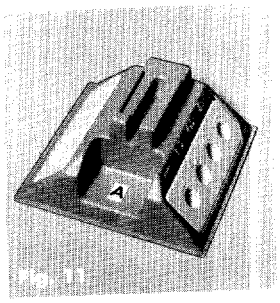
   NOTE: The amount of testing material needed to load the points of a MULTI-TEST test head is **much less** than a free-falling drop. Consequently, the standard 5 ml. dropper vial, when used with MULTI-TEST, will provide more than 500 test doses.

   When using multiple loading holders, each holder (containing eight vials) must be properly identified. For example, a loading holder containing six dropper vials of extracts, a positive control and a negative control, might be identified as battery "A". A loading holder containing additional, but different dropper vials of extracts and controls might be identified as battery "B". The use of alphabetic letters is recommended to identify each loading holder and the corresponding area at which the battery of eight tests is administered from the vials contained in that loading holder. The use of alphabetic identifying letters eliminates possible confusion when recording test sites by numbers 1 through 8. For example, test site No. 1 of battery "A" would identify the positive control, while test site No. 4, battery "A", would identify an extract. The most desirable location for identifying each loading holder is shown in Figure 11. Letter identification by use of a pressure sensitive label is convenient. An indelible marker can also be used to apply the identifying letter direct to the surface of the loading holder.

48

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14



2. The trays of loading holders containing allergenic extracts and controls should be stored in the refrigerator at 2° to 8°C when not in use. When stacking the trays, be sure that the tops of the three loading holders fit into the three recessed areas on the bottom of each tray. This provides a positive fit.

3. The dropper vial containing histamine (1:1000) should be placed in well No. 1 of the selected loading holder so that test head No. 1 of MULTI-TEST always administers the positive control. The dropper vial of glycerin (50%) should be placed in well No. 8 so that test head No. 8 always administers the negative control. Dropper vials of diagnostic extracts are placed in the remaining loading holder wells. This arrangement of extracts and controls should be used consistently. A negative control should be employed in each test battery of eight to provide a very effective system for grading the results from extracts against the results from the negative control at each test area.

   Dropper vials containing 5ml. of histamine (1:1000) can be purchased from Center Laboratories, 35 Channel Drive, Port Washington, New York 11050.

CAUTION: The sterility of MULTI-TEST is guaranteed only when the seal of the individual unit container is unbroken. The plastic MULTI-TEST unit will not withstand heat sterilization or exposure to alcohol, ether, or acetone. Attempts to resterilize can result in transmission of blood-borne diseases. Repeated use of a single device may result in inaccurate test results.

CAUTION: All cautions and precautions contained in the package insert for allergenic extracts must be observed.

CAUTION: All cautions and precautions contained in the package insert for histamine phosphate (1:1000) must be observed.

CAUTION: Federal Law restricts this device to use by or on the order of a physician.

HOW SUPPLIED: MULTI-TEST, Box of 6 sterile applicators, Stock No. MH-6
Loading Holders, packaged in any number ordered, Stock No. MHLH-1
Trays, packaged in any number ordered, Stock No. MHT-1

LINCOLN DIAGNOSTICS, INC.

DECATUR, ILLINOIS 62525

May, 1988

Printed in U.S.A.

W9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14 EXHIBIT F

A *NEW* SIMPLIFIED TECHNIQUE

MONO-Vacc*

FOR SMALLPOX VACCINATION

U. S. 3,062,212; 3,136,314 AND D 193,600

MONO-VACC, a disposable, multiple puncture vaccinator offers these **ADVANTAGES:**

- Elimination of "needle fear" and struggling of infants and children.
- High percentage of "takes" — 98.4% with MONO-VACC in previously unvaccinated infants.
- A cosmetically superior and uniformly smaller scar. Mean size .36 cm. with MONO-VACC as compared to .6 cm. with conventional method.
- Fewer secondary reactions such as high fever and secondary infection.
- A virtually painless procedure.
- A quick, convenient technique that is easily learned and administered by either doctor or nurse.
- Uniformity of puncture with minimal pricking of the dermis — with proper technique bleeding does not occur.
- Eliminates aiming of needle.
- No danger of multiple scars.
- Uniformity of technique thus reducing failures.
- Ideal for mass vaccinations in health clinics and during epidemics.

* REGISTERED TRADEMARK

DIRECTIONS:
(READ CAREFULLY)

1. Cleanse the area of insertion thoroughly with Acetone and allow to dry completely.
2. Remove vaccinator from sterile plastic bag by tearing from serrated edge down. Tear at V notch. (See Figure #1).
3. Lay thumb unit carefully on its side so as not to contaminate the points. (See Figure #2).
4. Slip rubber bulb onto capillary tube containing liquid vaccine and break off ends of tube in the usual manner.
5. While holding the vaccinator in one hand squeeze vaccine onto points with other hand so as to cover all nine points. (See Figure #3). The entire amount of vaccine contained in the capillary tube is usually not needed. It is important not to overflood the surface of the vaccinator base. Often two patients can be vaccinated from the contents of one capillary tube providing they are vaccinated in immediate succession with separate sterile thumb units.
6. Slip loaded vaccinator firmly onto thumb so the points protrude from the volar surface. (See Figure #4).
7. Grasp upper arm of subject to be vaccinated with free hand and make skin taut prior to puncture. Place fingers of hand containing thumb unit on medial side of upper arm and press vaccinator very firmly into the posterior lateral aspects of deltoid area to full depth of points and then remove. (See Figure #5). Because of the thumb unit design it is difficult to puncture too deeply into the dermis. The vaccine is deposited from the points into the skin and over the punctures. One MONO-VACC impression is recommended for vaccinating previously unvaccinated subjects, but 3 to 4 impressions through the same drop of vaccine at exactly the same site are recommended for revaccination.

FIGURE #1

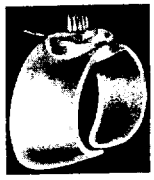


FIGURE #2

FIGURE #3

FIGURE #4

FIGURE #5

IMPORTANT:

Be sure vaccine covers all 9 points up to the tips and that skin is made taut prior to puncture. **Push firmly to full length of points to insure adequate penetration.** With proper pressure an imprint of the circular platform will be observed on the skin. With certain vaccines the active virus sometimes separates from the glycerin media and settles to one end of the fluid or to one side of the capillary tube depending on how the vaccine is stored. If this occurs a high percentage of "takes" may not be obtained with MONO-VACC in that the active virus is not being applied evenly to all points. For best results with MONO-VACC one of the following vaccines is recommended: the aqua colored calf lymph vaccine by The National Drug Company or the pink colored chick embryo vaccine by Lederle Laboratories.

PRECAUTIONS:

The sterility of this device is guaranteed only when the plastic bag is unbroken. Routine precautions related to standard vaccinating procedures must be observed with MONO-VACC. **Discard MONO-VACC after use.** The plastic unit will not withstand heat sterilization nor exposure to alcohol, ether, or acetone. Attempts to resterilize could result in transmission of serum hepatitis.

ADDITIONAL USES:

MONO-VACC can be employed to introduce certain steroids into dermatological lesions. The recommended procedure is to apply the steroid substance over the affected area and make multiple punctures through the steroid, introducing the steroid substance into the superficial layers of the skin. MONO-VACC may be used as a scarifier in skin allergy testing. The procedure is to cleanse the area properly and then make 4 to 6 scarifications in immediate succession with the allergen in each case being placed over the scarification. This procedure is repeated until the desired number of scarifications are obtained. When using MONO-VACC for skin allergy testing slip the unit onto the index finger leaving the second finger and thumb free to manipulate the dropper.

CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

AVAILABILITY:

Box of 12 sterile units. Stock #MV-12.
Box of 20 sterile units with freeze-dried vaccine. Stock #MV-20.

MONO-VACC REFERENCES:

1. Kravitz, H.: PEDIATRICS, February 1961, Vol. 27, p. 219-226.
2. Gellis, S. S.: YEAR BOOK OF PEDIATRICS, 1961-62, p. 85, 86.
3. Kempe, C. H.: J.A.M.A., October 5, 1964, Vol. 190, p. 87.
4. Smith, M. H. D.: PEDIATRICS, September 1963, Vol. 32, p. 447.
5. Kravitz, H.: INTERNATIONAL CONGRESS OF PEDIATRICS, September 9-15, 1962.

LINCOLN LABORATORIES, INC.
DECATUR, ILLINOIS, U.S.A.

Printed in U.S.A. Revised May, 1969

50

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT G
Includes Back Side

Consider these points:

Accuracy
Convenience
Disposability
Economy

Greer's unique new DermaPIK System represents a major advance in convenience and reliability in skin testing for Allergy Specialists. The DermaPIK System introduces a new plateau of convenience, reliability, safety and economy in skin testing.

The DermaPIK System introduces a new plateau of convenience, reliability, safety and economy in skin testing.

The DermaPIK System consists of three components: DermaPIKs, DermaWELLs, and the DermaRAK. To set up the system, partially fill each DermaWELL with a test antigen and place it in the DermaRAK in its numbered position. The DermaPIKs form self-sealing caps for each DermaWELL and, when removed for performing a skin test, a uniform amount of test antigen is automatically loaded between its six tines. After applying the DermaPIK with firm pressure to a marked position on your patient's skin, simply discard the DermaPIK and recap the DermaWELL with a new one.

The DermaPIK System is convenient, economical and yields accurate skin test results.

GREER DermaPIK SYSTEM

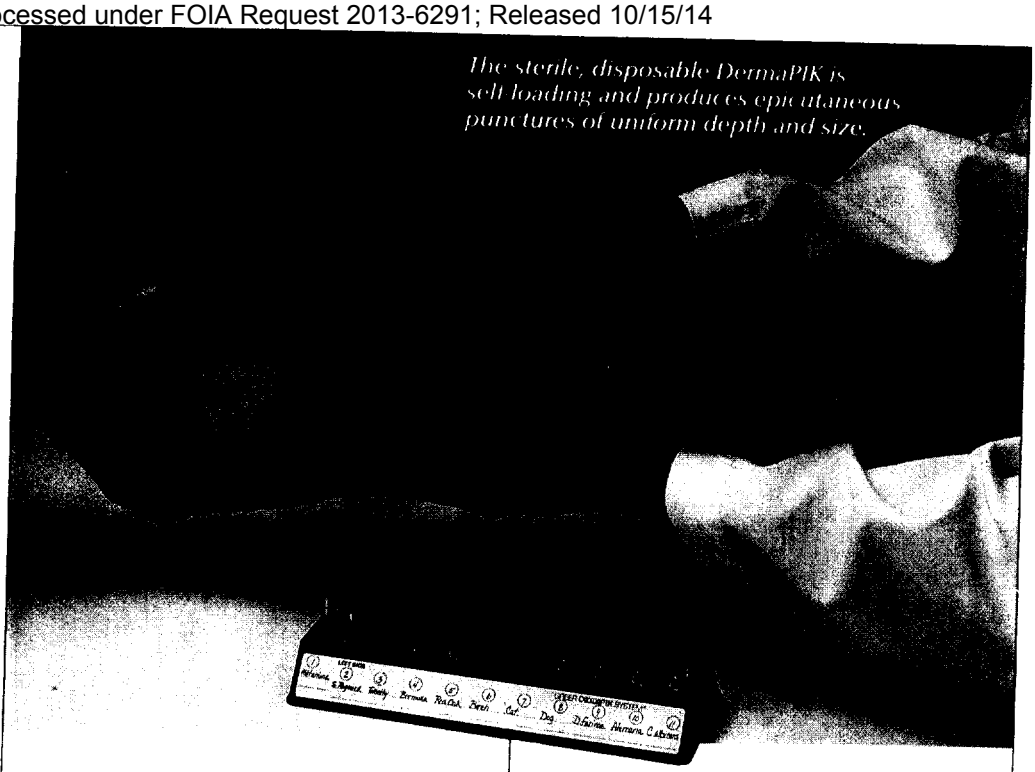
GREER LABORATORIES INC

GREER LABORATORIES, INC.
P.O. Box 800 • Lenoir, NC 28645 • (704) 754-5327 • FAX (704) 754-5320
Wats (800) 438-0088 • NC Wats (800) 524-7337

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

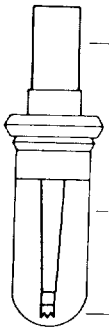
Accurate and Reproducible Test Results, Greater Convenience, Better Patient Acceptance



The sterile, disposable DermaPIK is self loading and produces epicutaneous punctures of uniform depth and size.

Convenience

No other skin testing device compares with the DermaPIK System for convenience. Preparation of the system is simple and straightforward: first, identify by name and number each test antigen on the labels provided, and apply the labels to both sides of the DermaRAK. Then fill each DermaWELL, seal it with a DermaPIK, and snap it into its corresponding position in the DermaRAK.



DermaPIK/ DermaWELL Assembly
(Actual size)

The DermaPIK System uses between .25ml to .50ml of test antigen in each DermaWELL and yields approximately 100 to 200 tests. This enables you to make several DermaPIK sets from each standard 5ml vial of test extract. The DermaPIK fits comfortably and securely in your hand and its compact dimensions of only 8.25 "L x 3 "W x 2 "H mean less counter and storage space.

Disposability

Two prime considerations in the design of the DermaPIK System have been the elimination of cross-contamination of puncture sites and the increased concern throughout the medical profession over the spread of infectious diseases. The sterile, disposable DermaPIK is the answer to both of these problems. A further advantage of the DermaPIK is that it makes only a minor contribution to the total volume of bio-hazardous waste materials you produce.

Reproducibility

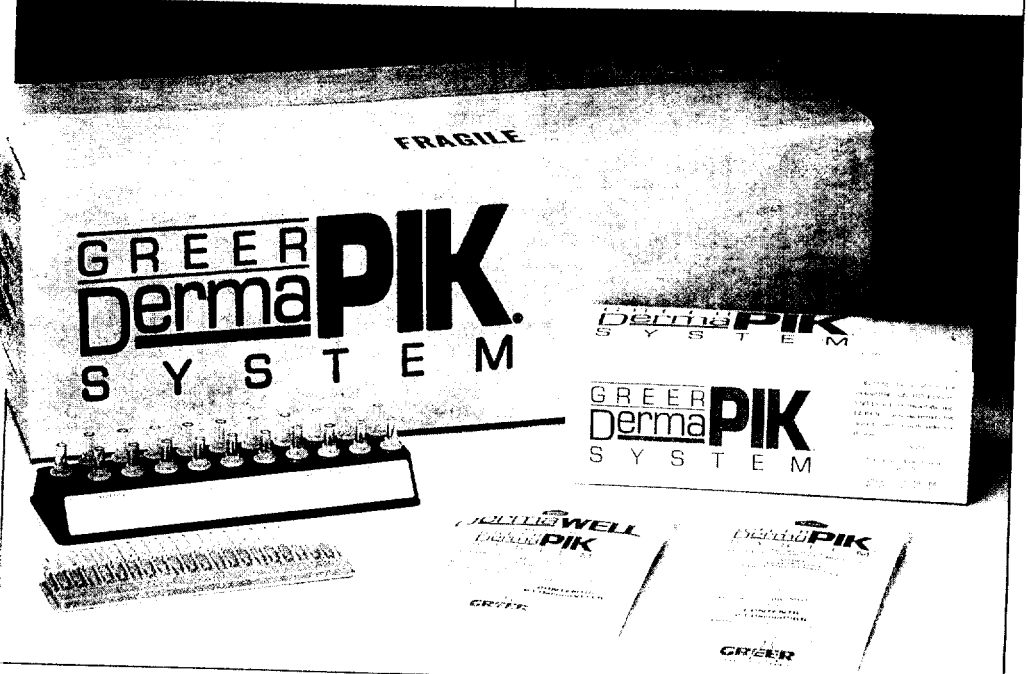
The past twenty years have seen a dramatic increase in the acceptance of the prick puncture test as a diagnostic procedure. However, the methodology of this procedure can be subject to considerable variation and interpretation of test results. Greer's new DermaPIK System has been specially designed to introduce a higher level of consistency to your diagnoses. The DermaPIK is easy to use and its six tines will penetrate to the correct depth but no further, resulting in punctures of uniform depth and size.

The unique self-loading antigen system of the DermaPIK guarantees that each puncture site receives the same amount of antigen, thus eliminating waste and reducing the potential for false negative reactions. Since each DermaPIK is disposable, cross-contamination is eliminated.

Economy & Efficiency

The DermaPIK's self-loading feature means an average *eight-fold* savings in cost of test extracts. Conventional dropper application of antigens yields around 100 tests/5ml vial; with the DermaPIK you achieve 750-1000 tests/5ml vial.

Further savings are realized when you consider the DermaPIK System is easy and convenient to set up, there is no laborious loading or placing of test antigens with droppers, and when you complete tests on one patient you are automatically ready for the next. Patient trauma is greatly reduced by the speed and efficiency of this system; the tines cause virtually no pain. As a result, you and your staff will have more time to devote to other activities.



- *DermaPIKs are sterile and supplied 21/tray in envelopes.*
- *DermaWELLs, also sterile, are packaged 21/envelope.*
- *DermaRAKs are available individually and feature 20 test positions and 1 control position.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT H

The ALO bifurcated needle is a sterile, disposable, two-tined needle for in-vivo diagnostic skin-testing using the puncture technique—a rapid, simple, and reproducible procedure.

The bifurcated needle is 6.6cm long, with 0.7mm between the tines. Each needle is individually sterilized and sealed in 10-strip packs, available in packages of 500.

DIRECTIONS

- Wipe the patient's skin with 70% ethanol or isopropyl alcohol and allow to air dry.
- Mark test sites with a pen, placing them 6 cm apart for accurate wheal measurements.
- Place one drop of the test antigen next to each site.
- Hold the shaft of a sterile bifurcated needle between thumb and forefinger, and lightly puncture the skin at a 90° angle. Penetrate the skin without drawing blood.
- Apply the positive and negative controls near the sites of the test allergens.

Because skin responses to mechanical and chemical stimulation can differ from patient to patient, we recommend using a positive control of 1mg/ml of histamine base or 5mg/ml of histamine phosphate, and a negative control of 50% glycerol saline, or whatever diluent is supplied with the allergenic extract.

- Grade the diagnostic site against the positive and negative sites. Record the readings 15 minutes after the puncture test and reinspect the sites in 30 minutes. If the test site has grown, discard the original reading. The positive control may determine whether a patient's reaction is impaired by certain drugs or for other reasons.

GRADING SYSTEM

Grade	Wheal (mm) after subtracting any wheal response to diluent control
0	No wheal
1+	< than half the histamine diameter
2+	half the size of histamine
3+	same size as histamine control
4+	size of histamine control +2mm
5+	> than 2×histamine control

ALTERNATE DIRECTIONS

- Place one drop of test antigen next to each marked site.
- Hold the shaft of a sterile bifurcated needle between thumb and forefinger at a 90° angle, and place the bifurcated tip in the center of the drop of test antigen.
- With gentle downward pressure and without lifting the tines from the skin, rock the shaft back and forth and side to side. Don't rotate or gouge the needle. Penetrate the skin but do not draw blood, and wipe off the extract immediately after removing the needle.
- Outline the reaction with a pen 15 minutes after the test, tracing first the flare and then the wheal.

Negative reactions occur when the wheal or flare is no larger than that produced at the negative test control site. Some patient's show wheal or flare with scratch or prick type instruments (dermographism), so compare results with the negative control.

A positive skin test only serves as one piece of information in identifying the causative allergen in an allergenic patient. The interpretation of test results requires a thorough knowledge of the patient's history, physical findings, medication, etc.

ALTERNATE GRADING SYSTEM

Grade	Wheal (mm) after subtracting any wheal response to diluent control
0	No wheal
1+	< than half the histamine diameter
2+	≥ half the histamine diameter
3+	same size as histamine control ±1mm
4+	> histamine diameter: <2×diameter
5+	≥2×histamine control

PRECAUTIONS FOR USE

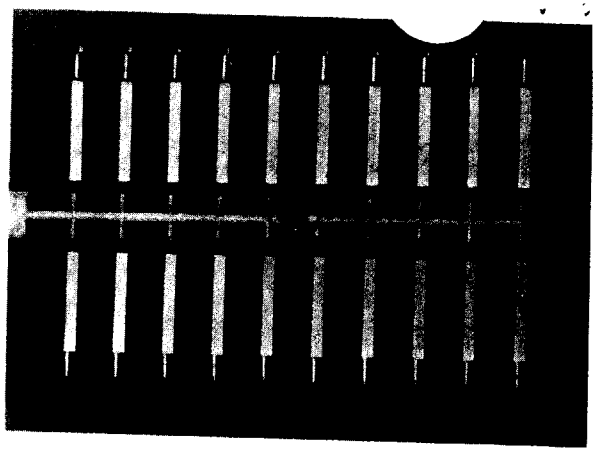
- ***Rinse prongs with 70% isopropyl alcohol and wipe with a water-saturated cotton ball after each skin puncture to avoid "carry-over" of extracts.***
- ***Discard needle after use on one patient.***
- ***The bifurcated needle may be used with any commercially available allergenic extract for in-vivo diagnostic puncture skin testing to assess a patient's reactivity to a particular allergen. ALO Laboratories, Inc. certifies that the bifurcated needle is sterile only when the seal of an individual unit is unbroken. The needle is for single patient use only; discard it after using it on one patient. Do not re-sterilize the needle, and take all necessary precautions associated with skin testing before using it. Federal law restricts this needle to sale by or on the order of a physician.***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

MORROW BROWN®
DISPOSABLE ALLERGY TEST NEEDLES!

EASY TO SEE • TRIANGULAR POINT FOR BETTER PENETRATION



GREATER PATIENT COMFORT

Allergy testing can be painless and nonfrightening with the Morrow Brown disposable needle. The needle administers a quick penetration of the skin.

NO ANTIGEN CARRYOVER

The Morrow Brown disposable needle virtually eliminates false positive results. Because you use each needle only once, the possibility of antigen carryover is eliminated.

MORE REPRODUCIBLE

Each Morrow Brown disposable needle consistently makes a standard penetration giving you more accuracy and eliminating irregular scarification from the scratch type needle.

EASY TO USE

A series of tests can be done in minutes with the Morrow Brown disposable needle and, because they are disposable, they require no cleaning or sterilization.

SAFE AND STERILE

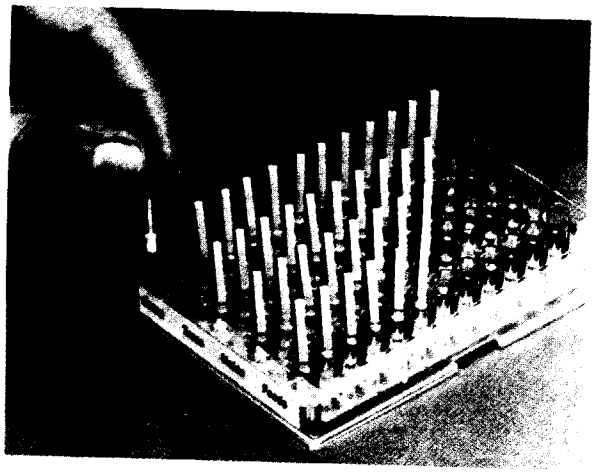
Each Morrow Brown disposable needle is made of NAS styrene methyl methacrylate copolymer, a nontoxic plastic. Packaged in blisterpacks of 20 and sterilized by gamma radiation, each individual needle breaks off for immediate use.

COST EFFICIENT

Inexpensive to use, the Morrow Brown disposable needle offers a safe, beneficial and economical answer to many problems common to traditional allergy testing methods.

EASY APPLICATION

WITH THE MORROW BROWN NEEDLE AND THE MULTIWELL™ EXTRACT TRAY



TRAY PREPARATION

Place MultiWell strips into the base tray. Use as many wells as needed to correspond to your test sheet. Each tray holds up to 96 wells of extract. For easier handling, leave an empty row between extract rows. Label each row. Add 1:10 or 1:20 w/v glycerinated extract to each well. Up to 7 drops per well can be used. If using histamine and saline controls, make sure they are glycerinated. Cover with lid — replace in storage bag to prevent evaporation and store in refrigerator.

TESTING PROCEDURE

Check points of needles for possible abrasion after removal from package. Remove MultiWell tray from refrigerator and place Morrow Brown disposable needles, point down, into each MultiWell used. Mark test sites on patient's arm or back. Remove each needle individually, and press firmly into the corresponding test site. Each needle delivers a consistent amount of extract (surface tension of the glycerinated extract allows extract to adhere to the needle without dripping). Dispose of needle. Read test sites 15-20 minutes after application. Add new needles to wells for use as needed. Each well yields up to 25 tests. When testing has been completed, replace lid, insert in storage bag provided and refrigerate.

ALTERNATIVE "DROP" METHOD:

Mark testing sites and place a small drop of glycerinated extract beside each ink dot. Holding the Morrow Brown needle perpendicular to the test site, punch firmly through testing extract and into epidermis. Discard needle immediately.

(Includes Back Side)

EXHIBIT I

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

SKIN TEST REACTION GRADING

Direct comparison of wheal diameters between different patients cannot be made because of differences in skin reactivity. A whealing reaction to a skin test must be compared to a Positive Standard using glycerinated histamine and a Negative Standard (diluent) in each patient.

METHOD

The grading system recommended by Aller//Guard is one originally developed by The Standardization Committee of the Northern Society of Allergy (Scandinavia). This system is precise enough for both clinical and most research purposes.

A wheal reaction the same size as the prick histamine control is graded + + + (3 plus) and a reaction the same size as the negative control is indicated by - or 0.

Summary of grading method:		
	+ + + =	size same as positive control glycerinated histamine 1.8mg/ml
	+ + + + =	wheal larger than control
	+ + =	wheal 2/3 of control
	+ =	1/3 of control

This grading system controls for differences in reactivity between patients and in the same patient at different times of testing. For more precise reading we recommend the Aller//Guard millimeter caliper which is supplied at no charge. If you are not presently using a positive histamine control, we recommend using 5mg/ml (1.8mg/ml of histamine base) or stronger if desired. Call if you have questions regarding use of histamine as

OTHER FINE PRODUCTS AVAILABLE FROM ALLER//GUARD®

MULTIWELL™ EXTRACT TRAY

A dip test accessory used with the Morrow Brown® needle. Includes tray, 48 wells and storage lid.

MITE-N-CASE® DUST PROOF MATTRESS ENCASINGS

Maximum dust-proof protection available in Plastibak Nylon and Plastisuede.

MITE-N-CASE® DUST PROOF PILLOW ENCASINGS

Available in soft Terry Cloth.

ACAROSAN® POWDER

A moist powder that eliminates house dust mites in carpeting.

HI-TECH FILTER

Easy installation. Maintains a dust-and pollen-free environment.

VITAIRE AIR PURIFIER

This portable, low maintenance purifier reduces allergens in the air.

ASSESS PEAK FLOW METER

This meter is an accurate and inexpensive aid in the management of asthma.

CALL TOLL FREE • 1-800-234-0816
OR • 913-267-9333

Aller//Guard®

Southgate Office Park
1645 SW 41st Street
Topeka, Kansas 66609-1250

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or

MORROW BROWN

DISPOSABLE ALLERGY TEST NEEDLES

EXCLUSIVE IN THE USA

Aller//Guard

Records processed under FOIA Request 2013-6291; Released 10/15/14 EXHIBIT J

DUOTIP-TEST®

Duotip-Test is a sterile, disposable, plastic bifurcated needle used to administer skin test substances. When employed with allergenic extracts it provides a quick, convenient and standardized procedure that is well accepted by patients. Before using Duotip-Test, or any testing device, the administrator must study carefully the package inserts accompanying allergenic extracts and control solutions.

The Duotip-Test system consists of these components:

1. The sterile, disposable applicator (Fig. 1).

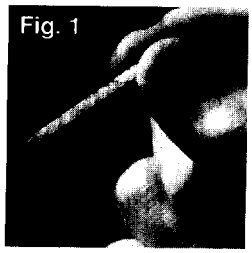


Fig. 1

2. The Dipwell Tray and its protective cover (Fig. 2).

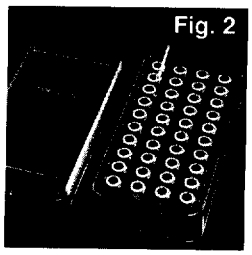


Fig. 2

Each tray consists of forty wells into which extracts and controls are placed. Points of individual Duotip-Test units are immersed into test solutions and pick up test doses via capillary attraction. See Dipwell Tray package insert for complete instructions on its use with Duotip-Test.

Directions for Use: Duotip-Test will administer test solutions via modified prick procedure (Fig. 3) or by rotation technique (Fig. 4).

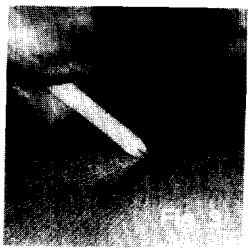


Fig. 3

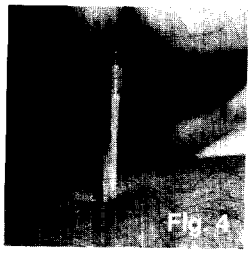


Fig. 4

When using either approach, these steps must be followed after cleansing skin and loading the points:

1. Modified Prick – Hold device so its shaft forms an approximate 45° angle with the skin plane. Prick and lift skin simultaneously.
2. Rotation Technique – Hold shaft between index finger and thumb. Press points vertically against skin with enough pressure to slightly indent skin. Maintain pressure on skin while rotating shaft clockwise or counter-clockwise 360°.

With either procedure allow test solutions to remain over test sites three to five minutes before wiping.

Reading Results: Because patients differ in response to mechanical and chemical stimulation of their skin, interpretations of test results are most reliable when positive (histamine) and negative (glycerosaline) controls are used. Response to histamine (1 mg/ml) is considered 3+, while response to glycerosaline is considered negative. Diagnostic extract sites are graded against positive and negative controls. Histamine results are read ten to fifteen minutes after administration. Results from negative controls and diagnostic extracts are read fifteen to twenty minutes after administration. Positive reactions to diagnostic extracts can occur up to thirty minutes. Use of histamine provides information on whether or not a patient's ability to react adequately to extracts is being impaired by drugs or other causes. Typical reactions from Duotip-Test, rotation technique, are as follows:

– No wheal or a wheal no larger in size than that produced at the negative control site. Erythema absent or area of erythema no larger than area of erythema occurring at the negative control site.

1+ Wheal may or may not be present. If present, wheal must be as large or larger than negative control. Area of erythema significantly larger than area of erythema at negative control site.

2+ Wheal 5mm. to 6mm. and area of erythema usually larger than 10mm.

3+ Wheal 7mm. to 9mm. and area of erythema usually larger than 20mm. Slight pseudopodia and itching may occur.

4+ Any reaction with a wheal larger than 10mm. or pronounced pseudopodia. Area of erythema may or may not be larger than that of a 3+ reaction. Pseudopodia and itching are likely to occur. Record actual size.

The above information is a guide to reading, but skin test results are not a substitute for carefully compiled allergic history and physical examination. Adults usually exhibit 7mm. to 9mm. wheals (3+) from properly administered histamine unless ability to react is impaired. Unimpaired histamine reactions in young children may not exceed 5mm.-6mm. wheals. Reactions comparable to those from negative controls are negative regardless of size. Modified prick test reactions may be smaller than those from rotation technique and are graded against histamine (3+) and negative controls. Convenient recording forms are available on request.

CAUTION: Sterility of Duotip-Test is guaranteed only when the unit container seal is unbroken. Duotip-Test will not withstand heat sterilization or exposure to alcohol, ether, or acetone. Attempts to resterilize can result in transmission of blood-borne diseases. Repeated use of a single device may produce inaccurate test results.

CAUTION: All cautions and precautions contained in package inserts for allergenic extracts must be observed.

CAUTION: All cautions and precautions contained in package inserts for histamine must be observed.

CAUTION: Federal Law restricts this device to use by or on the order of a physician.

SUPPLIED: Box of 100 sterile devices containing five individual packages of 20 each. Stock No. LDT-100.

LINCOLN DIAGNOSTICS, INC.
Decatur, Illinois 62525
Printed in U.S.A. August 1994

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

QUINTEST™

Skin Test Device

EXHIBIT K
(Includes Back Side)

FOR PUNCTURE SKIN TESTING

QUINTEST™ is a skin test device designed to apply test extract using the puncture technique.

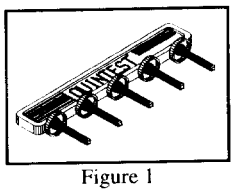


Figure 1

QUINTEST™ is designed for use by allergy practitioners who are trained in the application and interpretation of the puncture technique and who are trained in the recognition and treatment of adverse allergic reactions should they occur.

QUINTEST™ System consists of two components: The **QUINTEST™** skin test device (Figure 1) and the tray (Figure 2) that holds the allergenic extracts. The test devices are provided in individual sterilized bubble pack containers, 15 units per shelf pack. The **QUINTEST™** trays are provided in individual sterilized bubble packs, 10 units per shelf pack.

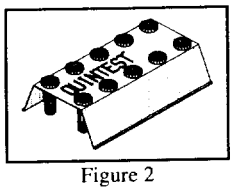


Figure 2

PRODUCT DESCRIPTION

The **QUINTEST™** device is a molded plastic handle with five testing probes (Figure 1). Inserted into each testing probe is a stainless steel lancet tip that protrudes from the probe enough to give the proper testing depth (Figure 3). Although the tray can be used for a week and then discarded, the **QUINTEST™** device is to be used once and discarded in a sharps container.

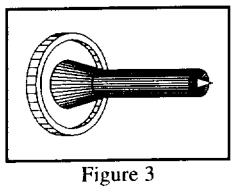


Figure 3

SET-UP INSTRUCTIONS

Remove one **QUINTEST™** tray from the shelf pack, peel back the paper label and remove the tray. Each **QUINTEST™** tray is supplied with pressure-sensitive labels. Each label strip has five designated areas corresponding to the wells. Write the name of each antigen in the area provided, remove the label backing and place on the side of the tray. Do the same for the other side. Fill the appropriate well with 3-4 drops using the dropper from the test extract vial. Glycerinated test extracts should be used because glycerinated extracts adhere to the test probes ensuring delivery of a proper diagnostic dose.

Once the trays are prepared, remove a **QUINTEST™** device from the bubble pack by peeling off the label. Pick up the device by the handle and place the tips in the wells. With the **QUINTEST™** device on the tray, the wells are covered to prevent foreign matter from entering the extract. To assure that test extracts are applied to the proper test sites, it may be helpful always to place the test device handle with the **QUINTEST™** name facing outward from the center of the tray.

Each tray holds two **QUINTEST™** devices. Once loaded, it can be used immediately or stored in the refrigerator until needed. When the extract-filled trays are not in use, store in the refrigerator with the test devices submersed in the wells.

SKIN TEST PROCEDURE

Prior to testing, clean the test area with alcohol and allow to dry. (See "Allergenic Extracts for Scratch and Prick/Puncture Testing" package insert for more detailed instructions.) Remove a **QUINTEST™** skin test device from a prepared tray by lifting it vertically, being careful not to touch the tips on the wells. With the **QUINTEST™** perpendicular to the skin, press down on the skin with medium pressure and rock the device end to end, without lifting the device from the skin, twice to ensure all tines have contacted the skin. Remove by lifting vertically and discard the **QUINTEST™** in a sharps container. Small circles about 4mm in diameter should remain at the test site indicating the correct amount of pressure was applied.

Following the above instructions will produce five uniform skin tests all at the proper depth without inducing bleeding. All test sites are three centimeters apart to avoid the axon reflex.

STORAGE AND DISPOSAL

Once you have completed a patient's test session, place new **QUINTEST™** devices in the antigen trays and refrigerate until the next test session.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

QUINTEST™ devices are designed to be used once and discarded in an approved sharps container (in accordance with all local, state and federal regulations). These devices cannot be cleaned sufficiently to prevent cross contamination from repeated use or to protect subsequent patients from possible transfer of serum hepatitis or other bloodborne pathogens.

It is recommended that **QUINTEST™** trays be used for one week and then discarded. If a used **QUINTEST™** device is inadvertently placed in a tray, the tray should be discarded and a new tray prepared prior to the next test session.

READING SKIN TEST REACTIONS

Measure wheal and erythema responses for histamine positive control at 10 minutes and allergens at 15 minutes. To improve accuracy, precision and uniformity of diagnostic testing and eliminate confusion as to the quantitation of the allergic response, we recommend recording wheal and erythema measurements.

Reactions from the **QUINTEST™** device may be graded as follows:

European Prick Test Grading System

Grade	Wheal (mm)	Erythema
Negative	<3	Not Measured
Positive	>3	Not Measured

Graduated System

Grade	Wheal (mm)	Erythema (mm)
0	<3	<15
2+	<6	<15
3+	7-9	16-30
4+	>9	>30

A positive skin reaction to any allergenic extract must be interpreted in light of the patient's history of symptoms, time of the year, known allergen exposures, and eating habits.

The skin tests are in no way a substitute for a careful allergic history. Rather, they serve as additional information to aid in identifying causative allergens in patients with allergic disorders.

HOW SUPPLIED

Item #	Description
8392ZA	**QUINTEST™** Skin Test Device (sterile), Shelf Pack of 15. Manufactured in England.
8394ZA	**QUINTEST™** Tray (sterile), Shelf Pack of 10.

Bayer

Bayer Corporation
Pharmaceutical Division
Allergy Products
Spokane, WA 99207

800-992-1120

Distributed in Canada by:
Bayer, Inc.
Healthcare Division
Etobicoke, ON M9W 1G6

800-268-1326

Bayer BAYER

385411-B01
New 12-27-95

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

DEVICE COM

PRODUCT & Manufacturer	LABELING	INTENDED USE	SPECIFICATIONS
Duotip-Test Lincoln Diagnostics, Inc.	See Exhibit J	System for delivering allergens in skin testing. Used as a prick or scratch test.	Specifications in this case do not appear applicable. Als Lincoln Diagnostics would not have access to specific information of this nature from each manufacturer of equivalent devices shown belo
Multi-Test Lincoln Diagnostics, Inc.	See Exhibit E	System for delivery of allergens in skin testing via prick puncture. Administers eight tests with one application.	See above statement at top of column.
★ Multi-Test II Lincoln Diagnostics, Inc.	See Exhibits A, B & C	Identical to Multi-Test referenced immediately above.	Specifications for Multi-Test II are provided in Exhibit D
★ Multi-Test II Dipwell Tray with Lid	See Exhibits A & C-1	Auxiliary tray for loading allergens on test points.	See Exhibit D
Mono-Vacc Lincoln Laboratories Inc.	See Exhibit F	Smallpox vaccination and delivery of allergens in skin testing. Prick puncture device.	See above statement at top of column.
DermaPIK Greer Laboratories	See Exhibit G	System for deliverying allergens in skin testing via scratch test or prick puncture.	See above statement at top of column.
DermaRAK/DermaWELLS	See Exhibit G	Loading allergens on test points.	
Morrow Brown Needle Aller//Guard	See Exhibit I	System for deliverying allergens in skin testing via prick puncture.	See above statement at top of column.
Morrow Brown Multiwell Tray	See Exhibit I	Loading allergens on test points.	
Bifurcated Needle Allergy Laboratories of Ohio	See Exhibit H	Smallpox vaccination and delivery of allergens in skin testing via prick puncture or scratch.	See above statement at top of column.
Quintest Bayer Corporation	See Exhibit K	System for delivery of allergens in skin testing via prick puncture. Administers five tests with one application.	See above statement at top of column
Quintest Tray	See Exhibit K	Loading allergens on test points.	

★ Multi-Test II is the subject device covered by this 510(k) submission

59

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

PARISON TABLE

EXHIBIT L

MATERIALS	PERFORMANCE	ANALYSIS OF COMPARABLE SAFETY AND EFFECTIVENESS	DESIGN
Acrylic Plastic Atohaas VM647 See Exhibit P	Since all comparable devices are epicutanous tests, having been used successfully for years, performance from each has been shown to be comparable in studies too numerous to practically cite. These are simple devices designed solely to penetrate or abrade the superficial epidermal layer of the skin.	See statement in this column that applies to all devices for which equivalence is claimed.	Plastic shaft with bifurcated point at end.
Acrylic Plastic Atohaas VM647 See Exhibit P	See Above. Reprints of five published studies are attached and identified as Exhibits 0-1 thru 0-5.	See Exhibits 0-1, 0-2, 0-3, 0-4 and 0-5.	Plastic handle with four arms on each side. At the end of each arm is a circular test head with nine protruding points.
Identical to Multi-Test above. See Exhibit P	Findings cited in Exhibits 0-1 thru 0-5 applicable.	See Exhibits 0-1, 0-2, 0-3, 0-4 and 0-5.	Identical to Multi-Test except that a non-utilized circular plastic pad is eliminated. See Exhibit D-1.
Acrylic Plastic Atohaas SG-7 See Exhibit M	Not Applicable		
Acrylic Plastic	See above statement at top of column.	All of these devices function in a like or similar manner, that is they prick and/or abrade the superficial epidermis as a means of introducing skin test allergens. This practice began with Charles Blackley in 1873 when he applied pollen to abraded skin. Since all referenced devices are epicutaneous test procedures, their safety and effectiveness have been shown to be comparable in studies too numerous to practically cite.	Plastic ring thumb unit with 9 protruding points.
"Delrin" Plastic	See above statement at top of column.		Plastic shaft with 6 points at end.
Plastic (Not Known)	Not Applicable		See Exhibit G
Plastic (Not Known)	See above statement at top of column.		Plastic shaft with one point at end.
Plastic (Not Known)	Not Applicable		See Exhibit I
Steel	See above statement at top of column.		Steel shaft with bifurcated point at end.
Plastic (Not Known) with steel lancet.	See above statement at top of column.		Plastic handle with five plastic shafts extending downward from the handle. At the end of each shaft is an inset steel lancet.
Plastic (Not Known)	Not Applicable		See Exhibit K

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2015-0291, Released 10/16/14

EXHIBIT M

PLEXIGLAS® SG-7

Gamma Resistant High Flow Impact Modified Acrylic Molding Resin

PLEXIGLAS SG-7 resin from AtoHaas represents the latest and most gamma radiation resistant high impact acrylic available.

PLEXIGLAS SG-7 maintains exceptional clarity after 5 megarads of gamma radiation with no adverse effect on physical properties.

In addition, PLEXIGLAS SG-7 has all the features of other AtoHaas high impact acrylics including excellent flow and moldability, biocompatibility, and chemical resistance. And, all AtoHaas resins are manufactured to certifiable quality standards.

PLEXIGLAS SG-7 passes USP VI and hemolysis tests.

For technical assistance contact one of the toll-free numbers listed below:

United States: 1-800-523-1532
Ontario and Quebec: 1-800-268-4270
Other locations in Canada: 1-800-268-4270

TYPICAL PHYSICAL PROPERTIES - PLEXIGLAS SG-7

Property	Test Method	Units	As Molded Plexiglas SG-7	Sterilized Plexiglas SG-7
Optical	ASTM D-1003			
Light Transmission	Total	%	92	92
Haze		%	1.5	1.5
Melt Flow Rate	ASTM D-1238 Condition I 230°C/3.8 Kg	G/10 Min.	13	-
Mechanical				
Tensile	ASTM D-638			
Strength at Yield		PSI	7,100	7,100
Elongation at Yield		%	4.3	4.3
Flexural	ASTM-790			
Strength at Max.		PSI	11,600	11,600
Modulus		PSI	350,000	350,000
Impact Strength	ASTM D-256			
Notched Izod		Ft-lbs/in of notch	0.6	0.6
Unnotched Charpy		Ft-lbs/.5" x 1"	15	15
Thermal				
DTUFL	ASTM D-648			
Annealed (4 hrs, 176°F)	264 PSI	°F	178	174
Vicat Softening Point	ASTM D-1525			
	90°F, 2.2 lbs	°F	201	200
	90°F, 11 lbs	°F	182	181
Miscellaneous				
Hardness	ASTM D-785	M Scale	60	60
Water Absorption	ASTM D-570 (24 hr)	%	0.3	0.3
Shrinkage from Mold	ASTM D-955	%	0.5	0.5

Data given are typical values and should not be used for specification purposes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14
(Includes Back Side) EXHIBIT N

Perfecseal® Medical Packaging Product Data

PERFECSEAL®, PERFECRAFT™ and PERFECPROOF™ COATED HEAT SEAL PACKAGING MATERIAL FOR STERILE DISPOSABLE MEDICAL PRODUCTS

GENERAL CHARACTERISTICS:

- Coating — overall coat, bright white thermoplastic adhesive, designed to seal most packaging materials, breathable for gas sterilization, maintains seal integrity during ETO or radiation serilization, provides contolled peel strength for convenient package opening
- Substrates
  - DuPont's Tyvek, spunbonded olefin, styles 1073B and 1059B
  - various grades of surgical kraft papers
  - films

FEATURES:

- Sealability - strong peelable bonds to most plastics used in rigid and flexible packaging
- Breathability - allows ETO gas to enter and exit packages during sterilization without damaging seals
- Peelability - a smooth, controlled strength peel for a sterile presentation when the package is opened
- Versatility - withstands radiation without seal degradation

PHYSICAL CHARACTERISTICS — PERFECSEAL COATED PRODUCTS:

Color	pure white coating
Identification	pink reaction with alkaline water
Activation Temperature	250°F
Application Temperature	250°- 300°F : 1 - 3 second dwell : 50 - 90 PSI
Curl	flat under humidity range of 20 - 80 %
Bond Peel Strength	1.0 to 3.0 pounds (1″ wide/180 peel at 12″ per minute)
Porosity Coated	always suitable for ETO & radiation sterilzation; varies with substrate and coating; see specific data sheets

APPLICATIONS:

Perfecseal coated products have been tested and used by a number of major medical device manufacturers for a variety of sterile products, e.g.,

- Urological Kits & Trays
- Foley Catheters and Foley Catheter Kits
- Spinal Anesthesia Trays & Kits
- I.V. Infusion Needles & Catheters
- Drainage Catheters and Suction Trays
- Packages - blister packs, lidded trays, pouches, and bags
- Tracheotomy Kits
- Dressing Change Trays
- Indwelling Catheters
- Suture Removal Kits
- I.V. Infusion Kits
- Intubation Feeding Trays
- Bulb Syringes
- Gauze Sponges
- Sutures
- Surgeon's Gloves
- Surgical Blades
- Irrigation Trays

Paper Manufacturers Company • Medical Products Division
9800 BUSTLETON AVENUE • PHILADELPHIA, PA 19115 • (215) 673-4800
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

SEALING CONDITIONS (tray):

- Sealing Temperature
  - 250°F to 300°F. Temperatures in excess of 300°F may cause melting & thinning of Tyvek
- Pressure
  - 50 - 90 pounds per square inch
- Dwell Time
  - one to three seconds dwell
- Other
  - if possible, allow 1/2″ for flange - 1/4″ is minimum recommended
  - platen should be constructed to effect a seal on the inside perimeter of the flange to prevent the packaged part from working its way into the sealed flange area
  - for continuous pouch packaging, where dwells are shorter and nip roll pressures are used, recommend sealing range of 300°- 350°F, sealing through opposite side of package

  NOTE: Above conditions will vary for different package openings

USE PROPERTIES:

- Adhesion to Different Surfaces
  - seals to most common plastic packaging materials, including PE, PP, PVC, XT Polymer, Polycarbonate, Polystyrene, Mylar, Surlyn, paper and foil
  - broad application simplifies inventories and provides flexibility in package development decisions
  - it is recommended that adhesives be tested with specific plastics
- Package Opening
  - generally, a cohesive splitting of the adhesive layer is obtained
  - visible adhesive transfer is obtained on the opposite seal surface upon opening the package; provides a simple check of seal integrity
- Gas Sterilization
  - adequate porosity allows effective gas sterilization under a variety of sterilization cycles.
- Sterile Barrier
  - users have tested and approved products packaged with Paper Manufacturers Company coated products for sterility, pyrogenicity, toxicity and allergic reaction
- Low Temperature Flexibility
  - sealed packages will withstand normal handling under conditions of O.F.; adhesive is not effected by even lower temperatures if package is not subjected to extreme shock or impact; many factors influence cold temperature performance, therefore we recommend testing the finished package under simulated use conditions
- Tyvek Static/ Cleanliness
  - Tyvek styles 1073B and 1059B are the only grades recommended for sterile disposable medical products; none are anti-static treated
  - since static charges tend to attract loose dust particles, care must be taken in processing and handling
- Food & Drug
  - all materials used in formulating Paper Manufacturers Company adhesives are FDA approved for direct food contact
  - all Perfecseal Adhesives have been assigned a Drug Master File number which can be referenced upon request
  - please contact Paper Manufacturers Company for additional specific technical information pertaining to properties or application of this product

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

PM Health Care Guide for Converted Films

Film Products	Structures	Special Features	Tensile* (PSI)	Tensile Modulus* (PSI)	Elmdorf Tear* (grams)	Elongation* (%)	Haze* (%)	Peel* Strength (lbs/in)	Environ-mental **	Sterilization
24-040 24-060	4 mil LLDPE 6 mil LLDPE	High clarity Breather Bag film	5,000 5,000	28,000 24,000	60 g/ml 60 g/ml	700 % 600%	14% 20%	1 lb. Minimum	Recycle #4 Recycle #4	ETO & Radiation ETO & Radiation
25-030 25-040	3 mil LLDPE 4 mil LLDPE	Tough Breather Bag film	5,000 5,000	24,000 24,000	300g/ml 300g/ml	600% 600%	11% 13%	1 lb. Minimum	Recycle #4 Recycle #4	ETO & Radiation ETO & Radiation
28-240	Double wall LLDPE for Breather Bags	Extra strength Breather Bag film	6,000	24,000	350g/ml	600%	15%	1 lb. Minimum	Recycle #4	ETO & Radiation
30-040 30-050	4 mil-1.5 poly/1 nylon/1.5 poly 5 mil-1.75 poly/1.5 nylon/1.75 poly	Puncture resistant	6,000 6,000	35,000 30,000	600g/ml 600g/ml	800% 800%	25% 35%	1 lb. Minimum	Recycle #7 Recycle #7	ETO & Radiation ETO & Radiation
19-4820	48 guage PET 2 mil MDPE lamination	Universal material for coated chevron peel pouches	7,000	550,000	300g/ml	110%	10%	1 lb. Minimum	Recycle #7	ETO & Radiation
16-4820	48 guage PET/extrusion coated with LDPE	Ideal for uncoated Tyvek pouches - Cost efficient	7,000	550,000	300g/ml	150%	10%	1 lb. Minimum	Recycle #7	ETO & Radiation
13-4820	48 guage PET/2 mil LDPE w/ 3-5% EVA lamination	EVA for better seal characteristics for pouches	7,000	550,000	350g/ml	150%	10%	1 lb. Minimum	Recycle #7	ETO & Radiation
Perfecform	4, 6 and 8 mil thermoformable film	Universal forming web for coated Tyvek and paper	5,000	110,000	100g/ml	800%	4%	1 lb. Minimum	Recycle #7	ETO & Radiation

* Characteristic	ASTM Test	Technical Explanation
Tensile	D-882	Breaking strength
Tensile Modulus	D-882	Toughness
Elmdorf Tear	D-1922	Tear strength
Elongation	D-882	Degree of stretch
Haze	D-882	Level of clarity
Peel Strength	D-4321	Heat seal peelability to the secondary web

** Society of Plastics Industry (SPI) Coding System

Perfecseal® Breather Bag® Packaging Quick Ship Program

Choose from these 8 stock sizes or place your custom order: (Width x Length)

6" x 10"	20" x 25.5"
8" x 12"	16" x 22.5"
10" x 15"	25" x 30.5"
12" x 20.5"	20" x 36"

Perfecseal® Pouch Packaging Quick Ship Program

PM Company offers CR-27 adhesive coated pouches in these stock sizes: (Width x Length)

3.5" x 5.5"	8.0" x 13.0"
4.0" x 8.0"	10.0" x 15.0"
5.0" x 10.25"	4.0" x 28.0"
6.0" x 12.0"	4.0" x 50.0"

EXHIBIT N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PM COMPANY

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT O-1

(b)(4) copyrighted material

CORRELATION OF IMMEDIATE SKIN TEST RESPONSES TO ANTIGENS INTRODUCED BY MULTI-TEST® AND INTRACUTANEOUS ROUTES

(b)(4) copyrighted material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

Reprinted from THE JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, St. Louis
Vol. 90, No. 6, pp. 979-985, December, 1992 (Printed in the U.S.A.)
(Copyright © 1992, by Mosby-Year Book, Inc.)

EXHIBIT O-2

Evaluation of the Multi-Test device for immediate hypersensitivity skin testing

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

78

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT O-3

Reprinted from, ANNALS of ALLERGY, Volume 71, Number 1, July, 1993

Validity and reproducibility of multi-test skin test device

Cassandra Mahan, MD; Sheldon Spector, MD; Sheldon Siegel, MD; Gary Rachelefsky, MD; Roger Katz, MD; and Albert Rohr, MD

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Printed in U.S.A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT O-4

Reprinted from Annals of Allergy, Vol. 71, Number 5, November 1993

Special Review

Multi-Test skin testing in allergy: a review of published findings

William T. Kniker, MD

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8119

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

(b)(4) copyrighted material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

(b)(4) copyrighted material

[redacted]

Printed in U.S.A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

EXHIBIT O-5

90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/1[redacted]14

ASTHMA AND ALLERGIC DISEASES DURING PREGNANCY: MANAGEMENT OF THE MOTHER AND PREVENTION IN THE CHILD. Schatz, Zeiger, Mellon, and Porreco; ALLERGY, Principles and Practice, Volume Two, Second Edition, Chapter 43.

"Infants can conveniently be evaluated at about 4 months, 1 year, and yearly thereafter by Multitest skin tests and/or serum IgE levels for the possible development of allergic sensitization. "

Multi-Test®

Excerpts From Published Data

Lincoln Diagnostics, Inc.
P.O. Box 1128
Decatur, Illinois 62525
(800) 537-1336

91

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

VALIDITY AND REPRODUCIBILITY OF MULTI-TEST SKIN TEST DEVICE. Mahan, Spector, Siegel, Rachelefsky, Katz and Rohr; Annals Of Allergy, Volume 71, July 1993.

"Thirty patients were skin tested by Multi-Test and Morrow Brown needle using antigens, histamine, glycerosaline, and blank controls to examine reproducibility and influence of positive reactions on adjacent negative controls. There was no evidence that histamine or strongly positive antigen reactions affected adjacent negative controls."

"When Multi-Test and Morrow Brown skin test results from antigens on the upper and lower right side of the back were compared with their duplicates on the left side, the correlation between reaction sizes was better with Multi-Test. The Pearson correlation coefficient for the Multi-Test of 0.91 was superior to that of the Morrow Brown needle which was 0.47."

"Finally, when patients were asked which skin test device they preferred, 29 out of 30 chose the Multi-Test. The principal reasons were that it was less painful because it diffused the pain and its quicker application."

"In conclusion, our experiences with Multi-Test, both in routine clinical use and under controlled study conditions, have been highly satisfactory and we have found this technique reliable, convenient and well accepted by patients."

POSITIVE MULTI-TEST REACTIONS DO NOT CAUSE FALSE POSITIVE REACTIONS AT ADJACENT SITES. Garibaldi and Slavin; Annals Of Allergy, Volume 65, December, 1990.

"To answer the question of whether proximity of Multi-Test skin test sites causes false positive reactions, 50 subjects with prior 4+ skin test responses were retested with antigens and ten additional subjects were tested with histamine (1.8 mg/ml). No positive readings occurred at any of the replicate saline control sites adjacent to 3+ or 4+ allergen sites or to 3+ histamine reactions."

"Our results would indicate that the proximity of test head sites does not contribute to false positive responses, and that those who use Multi-Test may be assured of the immunologic accuracy of positive skin test results."

EVALUATION OF THE MULTI-TEST DEVICE FOR IMMEDIATE HYPERSENSITIVITY SKIN TESTING. Berkowitz, Tinkelman, Lutz, Crummie and Smith; The Journal Of Allergy And Clinical Immunology, Volume 90, December 1992.

"An important observation from our study is that Multi-Test affords the user greater protection against blood-borne diseases than other skin testing techniques. Its construction and method of application are such that the user's fingers and hands are not in close proximity to any bleeding that might occur on the patient's skin. In addition, the design of Multi-Test and its method of administration greatly reduce the risk of inadvertent pricking of the user's skin."

"We found the Multi-Test technique of skin testing to be rapid, convenient, and well accepted by patients. Reproducibility of test results from Multi-Test was high, and variability of results between users low. We concluded that the Multi-Test technique of skin testing provided sufficient precision, sensitivity, and specificity to be classified as a reliable in-office diagnostic procedure."

CORRELATION OF IMMEDIATE SKIN TEST RESPONSES TO ANTIGENS INTRODUCED BY MULTI-TEST AND INTRACUTANEOUS ROUTES. Murphree and Kniker; Annals Of Allergy, Volume 43, November 1979.

"Skin testing is rapid and relatively painless. Because such a small quantity of antigen is introduced into the epidermis, the likelihood of an anaphylactic reaction is minimized."

"The Multi-Test device lends itself admirably to the standardization of testing technique, a goal greatly desired in allergy practice. A reasonably uniform amount of glycerinated material is deposited in a constant area of 2mm with penetration limited to the epidermis. Because of the simultaneous and standardized application, reactions to controls and antigens can be meaningfully compared."

"Skin test responses to glycerinated inhalant antigens, 1:20 or 1:10 W/V, administered by Multi-Test were comparable to those obtained from the same antigens applied intradermally in aqueous dilutions of 1:1,000 or 1:1,500 W/V."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

MULTI-TEST SKIN TESTING IN ALLERGY: A REVIEW OF PUBLISHED FINDINGS. W. T. Kniker; Annals Of Allergy, Volume 71, November 1993.

"In relation to other forms of skin testing, Multi-Test enjoys advantages such as speed, convenience, and good patient acceptance. When using Dip 'N Touch for loading heads, dozens of antigens can be applied to a patient's back or arms in a reproducible fashion very quickly."

"While rapid and convenient, it shares the advantages of intracutaneous testing that include a high level of sensitivity (comparable to that of intracutaneous testing with 1:1000 dilution of antigens wt/vol) and a comparable level of reproducibility. Further, Multi-Test is particularly adaptable for standardization of antigen application, interpretation of reactions and scoring, an attribute that is increasingly important in modern practice."

COMPARISON OF THREE PRICK TEST METHODS WITH THE INTRADERMAL TEST AND WITH THE RAST IN THE DIAGNOSIS OF MITE ALLERGY. Menardo, Bousquet, and Michel; Annals Of Allergy, Volume 48, April, 1982.

"The intradermal test was always positive in patients but induced two false positive reactions. All prick test methods gave false negative reactions. The Multi-Test device produced intermediate reactions between prick test and intradermal test."

"Multi-Test gave the best correlations among all four skin tests and specific IgE antibody titers. "

CHRONIC RHINITIS IN INFANTS AND CHILDREN : ETIOLOGIC, DIAGNOSTIC , AND THERAPEUTIC CONSIDERATION. Meltzer, Zeiger, Schatz, and Jalowayski; Pediatric Clinics Of North America, Vol. 30, No. 5, October 1983.

"Allergy skin tests can be very helpful in evaluating chronic rhinitis and should especially be directed to those with an allergy history and/or nasal eosinophilia with or without basophilic cells. A sterile, disposable, multi-head puncture device, MULTI-TEST, provides a convenient, rapid and sensitive technique."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

REPORT OF THE AMERICAN COLLEGE OF ALLERGISTS' COMMITTEE ON STANDARDIZATION OF ALLERGENIC EXTRACTS. Annals Of Allergy, Volume 49, July 1982.

"The Multitest holds a standard amount of antigen and when applied according to manufacturer's directions produces a uniform depth of puncture."

"The reproducibility of Multitest was evaluated by one investigator on 33 patients. Data are shown in Table III. The total percentage agreement was 85%, which may be considered excellent for this type of procedure. The percentage agreement could have been much higher had the criteria not been so stringent."

SPECIAL CONSIDERATIONS IN THE APPROACH TO ASTHMA IN INFANCY AND EARLY CHILDHOOD. R. S. Zeiger; Journal Of Asthma, Vol. 20, 1983.

"Although puncture skin testing in infants has been discouraged, appropriately performed testing with select food (milk, egg, wheat, corn, soy, peanut) and environmental (alternaria, hormodendrum, mite, dander and grass) allergens using a Multi-Test puncture device can be quite rapid, simple, helpful and predictive of subsequent atopic manifestations. We have found a strong correlation between positive Multi-test puncture tests and RAST testing in infants less than one year of age."

PHARMACOLOGIC MODULATION OF THE WHEALING RESPONSE TO HISTAMINE IN HUMAN SKIN: IDENTIFICATION OF DOXEPIN AS A POTENT IN VIVO INHIBITOR. T. J. Sullivan, Journal Of Allergy And Clinical Immunology, Volume 69, No. 3, March 1982.

"This study demonstrates that percutaneous administration of histamine with a MULTITEST device is a simple, rapid, reproducible method that permits the measurement of dose-related histamine responses in vivo in an acceptably precise manner. This method minimizes the requirement for skill that is known to be essential for reproducible testing by intradermal or needle-prick methods."

GM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-6291; Released 10/15/14

The Right Resin for Every Job

Wherever there's a need for good-looking, precise, tough, molded parts, you'll find the ideal combination of performance properties and value in the Rohm and Haas family of thermoplastic resins: excellent optical clarity, unsurpassed weatherability, and design flexibility. These resins are available in many grades and colors to meet your specific applications. Assemblies can be drilled, machined, engraved or embossed. Decorative coatings can be sprayed, silk-screened, hot-stamped, vacuum-metallized or chrome-plated.

No matter what the molding job, Rohm and Haas has a resin that's exactly right.

Plexiglas V-Series Resins

Exceptional optical clarity and resistance to ultraviolet-light degradation and discoloration make Plexiglas V-Series acrylic the standard of the industry. These resins are virtually unaffected by alkalis, hydrocarbons, non-oxidizing acids, saltwater, photographic or battery solutions. Choose transparent, translucent, opaque or custom colors in varying grades of melt flow and heat resistance.

Impact-Modified Resins

Plexiglas DR®, MI-7, and HFI Series resins offer 7 to 10 times the impact resistance of standard acrylics and superior optical properties. In addition, each resin is offered in a grade that resists gamma radiation sterilization. HFI Series resins are noted for superior flow and mold release properties for reduced cycle times.

Kamax Resins

Kamax resins offer a unique balance of high heat resistance, optical clarity, and outdoor durability. This family of amorphous acrylic-imide copolymers has a 50 percent lower coefficient of thermal expansion, a 33 percent higher modulus and a higher refractive index than standard acrylics. Easily processed on conventional equipment, Kamax resins can be injection molded, blow molded and coinjection blow-molded, making them excellent candidates for applications in the lighting, automotive, optical, packaging, medical, and appliance markets.

Other Important Properties

All clear Plexiglas resins, both V-grade and Impact-modified, have clearance under FDA Food Additive Regulation 21 CFR 177.1010 (Acrylics and Modified Acrylic Plastic, Rigid and Semi-Rigid) for use with all types of food, at or below room temperature, except for food with an alcoholic content greater than 8 percent. Kamax T-260 resin has clearance under Food Additive Regulation 21 CFR 177.1060.

All our impact-modified resins, except for the "T" versions, and Plexiglas V052 meet U.S. Pharmacopeia XXI Class VI toxicity requirements.

All Plexiglas and Kamax resins are listed by Underwriter's Laboratory as having a UL flame class of 94HB.

AVERAGE PHYSICAL PROPERTIES[a] OF PLEXIGLAS® AND KAMAX® MOLDING RESINS

Property	Test Method	Plexiglas V825	Plexiglas V826	Plexiglas V045 V052	Plexiglas V920 V920 UVT	Plexiglas VLD	Plexiglas VM	Plexiglas VH	Plexiglas VS VS UVT	Plexiglas DR-T	Plexiglas DR DR-G[b]	Plexiglas HFI-10 HFI-10G[b]	Plexiglas MI-7T	Plexiglas MI-7 MI-7G[b]	Plexiglas HFI-7 HFI-7G[b]	Plexiglas MI-4T	Kamax T-150	Kamax T-170	Kamax T-242 T-240
Refractive Index N_D	ASTM D-542	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.49	1.53	1.54	1.53
Specific Gravity	ASTM D-792	1.19	1.19	1.19	1.19	1.19	1.18	1.18	1.18	1.16	1.15	1.15	1.18	1.17	1.17	1.18	1.21	1.22	1.21
Melt Flow Rate	ASTM D-1238 g/10min Condition I	3.7	1.6	2.3/2.8	8	22	14.5	23	24	0.8	1	3.3	1.8	3.2	11	3.0			
	Condition J (508°F/27.5 lb.)																16	7	20
Light Transmission	ASTM D-1003 Total White, %	92	92	92	92[c]	92	92	92	92[c]	90	90	90	92	92	92	92	90	90	92/90
Haze	%	2%	2%	2%	2%	0.9%	2%	2%	2%	3%	3%	3%	2%	2%	2%	2%	2%	2%	2%
Rockwell Hardness	ASTM D-785 (M Scale)	97	97	96	95	94	89	89	84	46	45	38	68	68	65	78	98	100	98
MECHANICAL Tensile Strength	ASTM D-638[d] (0.1"/in/min) init. strain rate, Max., psi	10,200	10,200	10,200	10,000	7,900	9,600	9,600	9,400	5,500	5,500	5,500	8,000	7,000	6,800	8,500	11,200	11,500	11,200
Flexural Strength	ASTM D-790[d] Span-depth ratio 16 (0.1"/min) Max., psi	15,000	15,000	15,000	15,000	12,000	14,000	14,000	14,000	10,300	10,300	10,300	12,600	14,400	13,200	15,000	20,000	20,000	20,000
Flexural Modulus	psi	450,000	450,000	450,000	450,000	440,000	440,000	440,000	420,000	270,000	270,000	270,000	350,000	380,000	360,000	430,000	600,000	620,000	540,000
Impact Strength	ASTM D-256[d] IZOD Milled Notch (ft. lb./in. of notch)	0.23	0.23	0.23	0.23	0.3	0.23	0.23	0.23	1.1	1.1	0.9	0.6	0.6	0.6	0.4	0.4	0.4	0.4
	Falling Dart (6" x 6" x ⅛", 3-lb dart, ½" radius) ft.lb.	1	1	1	1	1	1	1	1	10	10	10	7	7	7	4	1	1	1
THERMAL Deflection Temp. Under Load, Annealed[e]	ASTM D-648 3.6°F/min., 264 psi	216	216	198	195	194	171	171	169	185	175	175	195	185	180	194	282	313	280
Vicat Softening Point	ASTM D-1525, Unannealed 90°F/hr., 2.2 lb.	232	232	214	212	N/A[f]	191	191	189	222	205	201	226	207	203	230	286	319	284
	90°F/hr., 11.0 lb.	220	220	200	196	N/A	180	180	178	203	185	181	207	191	185	216	275	308	271
Glass Transition Temperature, Tg	ASTM D-3418 °F	226	226	219/221	212	212	196	196	196	N/A	216	N/A	N/A	N/A	N/A	N/A	300	335	290
Continuous Service Temperature Range	°F (dependent on part 'molded- in' stresses)	185-215	185-215	165-190	160-185	160-185	145-170	145-170	145-170	170-190	160-180	160-180	180-200	165-185	165-185	180-200	255-275	300-320	245-265
Shrinkage from Mold Dimension	ASTM D-955 (cold mold to cold place) mils/in., 48 hr.	(4-7)	(4-7)	(4-7)	(4-7)	(4-7)	(4-7)	(4-7)	(4-7)	(3-8)	(3-8)	(3-8)	(3-6)	(3-6)	(3-6)	(3-6)	(3-6)	(3-6)	(3-6)
Water Absorption	ASTM D-570 Wt. gain on 24-hour water immersion, %	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.35	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.2
Chemical Resistance	Chemical resistance of Plexiglas and Kamax resins varies with stress level, temperature, reagent and resin grade. Rohm and Haas Co. recommends that selected Plexiglas and Kamax resins be tested with applicable solvents under appropriate conditions for the end-use appl. Chemical resistance of Plexiglas V826 is highest of all V-grade resins.																		

[a] Data given are average values and should not be used for specification purposes.
[b] Plexiglas DR-G, HFI-10G, MI-7G, and HFI-7G are gamma-radiation-resistant grades in the impact modified series. They are specially designed to minimize the discoloration that accompanies gamma radiation sterilization. When tested at up to 5 megarads dosage, radiation has no adverse effect on the bulk properties of these four grades.
[c] Plexiglas V920 UVT and VS UVT differ from standard resins in light transmission in ultraviolet region only as follows: minimum transmission @ 270 nm=12%; @ 290 nm=50%; @ 310 nm=70%; @ 340 nm=85%.
[d] Samples conditioned per ASTM D-618, Procedure B.
[e] Annealing cycles: Plexiglas V825, V826, V920, VLD, DR-T, MI-7T, MI-4T–4 hrs at 194°F; Plexiglas V045, V052, DR, DR-G, HFI-10, HFI-10G, MI-7, MI-7G, HFI-7, HFI-7G–4 hrs. at 180°F; Plexiglas VM, VH, VS–4 hrs. at 160°F; Kamax T-150, T-240–4 hrs. at 248°F, Kamax T-170, T-260–4 hrs. at 266°F
[f] N/A= Not Available

EXHIBIT P

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118