IMMULITE 3gAllergy

Allergen Component Testing

A valuable diagnostic decision-making tool

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Introduction

Component allergen testing provides clinicians with improved specificity for IgE-mediated allergies as compared to allergen extract testing. Following extract testing, component testing allows for differential diagnoses, differentiation between co-sensitization and cross-reactivity, and improvement of inclusion criteria for immunotherapy as well as the follow-up of immunotherapy.[1]

Allergen extracts contain both allergenic and non-allergenic elements, offering direction as to whether reflex testing with component allergens should be conducted. Component allergens are purified, isolated allergenic proteins found within the extract. Allergen extracts provide high levels of sensitivity, whereas allergen components offer the advantage of high specificity and help to generate a comprehensive clinical picture. Thus, testing with extracts often precedes component testing, which may be recommended as a follow-up step. Without component testing, there may be not enough specificity in extract testing for a number of allergens to provide for a differential diagnosis.[2]

Component testing is also advantageous to differentiate between cross-reactivity and co-sensitization—key for both allergen and autoimmune testing. Cross-reactivity occurs when IgE antibodies recognize allergens from one source but react to a similar protein from another source. Co-sensitization involves the presence of IgE toward epitopes that are not shared between allergenic sources.[1,2]

As with allergen extracts, the quality of a component remains paramount, and the Siemens Healthineers portfolio of 3gAllergy™ specific allergens complies with the acceptable clinical and analytical performance standards. The IMMULITE® 3gAllergy™ component allergen menu, containing some of the most prevalent and reactogenic allergens, provides clinicians with the necessary tools to satisfy comprehensive allergen testing needs. And as an aid in clinical decision making, literature-supported testing algorithms are provided to guide clinicians through the recommended step-by-step testing process.

For this white paper, 11 3gAllergy component allergens were selected with the goal of:

- Briefly explaining component allergens
- Reviewing the testing algorithms based on published literature
- Showing clinical performance

The 11 selected allergens cover a spectrum of component allergens available from Siemens Healthineers:

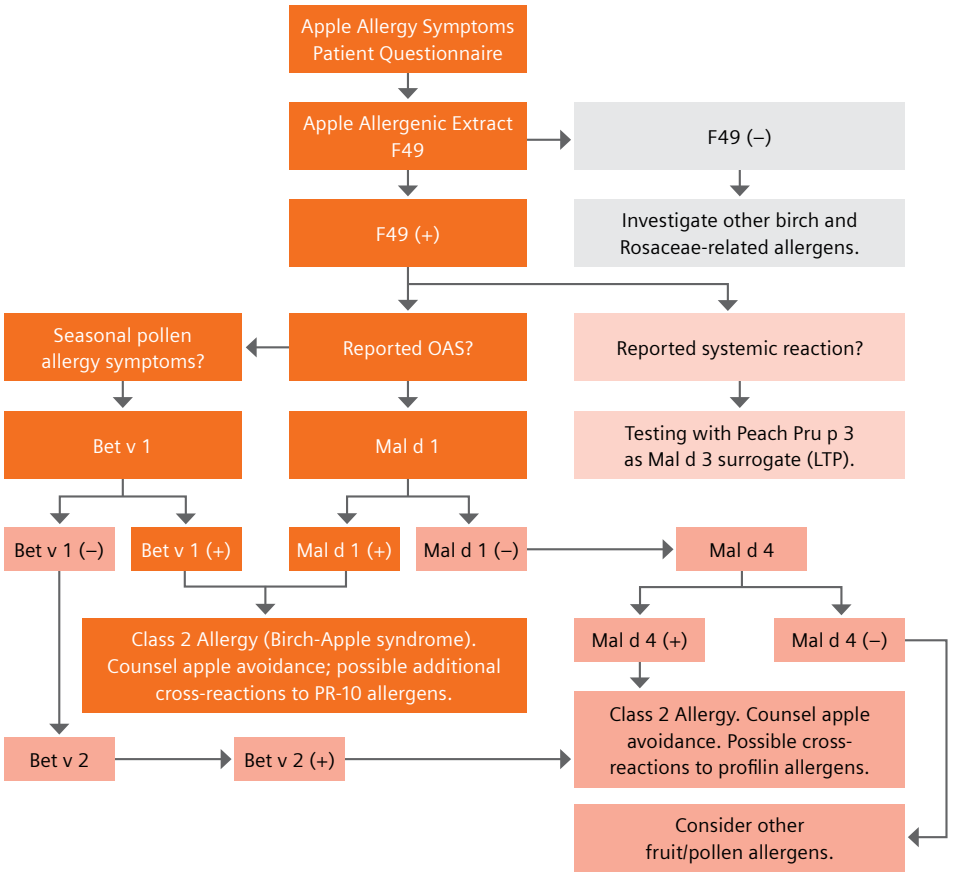
- Apple Component Allergen, rMal d 1 (*Malus domestica*)
- Apple Component Allergen, rMal d 4 (*Malus domestica*)
- Birch Pollen Component Allergen, nBet v 1 (*Betula verrucosa*)
- Birch Pollen Component Allergen, rBet v 2 (*Betula verrucosa*)
- Cherry Component Allergen, rPru av 1 (*Prunus avium*)
- Cherry Component Allergen, rPru av 3 (*Prunus avium*)
- Cherry Component Allergen, rPru av 4 (*Prunus avium*)
- Dust Mites Component Allergen, nDer p 1 & nDer p 2 (*Dermatophagoides pternonyssinus*)
- Mugwort Pollen Major Allergen, nArt v 1 (*Artemisia vulgaris*)*
- Olive Pollen Component Allergen, nOle e 1 (*Olea europaea*)
- Peach Component Allergen, nPru p 3 (*Prunus persica*)

**Not available for sale in the U.S.*

Apple Component Allergen, rMal d 1 (*Malus domestica*)

Mal d 1 is a PR-10 protein associated with oral allergy syndrome (OAS) to apple.[3] It is a homologous protein to Bet v 1, which has been identified as a primary pollen sensitizer eliciting specific IgE antibodies.[4] Although Mal d 1 shares only 57% sequence homology with Bet v 1, 75% of the Mal d 1 tertiary structure binds anti-Bet v 1 antibodies.[5] Approximately 50–93% of birch pollen-allergic patients develop concomitant OAS reactions to fruits, nuts, and vegetables. Mal d 1-allergic individuals do not experience systemic reactions, as PR-10 proteins are susceptible to degradation by heat and gastric digestion.[6,7]

Testing algorithm according to published literature[3,4,6,8]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rMal d 1-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	50	1	**51**
Negative	4	116	**120**
Total	**54**	**117**	**171**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
92.6% (82.1–97.9%)	99.1% (95.3–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

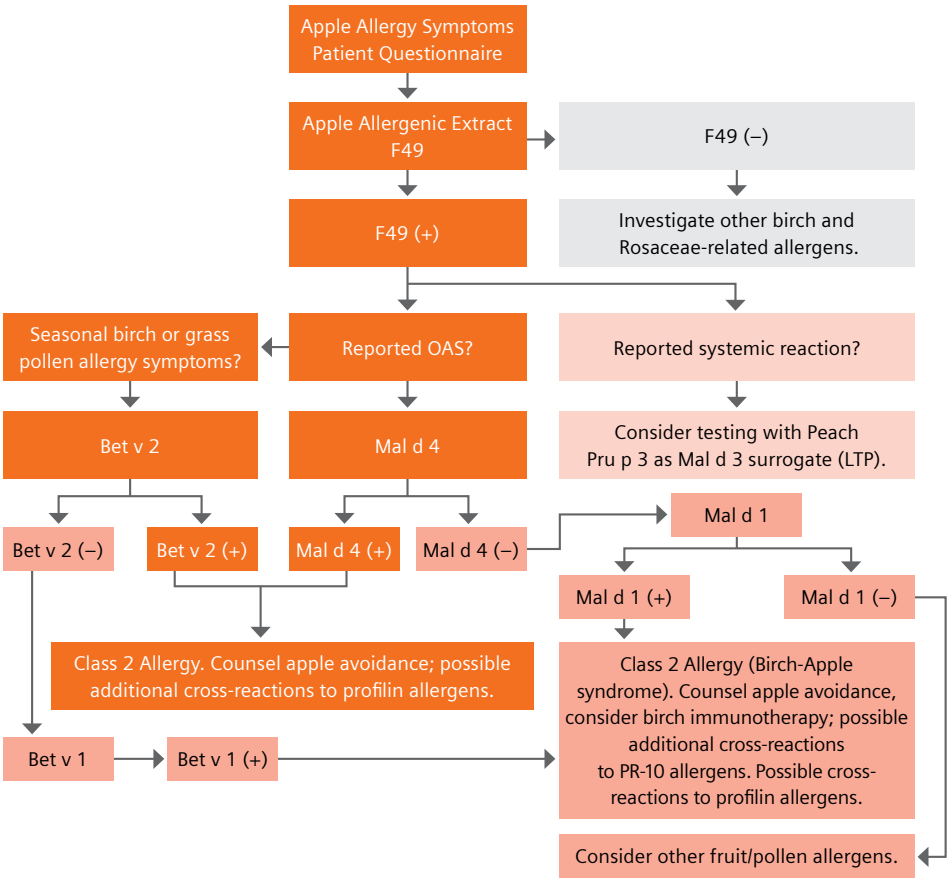
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F49 (Reference Method) A464 (Test Method)	145	92% (133/145)	77% (36/47)	99% (97/98)

†This data is from Siemens Healthineers verification studies.

Apple Component Allergen, rMal d 4 (*Malus domestica*)

Mal d 4, a member of the profilin family of allergens, is an approximately 14 kD protein associated with oral allergy syndrome (OAS) to apple.[9] It is a homologous protein to Bet v 2, which has been identified as a minor pollen sensitizer in approximately 10–30% of pollen-allergic individuals.[10] As with other profilins, Mal d 4 is highly thermolabile and rapidly enzyme-degradable, accounting for its inability to elicit systemic reaction and its loss of allergenicity in cooked foods.[8] Primary sensitization to Mal d 4 develops through pollinosis and cross-reactivity to Bet v 2 and is not presumed to arise directly from apple ingestion without previous sensitization to birch or grass profilin.[3,8,11]

Testing algorithm according to published information[3,4,8,10-12]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rMal d 4-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	15	1	**16**
Negative	39	116	**155**
Total	**54**	**117**	**171**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
27.8% (16.5–41.6%)	99.1% (95.3–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

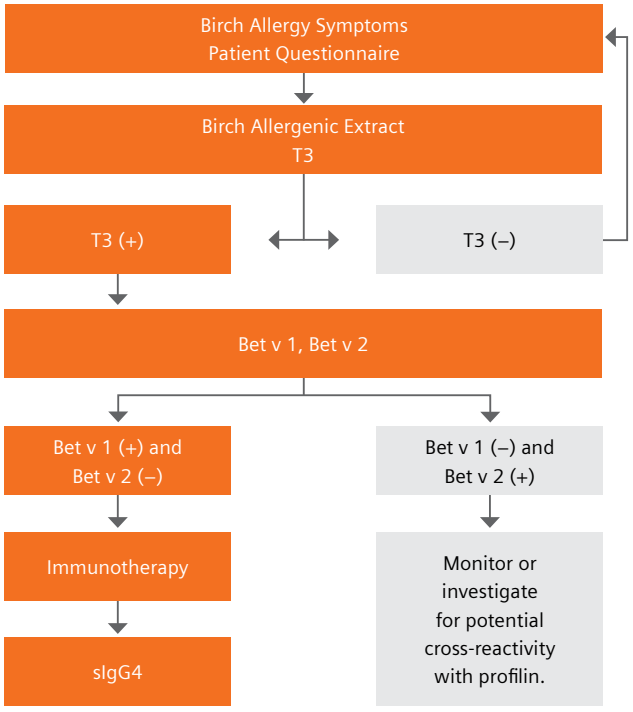
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F49 (Reference Method) A796 (Test Method)	159	79% (126/159)	49% (27/55)	95% (99/104)

†This data is from Siemens Healthineers verification studies.

Birch Pollen Component Allergen, nBet v 1 (*Betula verrucosa*)

Birch (*Betula verrucosa*) pollen is a major cause of allergy in the northern parts of Europe and America that is attributed to about 22% of allergic individuals suffering from pollinosis.[13] Six birch pollen allergens have already been identified (Bet v 1, Bet v 2, Bet v 3, Bet v 4, Bet v 6, Bet v 7). Bet v 1, a major allergenic protein of birch pollen, is a 17 kDa protein consisting of several isoallergens[14] and recognized by IgE antibodies from almost all birch pollen-allergic patients.[15] Oral allergy syndrome (OAS) as a result of primary sensitization to Bet v 1 has been previously reported.

Testing algorithm according to published literature[13,16-18]



Clinical Performance[60]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the nBet v 1-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	37	5	**42**
Negative	6	95	**101**
Total	**43**	**100**	**143**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
86% (not available)	95% (not available)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

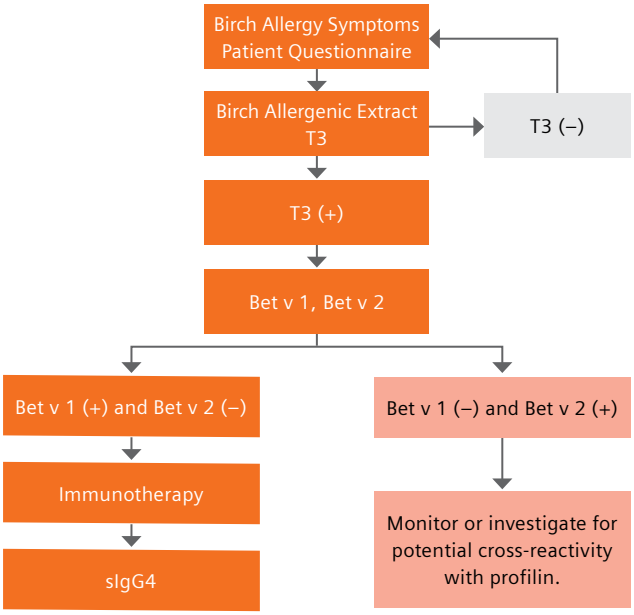
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F49 (Reference Method) A796 (Test Method)	143	92% (132/143)	79% (42/53)	100% (90/90)

†This data is from Siemens Healthineers verification studies.

Birch Pollen Component Allergen, rBet v 2 (*Betula verrucosa*)

Profilin allergens are responsible for multiple pollen and food sensitization with extensive cross-reactivity.[19,20] The IgE conformational epitopes in profilin are highly conserved, which is key to maintaining its cross-reactive nature in plant allergens. The Bet v 2 profilin from birch pollen may be used to evaluate IgE reactivity in patients with suspected birch allergy or other cross-reactivities between mugwort, grass pollen, celery, carrots, and hazelnut.[21-23]

Testing algorithm according to published literature[16-18, 24]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rBet v 2-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	25	1	**26**
Negative	45	116	**161**
Total	**70**	**117**	**187**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
35.7% (24.6–48.1%)	99.1% (95.3–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

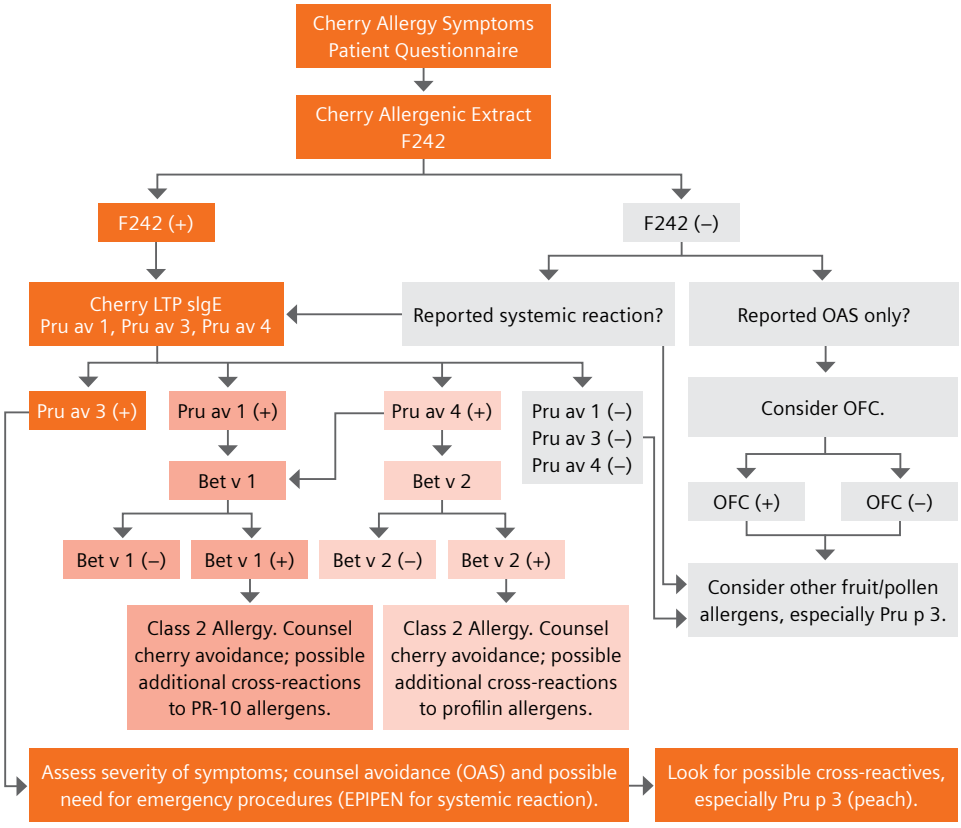
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
T3 (Reference Method) A89 (Test Method)	156	80% (125/156)	51% (30/59)	98% (95/97)

†This data is from Siemens Healthineers verification studies.

Cherry Component Allergen, rPru av 1 (*Prunus avium*)

Pru av 1 is a 17.7 kDa PR-10 protein associated with oral allergy syndrome (OAS) to cherry.[10,25] It is a homologous protein to Bet v 1, which has been identified as a primary pollen sensitizer eliciting specific IgE antibodies and is considered a major allergen.[10,25,26] Although Pru av 1 shares only 59–64% sequence homology with Bet v 1, 75% of the tertiary structures of the two proteins are virtually identical, and preincubation of cherry-allergic patient sera with Bet v 1 inhibits binding by Pru av 1.[27] Up to 90% of cherry-allergic patients manifest a concomitant allergy to birch pollen, as primary sensitization arises via pollinosis.[28,29] Pru av 1-allergic individuals typically do not experience systemic reactions, as PR-10 proteins are rapidly degraded by heat and gastric digestion.[28,29]

Testing algorithm according to published literature[10,12,25-29]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 1-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	33	5	**38**
Negative	4	112	**116**
Total	**37**	**117**	**154**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
89.2% (74.6–97.0%)	95.7% (90.3–98.6%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

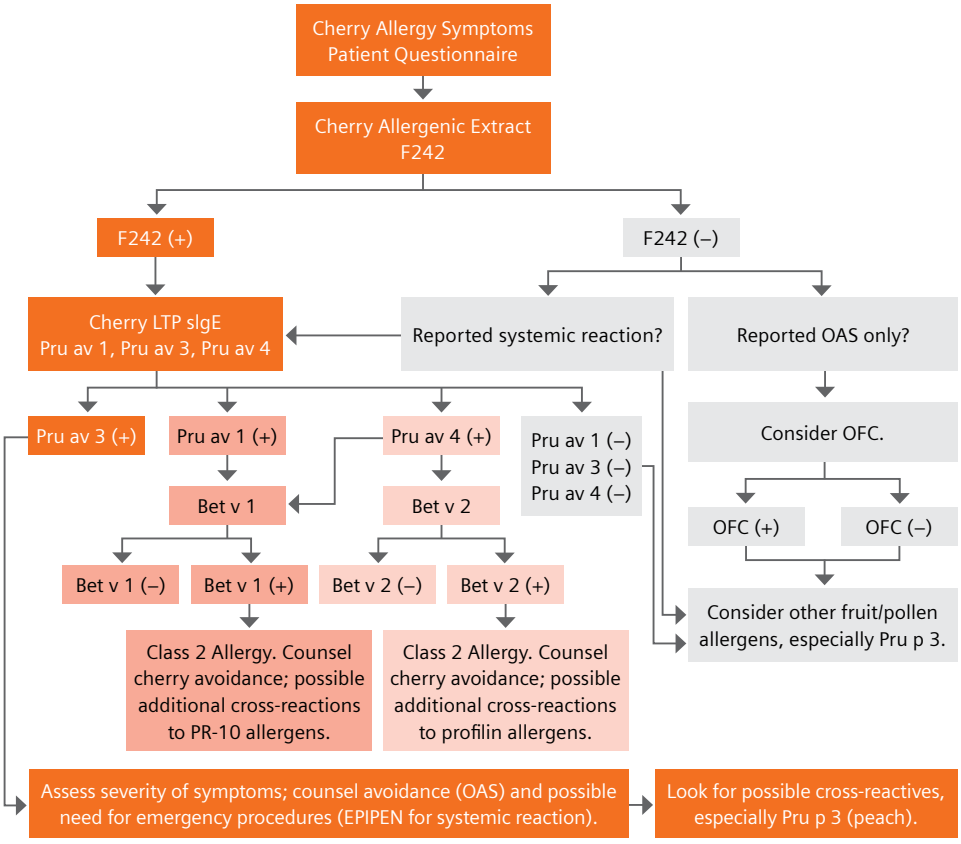
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F242 (Reference Method) A597 (Test Method)	159	89% (142/159)	75% (46/61)	98% (96/98)

†This data is from Siemens Healthineers verification studies.

Cherry Component Allergen, rPru av 3 (*Prunus avium*)

Plant lipid transfer proteins (LTP) are highly conserved proteins of approximately 10 kDa.[30] They are typically associated with more-severe and systemic reactions such as urticaria and anaphylaxis in some populations, but less-severe reactions in the form of oral allergy syndrome (OAS) in others.[28,29] Because these proteins are so highly conserved, sensitization to LTP from one plant can result in allergic responses to other taxonomically related or unrelated fruits and vegetables.[28-30] Pru av 3 is an LTP isolated from cherry[26,31] and may be used to evaluate specific IgE reactivity in patients with suspected cherry allergy.[26,28-31] Monosensitization to Pru av 3 is rare; studies suggest that peach LTP (Pru p 3) is the likely primary allergic sensitizer, triggering allergic response to other Rosaceae via LTP cross-reactivity.[28,29]

Testing algorithm according to published literature[12,26,28-31]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 3-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	10	0	**10**
Negative	27	117	**144**
Total	**37**	**117**	**154**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
27% (13.8–44.1%)	100% (96.9–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

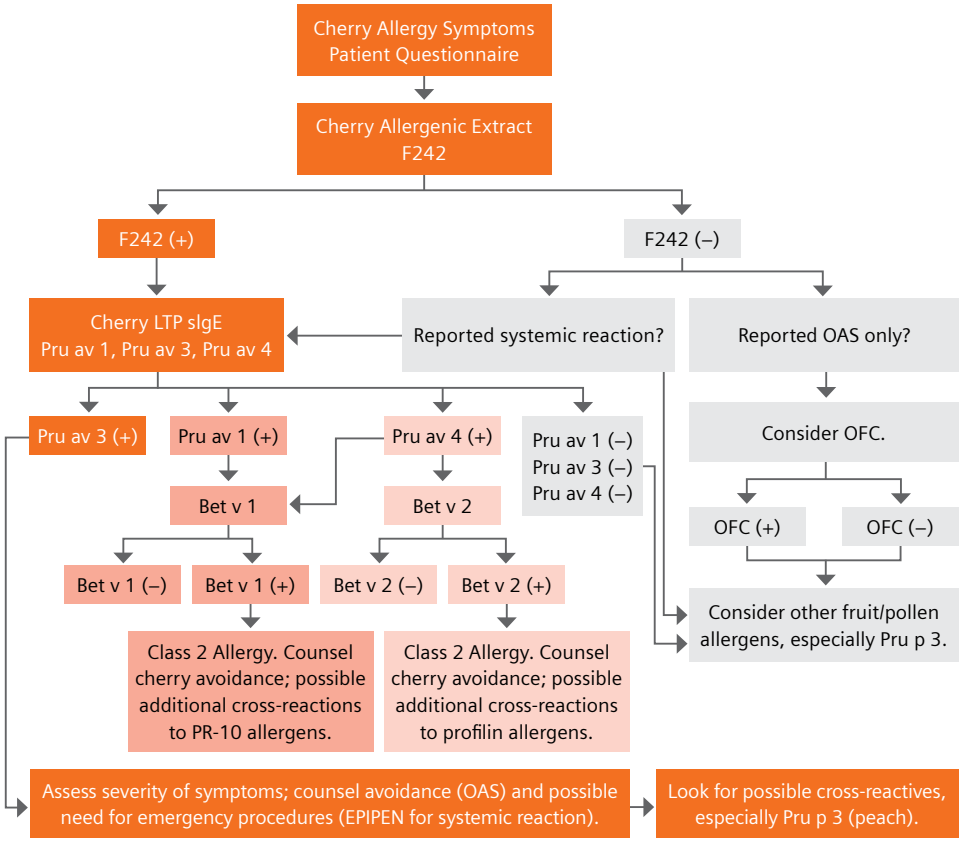
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F242 (Reference Method) A599 (Test Method)	145	80% (116/145)	44% (21/48)	98% (95/97)

†This data is from Siemens Healthineers verification studies.

Cherry Component Allergen, rPru av 4 (*Prunus avium*)

Pru av 4, a member of the profilin family of allergens, is an approximately 15 kDa protein associated with oral allergy syndrome (OAS) to cherry.[28,32] It is a homologous protein to Bet v 2, which has been identified as a minor pollen sensitizer in approximately 10–30% of pollen-allergic individuals.[10,20,28] Pru av 4 shares over 70% amino acid homology and a very similar tertiary structure with other profilins.[20] It is highly thermolabile and rapidly enzyme-degradable, accounting for its inability to elicit systemic reaction and its loss of allergenicity in cooked foods.[10] Primary sensitization to Pru av 4 develops through pollinosis and cross-reactivity to Bet v 2 and is not presumed to arise directly from cherry ingestion without previous sensitization to birch or grass profilin.[10]

Testing algorithm according to published literature[12,20,26,28,29]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the rPru av 4-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	9	1	**10**
Negative	28	116	**144**
Total	**37**	**117**	**154**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
24.3% (11.8–41.2%)	99.1% (95.3–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F242 (Reference Method) A600 (Test Method)	156	80% (125/156)	50% (26/52)	95% (99/104)

†This data is from Siemens Healthineers verification studies.

Dust Mites Component Allergen, nDer p 1 and nDer p 2 (*Dermatophagoides pternonyssinus*)

Development of allergic asthma in adults and children is commonly associated with sensitization to house dust mites (HDM).[33] IgE sensitivities are often directed toward major HDM allergens such as Der p 1 (24 kDa) and Der p 2 (15 kDa) from *Dermatophagoides pteronyssinus* (allergen code: D1).[34,35] Der p 1 and Der p 2 individually are recognized by more than 80% of D1-senstitized patient IgE and have a predictive value for D1 greater than 95%.[36] Cross-reactivity has been observed between homologous proteins Der f 1 and Der f 2 from *Dermatophagoides farinae*, to which *D. pteronyssinus* shares 80–90% sequence identity.[37]

Clinical Performance[62]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the nDer p 1- and nDer p 2-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Testing algorithm according to published literature[12,38,39]

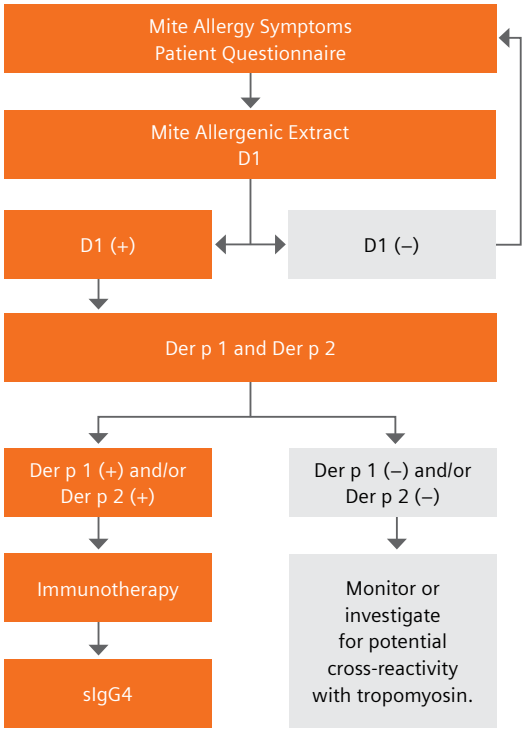


Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
nDer p 1			
Positive (≥0.10 kU/L)	49	3	**52**
Negative	7	109	**116**
Total	**56**	**112**	**168**
nDer p 2			
Positive (≥0.10 kU/L)	51	2	**53**
Negative	5	110	**115**
Total	**56**	**112**	**168**

Table 2. Clinical performance: sensitivity and specificity.

nDer p 1		nDer p 2	
Sensitivity (95% CI)	**Specificity (95% CI)**	**Sensitivity (95% CI)**	**Specificity (95% CI)**
88% (79–96%)	97% (94–100%)	91% (84–99%)	98% (96–101%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

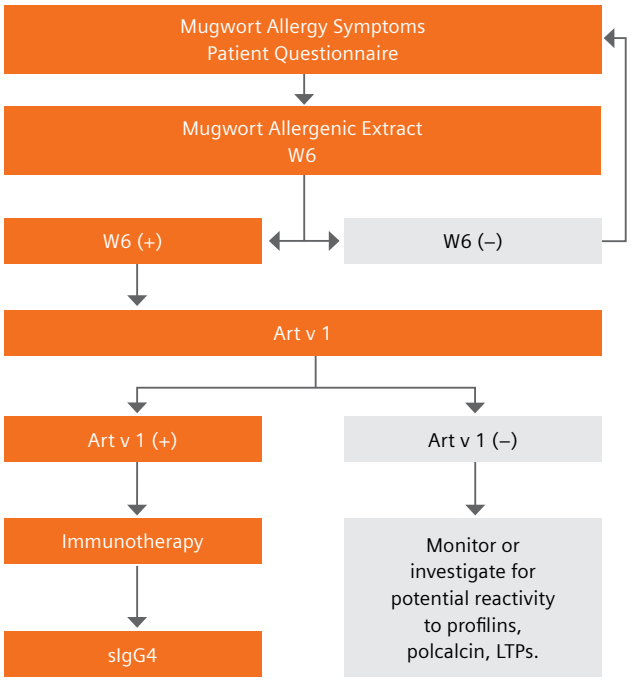
nDer p 1 and nDer p 2	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
D1 (Reference Method) A310 and A316 (Test Method)	107	99% (106/107)	98% (50/51)	100% (56/56)

†This data is from Siemens Healthineers verification studies.

Mugwort Pollen Major Allergen, nArt v 1 (*Artemisia vulgaris*)*

Mugwort (*Artemisia vulgaris*) is one of the main causes of seasonal pollinosis in Europe and is also found throughout the Northern Hemisphere.[40] Six mugwort pollen allergens have been identified (Art v 1, Art v 2, Art v 3, Art v 4, Art v 5, Art v 6).[41] Art v 1, a glycoprotein, has an approximate molecular weight of 24–28 kDa and appears as a double-band due to its heterogenous glycosylation.[40] Native Art v 1 is preferred over the recombinant molecule produced by *E. coli* due to only 30–50% recognition by nArt v 1-positive sera.[42] Art v 1 is a major allergenic protein of mugwort pollen that is recognized by more than 70% of mugwort-sensitized patient IgE.[43] A homologous protein in ragweed (Amb a 4) has been identified.[44]

Testing algorithm according to published literature[12,45]



Clinical Performance[60]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the nArt v 1-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	20	7	**27**
Negative	10	93	**103**
Total	**30**	**100**	**130**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
67% (50–84%)	93% (88–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

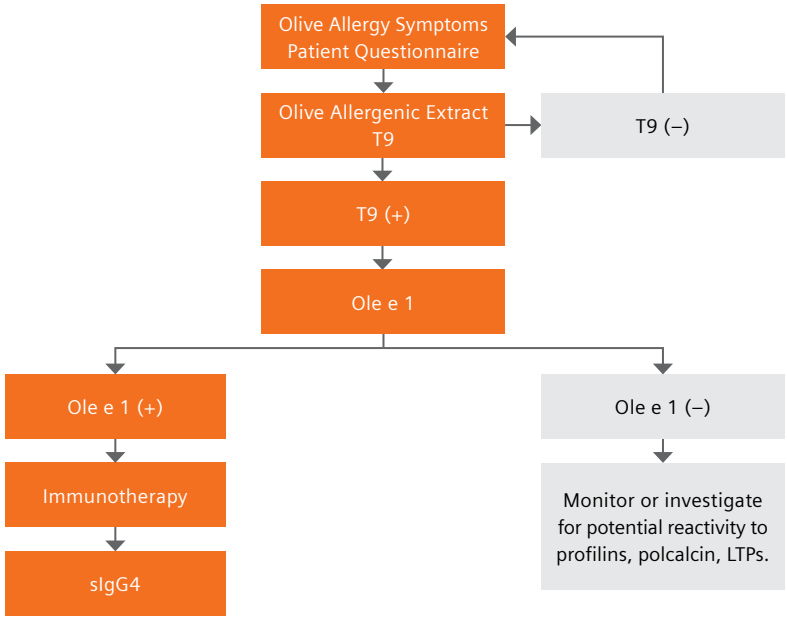
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
W6 (Reference Method) A753 (Test Method)	142	83% (117/142)	93% (25/27)	80% (92/115)

**Not available for sale in the U.S.*
†This data is from Siemens Healthineers verification studies.

Olive Pollen Component Allergen, nOle e 1 (*Olea europaea*)

Olive tree (*Olea europaea*) pollen is a major cause of type 1 seasonal allergy in the Mediterranean and can also be found in areas with a Mediterranean-type climate, including parts of Australia, South Africa, and North America.[46,47] Ten olive tree pollen allergens have been identified (Ole e 1, Ole e 2, Ole e 3, Ole e 4, Ole e 5, Ole e 6, Ole e 7, Ole e 8, Ole e 9, Ole e 10).[48] Ole e 1 is a major allergenic protein of olive tree pollen that exists in two main forms: glycosylated (~20 kDa) and non-glycosylated (~18.5 kDa).[49] Homologous proteins are found in other members of the Oleaceae family, such as ash (Fra e 1), privet (Lig v 1), and lilac (Syr v 1).[50] More than 80% of patients sensitized to olive pollen have IgE reactivity to the Ole e 1 allergenic molecule, and common symptoms of exposure include asthma, rhinitis, and conjunctivitis.[51-53]

Testing algorithm according to published literature[12,53,54]



Clinical Performance[60]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the nOle e 1-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	37	3	**40**
Negative	2	97	**99**
Total	**39**	**100**	**139**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
95% (not available)	97% (not available)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

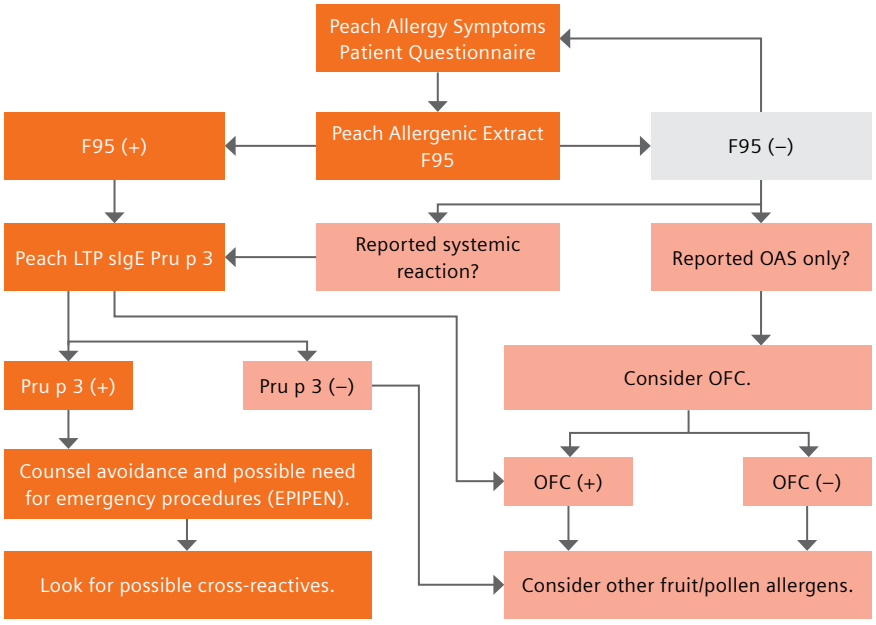
	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
T9 (Reference Method) A482 (Test Method)	139	97% (135/139)	98% (39/40)	97% (96/99)

†This data is from Siemens Healthineers verification studies.

Peach Component Allergen, nPru p 3 (*Prunus persica*)

Plant lipid transfer proteins (LTP) are highly conserved proteins of approximately 10 kDa.[30] They are found in the seeds, stems, flowers, leaves, and pollen of plants and are considered panallergens.[30] LTPs are typically associated with more-severe and systemic reactions such as urticaria and anaphylaxis.[30,55] Because these proteins are so highly conserved, sensitization to LTP from one plant can result in unexpected allergic responses to other taxonomically unrelated fruits or vegetables.[30,55,56] Pru p 3 is an LTP isolated from peach skin and pulp[30] and may be used to evaluate specific IgE reactivity in patients with suspected peach allergy.[30,55-57] While peach LTP is typically the primary allergic sensitizer, cross-reactivity to LTP of other taxonomically related or unrelated plants may be responsible for peach allergy in some patients.[57]

Testing algorithm according to published literature[12,55-59]



Clinical Performance[61]

Clinical performance was demonstrated by testing serum samples from clinically diagnosed atopic patients and apparently healthy individuals against the nPru p 3-specific allergen. The results were obtained using the IMMULITE 2000/XPi 3gAllergy Specific IgE assay. Overall agreement, sensitivity, and specificity are presented in the tables below.

Table 1. Clinical performance: overall agreement.

	Atopic	Non-atopic	Total
Positive (≥0.10 kU/L)	11	0	**11**
Negative	27	117	**144**
Total	**38**	**117**	**155**

Table 2. Clinical performance: sensitivity and specificity.

Sensitivity (95% CI)	Specificity (95% CI)
28.9% (15.4–45.9%)	100% (96.9–100%)

Additional clinical performance of the specific allergens was demonstrated in comparison to the whole extract allergen. The results are presented below.

Table 3. Clinical performance of the specific allergens in comparison to the whole extract allergen.†

	Number of Samples	Overall Percent Agreement	Positive Percent Agreement	Negative Percent Agreement
F95 (Reference Method) A603 (Test Method)	156	84% (122/146)	49% (23/47)	100% (99/99)

†This data is from Siemens Healthineers verification studies.

Conclusion

Allergen component testing plays a critical role, as it allows clinicians to provide a better differential diagnosis than extract testing alone. The era of protein mixture testing has given way to this new frontier of highly specific, single-allergen component testing, proving it to be an aid in the clinical diagnosis of IgE-mediated allergic disorders. Being equipped with an in-house portfolio of rigorously tested and validated component allergens may provide for a more comprehensive and accelerated testing process.

The Siemens Healthineers portfolio of commonly tested component allergens is currently available for testing on the IMMULITE 2000/XPi platform and has undergone rigorous clinical and analytical scrutiny to validate the quality of the tests. Please refer to the IMMULITE 2000/XPi 3gAllergy menu online for the full list of available component allergens.

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