A Procedural Competency Demonstration of Skin Testing and Extract Preparation

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UMKC
School of Medicine

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Disclosures

- None related to this topic

ACGME Requirements

- IV.B.1.b).(1).(b) Residents must, to the satisfaction of the program director or designated faculty member, demonstrate proficiency in performing and evaluating results for the following:

(Core) IV.B.1.b).(1).(b).(i) allergen immunotherapy; (Core)
IV.B.1.b).(1).(b).(ii) contact or delayed hypersensitivity testing; (Core)
IV.B.1.b).(1).(b).(iii) drug hypersensitivity diagnosis and treatment; (Core)
IV.B.1.b).(1).(b).(iv) food hypersensitivity diagnosis and treatment; (Core)
IV.B.1.b).(1).(b).(v) immediate hypersensitivity skin testing; (Core)
IV.B.1.b).(1).(b).(vi) immunoglobulin treatment and/or other immunomodulator therapies; and, (Core)

IV.B.1.b).(1).(b).(vii) pulmonary function testing. (Core)

Historical Perspective: Clinical Competency Workgroup

- In 2012 the ACGME RRC for Allergy/Immunology announced they were going to be looking at Procedural Competency and wanted to set a “number” .
- **Core Curriculum Education & Residency Review Committee (CCERR) of the Program Director’s Assembly** wanted to decide what procedural competency should look like and developed checklists to assess competency
- These are: **knowledge based**; look at **performance of the test**; **interpretation**; and the **overall ability to perform the procedure competently and safely.**
- **Today will discuss performing skin testing and immunotherapy workshops with your own fellows**

Procedural Competency Workshop

- Offer Hands on Experience for Fellows and Nurses
- Important for fellows to know how to do be proficient not only in knowledge but skills in caring for patients
- Way of verifying these skills on an annual basis

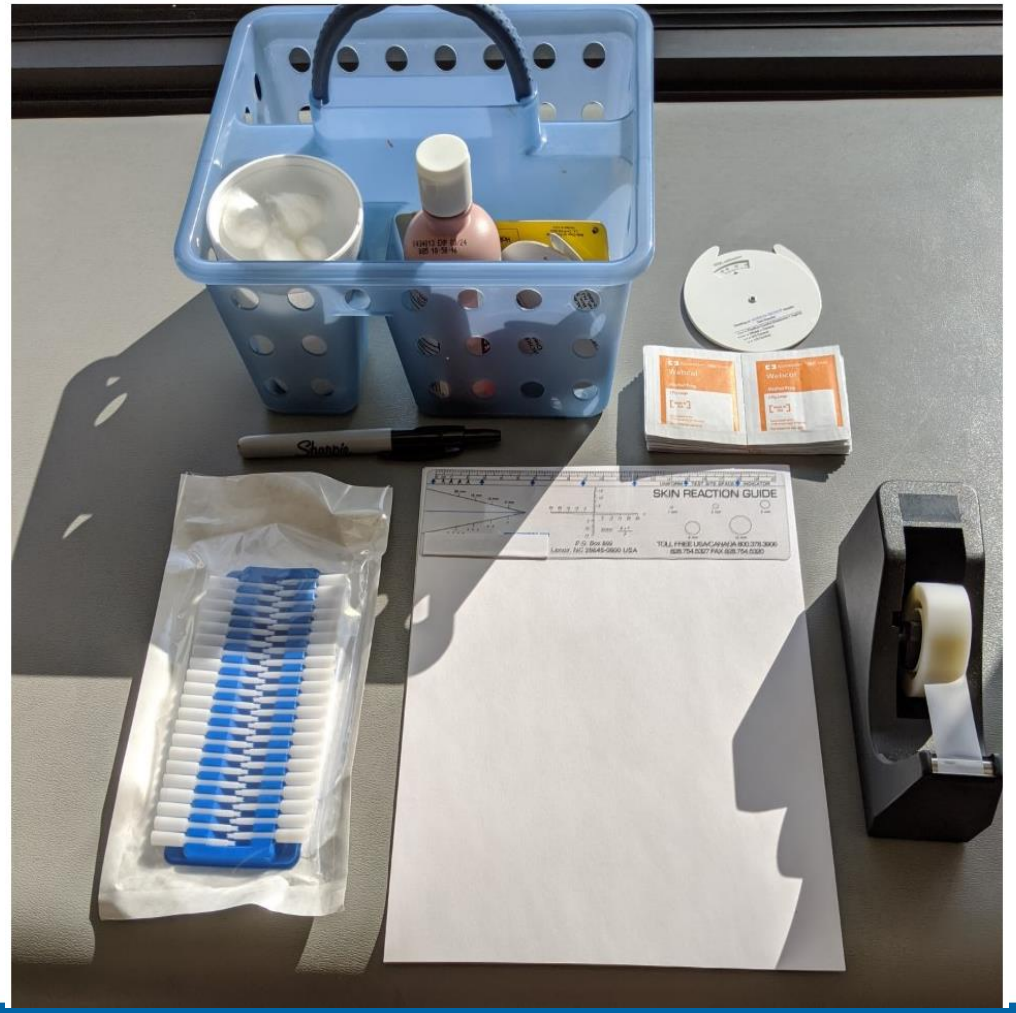
Performing Competency Training Workshops

- Schedule during teaching conference time
- Pick relaxed quiet location
- Enlist your associate program director's help
- **To pass they must get all the information correct / individual judgement**
- Allow 1st year fellows to do competency training while waiting to have enough experience to get signed off

Immediate Hypersensitivity Skin Testing

- Guidelines suggested by: **Oppenheimer and Nelson "Skin Testing" Ann of Allergy Asthma Immnunol 2006:96 (Suppl 1) S6-S12.**
- Suggested Proficiency Testing and Quality assurance Technique for Skin Prick Testing
- **Coefficient of variation should be less than 30%**

Immediate Hypersensitivity Skin Testing



Materials Needed

- Alcohol wipes
- Scotch Tape
- Black Fine Tip Marker
- White Copy Paper
- Dermapiks (or similar skin test device)
- Skin test concentrations for histamine and saline
- Timer
- Ruler of some type
- Willing subject

Procedural Competency Workshop

Taken from:

Openheimer J, Nelson H. Skin Testing Ann *Allergy Asthma Immunol.* 2006;96(Suppl 1):S6–S12.

Suggested Proficiency Testing and Quality Assurance Technique for Skin Prick Testing:

- Using desired skin test device, perform skin testing with positive (histamine 1-10) and negative controls (saline 1-10) in an alternate pattern on a subject's back
- Record histamine results at 8 minutes by outlining wheals with a felt-tip pen and transferring results with transparent tape to a blank sheet of paper
- Record saline results at 15 minutes by outlining wheal and flares with a felt-tip pen and transferring results with transparent tape to a blank sheet of paper
- Calculate the mean diameter X=(D+d)/2; D=largest diameter and d=perpendicular diameter at midpoint of D
- **Histamine**

Calculate the mean and standard deviations of each mean wheal diameter

Determine coefficient of variation = standard deviation/mean

Quality standard should be less than 30%

- **Saline**

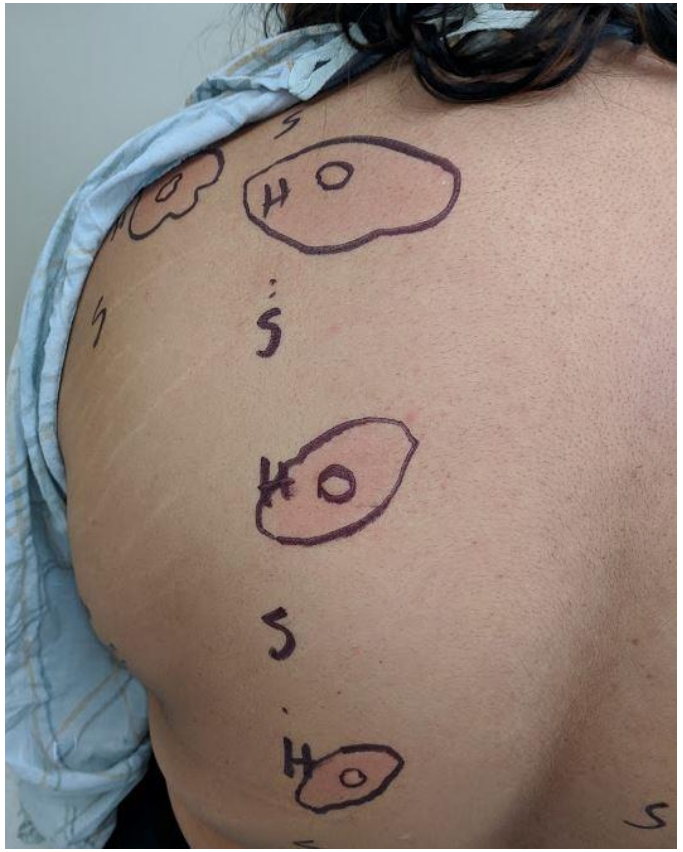
All negative controls should be <3-mm wheals and <10-mm flares

Figure 2. Suggested proficiency testing and quality assurance technique for skin prick testing.

Alternating Skin Tests with Histamine and Saline

- Back (or forearm) is cleaned with alcohol
- Skin is marked with alternating “H’s” and “S’s” at a sufficient distance apart in 2 or 3 columns
- A total of 10 Saline prick test are placed, followed by 10 Histamine skin tests
- A timer is set for 8 minutes for measuring histamine; 15 minutes for saline
- These are followed by 4 intradermals with saline and histamine (2 each)

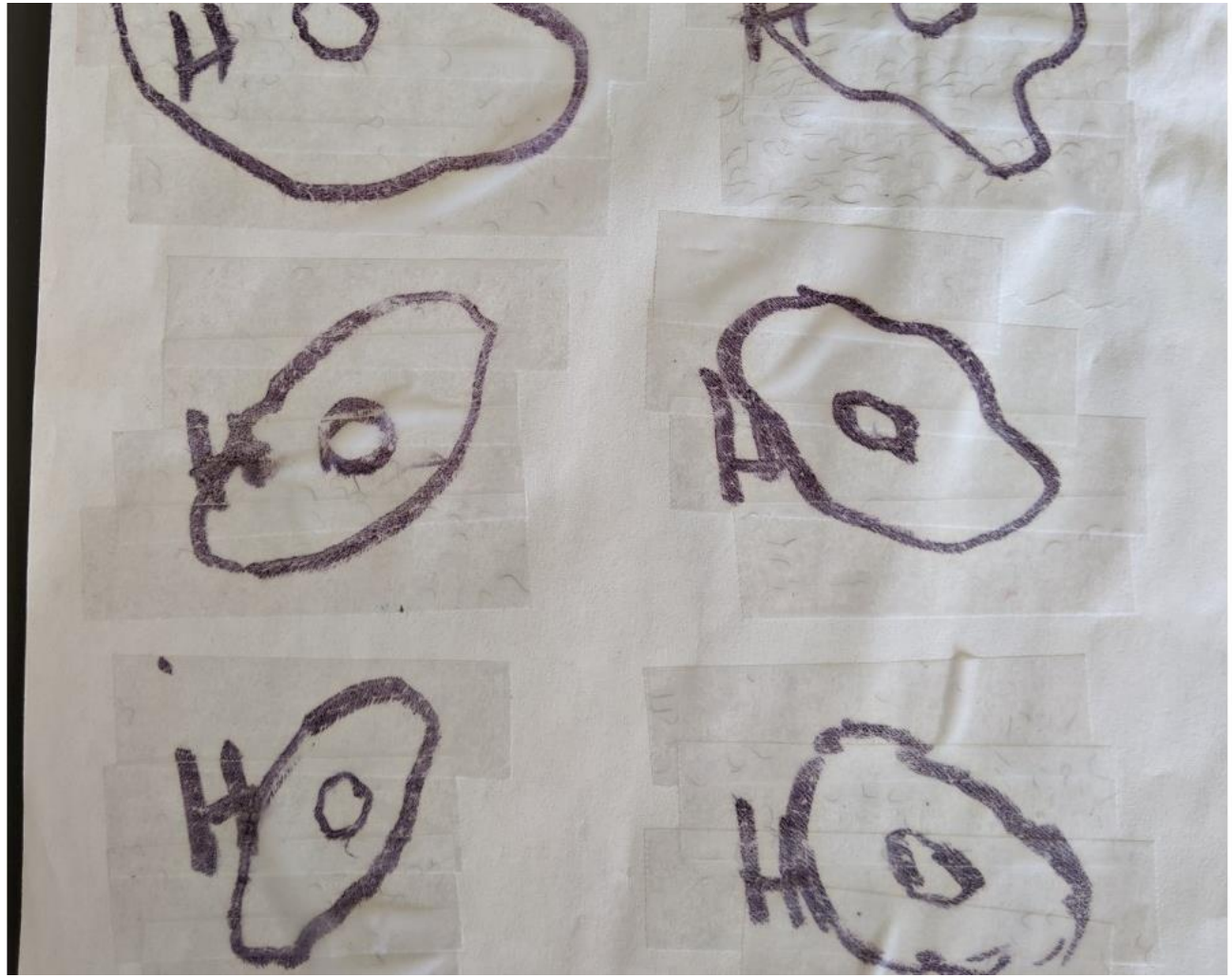
Immediate Skin Testing Procedural Competency Workshop



Covid Protocol

Taping the individual skin tests:

- After marking the outline of the wheal & flare with a fine tip black marker, apply overlapping strips of scotch tape to each wheal and flares
- Press firmly over the entire surface
- Lift the edge and remove as one piece
- Transfer to a white piece of copy paper



Measuring the Largest Diameter of the Wheal

- Calculate the mean diameter (X) = D +d/2 ; D = largest diameter, d = perpendicular diameter and midpoint of D
- **All negative controls should be < 3mm of wheal and <10mm of flare**

Coefficient of Variation (CV)

- **CV = standard deviation / mean x 100**
- Should be **less than 30%**

How To Calculate Standard Deviation 80

By sonia

First, you need to determine the mean. The mean of a list of numbers is the sum of those numbers divided by the quantity of items in the list (read: add all the numbers up and divide by how many there are).

Then, subtract the mean from every number to get the list of deviations. Create a list of these numbers. It's OK to get negative numbers here. Next, square the resulting list of numbers (read: multiply them with themselves).

Add up all of the resulting squares to get their total sum. Divide your result by one less than the number of items in the list.

To get the standard deviation, just take the square root of the resulting number

I know this sounds confusing, but just check out this example:

your list of numbers: 1, 3, 4, 6, 9, 19

mean: (1+3+4+6+9+19) / 6 = 42 / 6 = 7

list of deviations: -6, -4, -3, -1, 2, 12

squares of deviations: 36, 16, 9, 1, 4, 144

sum of deviations: 36+16+9+1+4+144 = 210

divided by one less than the number of items in the list: 210 / 5 = 42

square root of this number: square root (42) = about 6.48

Immediate Hypersensitivity Skin Test Competency Check List

	Knowledge Based	Performance of the test	Interpretation of the test	Overall Perform safely and competently
A/I Fellow understands the indications for performing the test and alternatives to skin testing.	x			
A/I Fellow understands the factors that can effect testing (age, location of placement of tests, concurrent medications).	x			
A/I Fellow understands the need for positive and negative controls.	x			
A/I Fellow understands when the test should be read.	x			
A/I Fellow understands the reliability of the test depends on the skill of tester, test instrument, skin color, skin reactivity, age and potency and stability of test reagents	x			
A/I Fellow understands the difference between prick/puncture and intradermal testing and what allergens appropriate for each testing method.	x			
A/I Fellow understands the risk and risk factors for systemic reactions by either prick/puncture or intradermal testing.	x			
A/I Fellow understands the intervention needed to treat systemic reactions.	x			
A/I Fellow adequately completes the Proficiency Testing Technique for Prick/Puncture. (Oppenheimer and Nelson, 2006)		x (can put the date completed)		
A/I Fellow adequately completes the Proficiency Testing Technique for Intradermal tests. (Oppenheimer and Nelson, 2006)		x (can put the date completed)		
A/I Fellow is able to differentiate significant from insignificant responses including dermatographism.			x	
A/I Fellow understands that the preferred documentation should be measuring the wheal and flare response.			x	
A/I Fellow adequately explains the results to the patient or patient's families.			x	

Mercy

Immunotherapy/ Extract Mixing Workshop and Competency

Covid Protocol

Procedural Competency Workshop

- Selection of Cases covering various common scenarios
- Opportunity to do actual mixing of extracts
- Review of sterile technique
- Opportunity to do a Fill test
- Do workshop 2 times/yr.

Covid Protocol

Materials Needed

- Alcohol Pads
- Sanitizing Wipes
- Vinyl gloves
- 1 and 5 ml syringes
- 21 or 23 gauge needles
- Paper labels, labels for extract grouping, copy of skin test sheet
- 5 ml extract bottles with colored tops or tags (Green, Blue, Yellow, Red)
- Diluent or Sterile Saline
- Sharps container
- Expired extract bottles relabeled as common allergen extracts used in your clinic

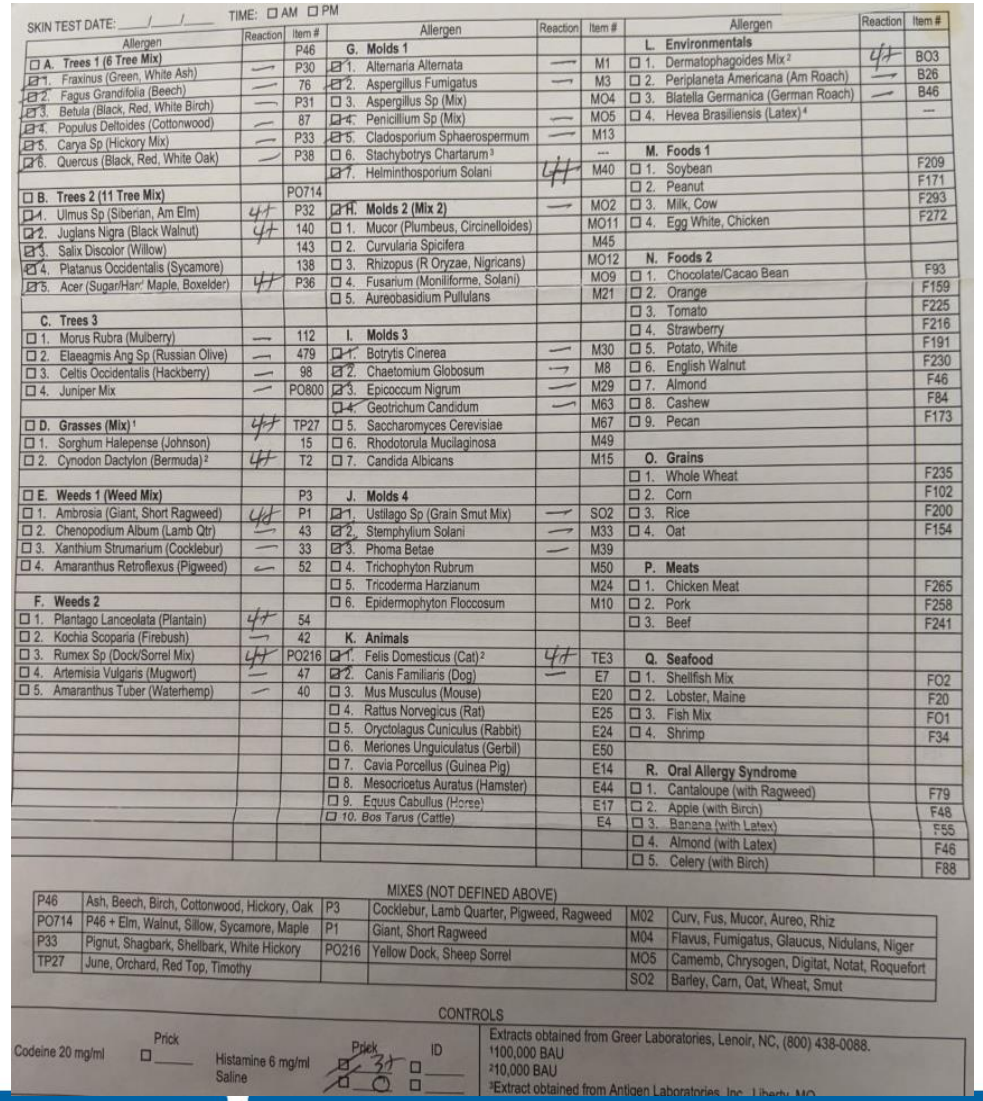
Extract Mixing Case Scenario

Case 1:

A patient recently transferred into your office. He had been receiving IT for 2.5 years from an allergist in Kentucky. The family believes he is much better on shots. He has been receiving allergy shots once a month as Maintenance. The family has a copy of his prescription from his last allergist and his skin test sheet. The test are with extracts not used in your office and are reported on a scale of 1+ - 4 + with no measurements recorded. The family is requesting shots ASAP.

What do you do?

Extract Mixing Case Materials



SKIN TEST DATE: ___/___/___ TIME: ☐ AM ☐ PM

Allergen	Reaction	Item #
A. Trees 1 (6 Tree Mix)		P46
☑ 1. Fraxinus (Green, White Ash)	—	P30
☑ 2. Fagus Grandifolia (Beech)	—	76
☑ 3. Betula (Black, Red, White Birch)	—	P31
☑ 4. Populus Deltoides (Cottonwood)	—	87
☑ 5. Carya Sp (Hickory Mix)	—	P33
☑ 6. Quercus (Black, Red, White Oak)	—	P38
B. Trees 2 (11 Tree Mix)		PO714
☑ 1. Ulmus Sp (Siberian, Am Elm)	4+	P32
☑ 2. Juglans Nigra (Black Walnut)	4+	140
☑ 3. Salix Discolor (Willow)		143
☑ 4. Platanus Occidentalis (Sycamore)		138
☑ 5. Acer (Sugar/Hard Maple, Boxelder)	4+	P36
C. Trees 3		
☐ 1. Morus Rubra (Mulberry)	—	112
☐ 2. Elaeagmis Ang Sp (Russian Olive)	—	479
☐ 3. Celtis Occidentalis (Hackberry)	—	98
☐ 4. Juniper Mix	—	PO800
D. Grasses (Mix) [1]	4+	TP27
☐ 1. Sorghum Halepense (Johnson)		15
☐ 2. Cynodon Dactylon (Bermuda) [2]	4+	T2
E. Weeds 1 (Weed Mix)		P3
☐ 1. Ambrosia (Giant, Short Ragweed)	4+	P1
☐ 2. Chenopodium Album (Lamb Qtr)	—	43
☐ 3. Xanthium Strumarium (Cocklebur)	—	33
☐ 4. Amaranthus Retroflexus (Pigweed)	—	52
F. Weeds 2		
☐ 1. Plantago Lanceolata (Plantain)	4+	54
☐ 2. Kochia Scoparia (Firebush)	—	42
☐ 3. Rumex Sp (Dock/Sorrel Mix)	4+	PO216
☐ 4. Artemisia Vulgaris (Mugwort)	—	47
☐ 5. Amaranthus Tuber (Waterhemp)	—	40

Allergen	Reaction	Item #
G. Molds 1		
☑ 1. Alternaria Alternata	—	M1
☑ 2. Aspergillus Fumigatus	—	M3
☐ 3. Aspergillus Sp (Mix)		MO4
☐ 4. Penicillium Sp (Mix)	—	MO5
☑ 5. Cladosporium Sphaerospermum	—	M13
☐ 6. Stachybotrys Chartarum [3]		---
☑ 7. Helminthosporium Solani	4+	M40
H. Molds 2 (Mix 2)	—	MO2
☐ 1. Mucor (Plumbeus, Circinelloides)		MO11
☐ 2. Curvularia Spicifera		M45
☐ 3. Rhizopus (R Oryzae, Nigricans)		MO12
☐ 4. Fusarium (Moniliforme, Solani)		MO9
☐ 5. Aureobasidium Pullulans		M21
I. Molds 3		
☑ 1. Botrytis Cinerea	—	M30
☑ 2. Chaetomium Globosum	—	M8
☑ 3. Epicoccum Nigrum	—	M29
☐ 4. Geotrichum Candidum	—	M63
☐ 5. Saccharomyces Cerevisiae		M67
☐ 6. Rhodotorula Mucilaginosa		M49
☐ 7. Candida Albicans		M15
J. Molds 4		
☑ 1. Ustilago Sp (Grain Smut Mix)	—	SO2
☑ 2. Stemphylium Solani	—	M33
☑ 3. Phoma Betae	—	M39
☐ 4. Trichophyton Rubrum		M50
☐ 5. Tricoderma Harzianum		M24
☐ 6. Epidermophyton Floccosum		M10
K. Animals		
☑ 1. Felis Domesticus (Cat) [2]	4+	TE3
☑ 2. Canis Familiaris (Dog)	—	E7
☐ 3. Mus Musculus (Mouse)		E20
☐ 4. Rattus Norvegicus (Rat)		E25
☐ 5. Oryctolagus Cuniculus (Rabbit)		E24
☐ 6. Meriones Unguiculatus (Gerbil)		E50
☐ 7. Cavia Porcellus (Guinea Pig)		E14
☐ 8. Mesocricetus Auratus (Hamster)		E44
☐ 9. Equus Cabullus (Horse)		E17
☐ 10. Bos Tarus (Cattle)		E4
L. Environmentals		
☐ 1. Dermatophagoides Mix [2]	4+	BO3
☐ 2. Periplaneta Americana (Am Roach)	—	B26
☐ 3. Blatella Germanica (German Roach)	—	B46
☐ 4. Hevea Brasiliensis (Latex) [4]		---
M. Foods 1		
☐ 1. Soybean		F209
☐ 2. Peanut		F171
☐ 3. Milk, Cow		F293
☐ 4. Egg White, Chicken		F272
N. Foods 2		
☐ 1. Chocolate/Cacao Bean		F93
☐ 2. Orange		F159
☐ 3. Tomato		F225
☐ 4. Strawberry		F216
☐ 5. Potato, White		F191
☐ 6. English Walnut		F230
☐ 7. Almond		F46
☐ 8. Cashew		F84
☐ 9. Pecan		F173
O. Grains		
☐ 1. Whole Wheat		F235
☐ 2. Corn		F102
☐ 3. Rice		F200
☐ 4. Oat		F154
P. Meats		
☐ 1. Chicken Meat		F265
☐ 2. Pork		F258
☐ 3. Beef		F241
Q. Seafood		
☐ 1. Shellfish Mix		FO2
☐ 2. Lobster, Maine		F20
☐ 3. Fish Mix		FO1
☐ 4. Shrimp		F34
R. Oral Allergy Syndrome		
☐ 1. Cantaloupe (with Ragweed)		F79
☐ 2. Apple (with Birch)		F48
☐ 3. Banana (with Latex)		F55
☐ 4. Almond (with Latex)		F46
☐ 5. Celery (with Birch)		F88

MIXES (NOT DEFINED ABOVE)

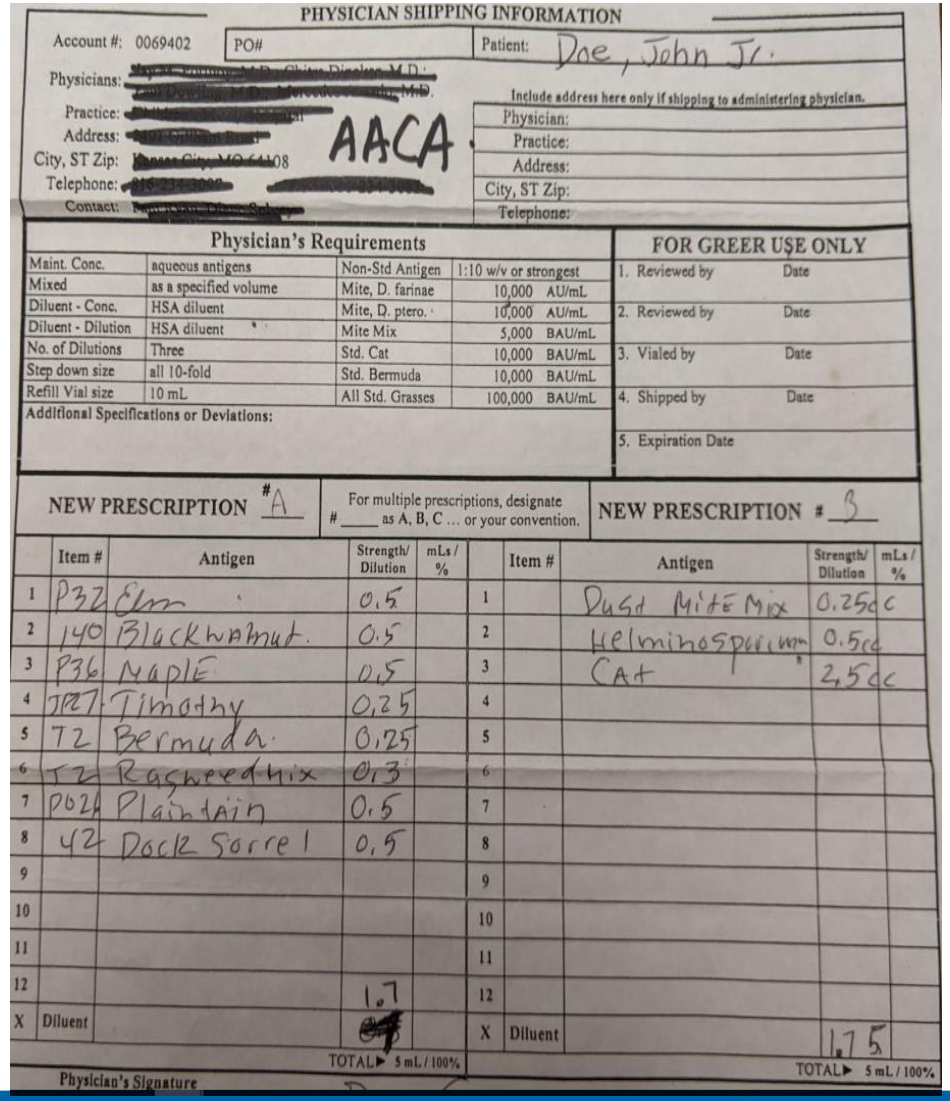
P46	Ash, Beech, Birch, Cottonwood, Hickory, Oak	P3	Cocklebur, Lamb Quarter, Pigweed, Ragweed	M02	Curv, Fus, Mucor, Aureo, Rhiz
PO714	P46 + Elm, Walnut, Sillow, Sycamore, Maple	P1	Giant, Short Ragweed	M04	Flavus, Fumigatus, Glaucus, Nidulans, Niger
P33	Pignut, Shagbark, Shellbark, White Hickory	PO216	Yellow Dock, Sheep Sorrel	MO5	Camemb, Chrysogen, Digitat, Notat, Roquefort
TP27	June, Orchard, Red Top, Timothy			SO2	Barley, Carn, Oat, Wheat, Smut

CONTROLS

Codeine 20 mg/ml — Prick ☐ ____ — Histamine 6 mg/ml — Prick ☑ 3+ — ID ☐ ____

Saline — ☐ ○ — ☐ ____

Extracts obtained from Greer Laboratories, Lenoir, NC, (800) 438-0088.
[1]100,000 BAU
[2]10,000 BAU
[3]Extract obtained from Antigen Laboratories, Inc., Liberty, MO



PHYSICIAN SHIPPING INFORMATION

Account #: 0069402 — PO# — Patient: Doe, John Jr.

Physicians: [redacted]

Practice: [redacted]

Address: [redacted] AACA

City, ST Zip: [redacted]08

Telephone: [redacted]

Contact: [redacted]

Include address here only if shipping to administering physician.

Physician:
Practice:
Address:
City, ST Zip:
Telephone:

Physician's Requirements

Maint. Conc.	aqueous antigens	Non-Std Antigen	1:10 w/v or strongest
Mixed	as a specified volume	Mite, D. farinae	10,000 AU/mL
Diluent - Conc.	HSA diluent	Mite, D. ptero.	10,000 AU/mL
Diluent - Dilution	HSA diluent	Mite Mix	5,000 BAU/mL
No. of Dilutions	Three	Std. Cat	10,000 BAU/mL
Step down size	all 10-fold	Std. Bermuda	10,000 BAU/mL
Refill Vial size	10 mL	All Std. Grasses	100,000 BAU/mL

Additional Specifications or Deviations:

FOR GREER USE ONLY

1. Reviewed by — Date
2. Reviewed by — Date
3. Vialed by — Date
4. Shipped by — Date
5. Expiration Date

NEW PRESCRIPTION # A — For multiple prescriptions, designate # ____ as A, B, C ... or your convention. — NEW PRESCRIPTION # B

	Item #	Antigen	Strength/ Dilution	mLs / %		Item #	Antigen	Strength/ Dilution	mLs / %
1	P32	Elm	0.5		1		Dust Mite Mix	0.25cc	
2	140	Blackwalnut	0.5		2		Helminosporium	0.5cc	
3	P36	Maple	0.5		3		Cat	2.5cc	
4	JR7	Timothy	0.25		4				
5	T2	Bermuda	0.25		5				
6	T2	Ragweed mix	0.3		6				
7	P024	Plaintain	0.5		7				
8	42	Dock Sorrel	0.5		8				
9					9				
10					10				
11					11				
12			1.7		12				
X	Diluent		[redacted]		X	Diluent		1.75	

TOTAL ▶ 5 mL / 100% — TOTAL ▶ 5 mL / 100%

Physician's Signature

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Immuno-therapy Competency Checklist

Knowledge Based

Performance of Test

Interpretation of Test

Overall Perform Competently and Safely

	Knowledge Based	Performance of the test	Interpretation of the test	Overall Perform safely and competently
A/I Fellow identifies indications for immunotherapy (IT).	x			
A/I Fellow identifies contraindications for immunotherapy	x			
A/I Fellow understands the need for positive and negative controls.	x			
A/I Fellow identifies what allergens are positive on skin testing and should be included in extracts	x			
A/I Fellow differentiates which extracts can be mixed in the same vial	x			
A/I Fellow determines the optimal dose for each component in extract	x			
A/I Fellow obtains appropriate paperwork and consent prior to start IT.	x			
A/I Fellow explains procedure, purpose and important information to patient and family	x			
A/I Fellow explains risks and benefits of IT.	x			
A/I Fellow identifies contraindications to receiving injection:	x			
A/I Fellow receives a passing score on JCAI Immunotherapy Module	x			
A/I Fellow Demonstrates how to properly write extract prescription and order extracts. Test Patient/skin test # 1 Test Patient/skin test # 2		x		
A/I Fellow describes colors and demonstrates how to dilute the bottles: • 1:1000 • 1:100 • 1:10 • Maintenance (1:1)		x	x	
A/I Fellow Successfully performs "Fill Test" to check sterile technique		x	x	
A/I Fellow verbalizes potential reactions from immunotherapy.			x	
A/I Fellow verbalizes treatment for reactions	x			
A/I Fellow verbalizes when to stop immunotherapy:	x			

Procedural Competency Sign Off

CHECK LEARNING RESOURCES USED:

_____ Observation of procedure/review with faculty & staff
_____ Lecture(s)
_____ Selected readings
_____ Problem Based Learning / Case studies
_____ Web based resources

I attest that A/I fellow, _____, is competent in the use of **immediate hypersensitivity skin testing** in appropriately selected adult and pediatric patients. **The fellow meets or exceeds a Level 4 Milestone for this procedure.**

Date _____ Program Director's signature _____

Chapter 797 USP Compounding Guidelines

- Beyond the scope of this talk
- USP has finalized **Chapter 797** standards for sterile compounding, including standards specifically for physician in-office compounding of allergen extracts in allergy practices. The purpose of the standards is to ensure safe treatment of an allergy clinic's patients
- Both the **AAAAI and the ACAAI have resources on their websites** outlining the new requirements

  https://education.aaaai.org/compounding-corner
- Important for your fellows and your staff to know the new requirements especially if you are doing any mixing in your clinics

Handy Hints in Preparation

- Inform fellows to avoid antihistamines for 1 week prior to Skin Testing Competency
- Check vacation schedules when planning competency testing
- Make sure the fellows have had a minimum required number of procedures under their belts prior to scheduling …i.e.. easy to do skin testing in the late Fall of year 1; Immunotherapy likely end of year 1
- Fellows may do a competency earlier for practice but will need to repeat it once they meet minimum requirements and the program director thinks they are competent.

Handy Hints in Preparation II

- Extract mixing workshop is done 2 times/year regardless of competency status for training purposes
- With new requirements important fellows and staff have training and certification in mixing in case an extract is needed immediately for training programs without a dedicated person mixing extracts on site
- I do not test for intradermals if a female fellow is pregnant, wait until after delivery

Summary

- Documenting Procedural Competencies is a required part of fellowship training
- Procedural Competency Checklists are available for all ACGME/ABAI required procedures
- Some competencies lend themselves to hands on training workshops
- With a little effort these workshops can easily be done in any program

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Thank You for Your Attention!

Questions ?


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