RAPID.VALID.
PRECISE.

FCP FastCheckPOC®
FastCheckPOC® – Near-patient rapid allergy screening test for qualitative determination of allergen specific IgE antibody levels from serum, capillary, serum blood or venous blood. It is suitable for ascertaining the presence of frequently occurring allergies within approximately 30 minutes without any special laboratory setup or equipment.*

DST groups core allergens according to different influencing factors, e.g., according to region, season and food culture. Through our own research and laboratory developments, our core allergens possess excellent reactivities in a combination of quality, purity, precision and validity. This ensures fast and clear diagnostic values of the highest informational value. These qualities have been incorporated into our FastCheckPOC® and achieve an excellent diagnostic quality.

FastCheckPOC® – FOR RAPID, VALID AND PRECISE RESULTS.

FastCheckPOC® – Rapid screening tests available for inhalant and food allergies.

FastCheckPOC® – e.g. for the diagnosis of outdoor allergies, such as grass pollen, tree pollen, weed pollen. Early and late bloomers are differentiated.

FastCheckPOC® – 90% coverage of the most frequent allergens in Northern and Central Europe. Also suitable for other regions.

FastCheckPOC® – e.g. for the diagnosis of allergies to animal hair and house dust mites.

FastCheckPOC® – e.g. for the diagnosis of food allergies.

FastCheckPOC® – Particularly well-suited for patients being treatment with antihistamines or patients suffering from dermatitis or other skin conditions with contraindications to skin testing. The test is also ideal for individuals averse to skin prick, scratch or intracutaneous allergy testing (e.g., children, elderly persons, pregnant women) or for patients who are predisposed to anaphylactic episodes.

Intended Use
FastCheckPOC® is a portable enzyme immunoassay for the qualitative determination of allergen specific IgE from capillary or venous blood. This test is intended for use as a tool to support the diagnosis of type I allergic sensitisations in patients who show clinical symptoms such as:

- seasonal and perennial rhinitis and conjunctivitis
- allergic asthma
- allergic eczema
- allergic gastrointestinal disorders.

This test should only be performed by medical personnel who have been trained in the use of in vitro diagnostics products.

2–3 DROPS AND 30 MINUTES TO A RESULT.
A SMART TEST FOR THE DETECTION OF SPECIFIC IgE.

DST has developed with FastCheckPOC® an ELISA rapid test to determine specific IgE, which shows the best characteristics: through the optimisation of the allergens and chemicals used, as well as the merging of individual steps, the DST laboratory has achieved an optimal coordination of the components. The result: with only 2-3 drops of blood a valid result is provided at room temperature within 30 minutes.

Fast, valid, clear.
- Result in only 30 minutes.
- Clear results through the use of highly sensitive allergens from the DST laboratory.
- High agreement between the results in comparison with the Thermo Fisher ImmunoCAP® lab test.

EXPERTISE AND PROFESSIONAL SOLUTIONS.

With every drop you get a valid result from DST. For your requirements and enquiries we offer a comprehensive and supportive expert service in the background.

Three diagnostic possibilities and still more reasons to work together with us: our own laboratory, LAS, Fast-CheckPOC® and cerascreen®.

Every contact to DST helps you.
- We advise you at any time and provide answers to your questions.
- We offer validation of your results upon request.
- We provide you with individual allergen compositions.
- Further well-founded lab tests (e.g. LAS) give you the highest possible flexibility and quality in the diagnostics.
- Additionally we offer allergen extracts of the highest quality.
Current allergen panels used in the fast allergy test for 12 inhalation or food allergens

Table 1:

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>f74</td>
<td>Hen egg</td>
</tr>
<tr>
<td>t74</td>
<td>Fish mix</td>
</tr>
<tr>
<td>f73</td>
<td>Meat mix</td>
</tr>
<tr>
<td>f24</td>
<td>Shrimp</td>
</tr>
<tr>
<td>f17</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f14</td>
<td>Wheat</td>
</tr>
<tr>
<td>t74</td>
<td>Fish Mix</td>
</tr>
<tr>
<td>f13</td>
<td>Peanut</td>
</tr>
<tr>
<td>f11</td>
<td>Orange</td>
</tr>
<tr>
<td>f73</td>
<td>Meat Mix</td>
</tr>
<tr>
<td>f14</td>
<td>Soy Bean</td>
</tr>
<tr>
<td>f24</td>
<td>Shrimp</td>
</tr>
<tr>
<td>f5</td>
<td>Rye flour</td>
</tr>
<tr>
<td>f199</td>
<td>Milk, raw</td>
</tr>
</tbody>
</table>

Available Panel Layout – INHALATION

<table>
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<tr>
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</tr>
</thead>
<tbody>
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<td>e1</td>
<td>Cat epithelium</td>
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<tr>
<td>x20</td>
<td>Stinging nettle</td>
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<tr>
<td>f14</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f3</td>
<td>Silver Birch</td>
</tr>
<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
</tr>
<tr>
<td>m1</td>
<td>Grass Myc</td>
</tr>
<tr>
<td>w6</td>
<td>Mugwort</td>
</tr>
<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Available Panel Layout – FOOD

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
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<td>f74</td>
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<tr>
<td>f13</td>
<td>Peanut</td>
</tr>
<tr>
<td>f11</td>
<td>Orange</td>
</tr>
<tr>
<td>f73</td>
<td>Meat Mix</td>
</tr>
<tr>
<td>f14</td>
<td>Soy Bean</td>
</tr>
<tr>
<td>f24</td>
<td>Shrimp</td>
</tr>
<tr>
<td>f5</td>
<td>Rye flour</td>
</tr>
<tr>
<td>f199</td>
<td>Milk, raw</td>
</tr>
</tbody>
</table>

Available Panel Layout – MEDITERRANEAN

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<th>Allergen</th>
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</thead>
<tbody>
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<td>Hen egg</td>
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<tr>
<td>f17</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f14</td>
<td>Wheat</td>
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<tr>
<td>f74</td>
<td>Fish Mix</td>
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<tr>
<td>f13</td>
<td>Peanut</td>
</tr>
<tr>
<td>f11</td>
<td>Orange</td>
</tr>
<tr>
<td>f73</td>
<td>Meat Mix</td>
</tr>
<tr>
<td>f14</td>
<td>Soy Bean</td>
</tr>
<tr>
<td>f24</td>
<td>Shrimp</td>
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<td>f5</td>
<td>Rye flour</td>
</tr>
<tr>
<td>f199</td>
<td>Milk, raw</td>
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</table>

Available Panel Layout – UK

<table>
<thead>
<tr>
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<tbody>
<tr>
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<tr>
<td>f14</td>
<td>Wheat</td>
</tr>
<tr>
<td>f74</td>
<td>Fish Mix</td>
</tr>
<tr>
<td>f13</td>
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<tr>
<td>f24</td>
<td>Shrimp</td>
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<td>f5</td>
<td>Rye flour</td>
</tr>
<tr>
<td>f199</td>
<td>Milk, raw</td>
</tr>
</tbody>
</table>

Available Panel Layout – EUROPE

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1</td>
<td>House dust mite</td>
</tr>
<tr>
<td>e1</td>
<td>Cat epithelium</td>
</tr>
<tr>
<td>x20</td>
<td>Stinging nettle</td>
</tr>
<tr>
<td>f14</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f3</td>
<td>Silver Birch</td>
</tr>
<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
</tr>
<tr>
<td>m1</td>
<td>Grass Myc</td>
</tr>
<tr>
<td>w6</td>
<td>Mugwort</td>
</tr>
<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Available Panel Layout – SWISS

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
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</thead>
<tbody>
<tr>
<td>d1</td>
<td>House dust mite</td>
</tr>
<tr>
<td>e1</td>
<td>Cat epithelium</td>
</tr>
<tr>
<td>x20</td>
<td>Stinging nettle</td>
</tr>
<tr>
<td>f14</td>
<td>Hazelnut</td>
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<tr>
<td>f3</td>
<td>Silver Birch</td>
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<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
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<tr>
<td>m1</td>
<td>Grass Myc</td>
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<tr>
<td>w6</td>
<td>Mugwort</td>
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<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Available Panel Layout – MIDDLE EAST

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1</td>
<td>House dust mite</td>
</tr>
<tr>
<td>e1</td>
<td>Cat epithelium</td>
</tr>
<tr>
<td>x20</td>
<td>Stinging nettle</td>
</tr>
<tr>
<td>f14</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f3</td>
<td>Silver Birch</td>
</tr>
<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
</tr>
<tr>
<td>m1</td>
<td>Grass Myc</td>
</tr>
<tr>
<td>w6</td>
<td>Mugwort</td>
</tr>
<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Available Panel Layout – EASTERN EUROPE

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
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</thead>
<tbody>
<tr>
<td>d1</td>
<td>House dust mite</td>
</tr>
<tr>
<td>e1</td>
<td>Cat epithelium</td>
</tr>
<tr>
<td>x20</td>
<td>Stinging nettle</td>
</tr>
<tr>
<td>f14</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f3</td>
<td>Silver Birch</td>
</tr>
<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
</tr>
<tr>
<td>m1</td>
<td>Grass Myc</td>
</tr>
<tr>
<td>w6</td>
<td>Mugwort</td>
</tr>
<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Available Panel Layout – NORTHERN AMERICA

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1</td>
<td>House dust mite</td>
</tr>
<tr>
<td>e1</td>
<td>Cat epithelium</td>
</tr>
<tr>
<td>x20</td>
<td>Stinging nettle</td>
</tr>
<tr>
<td>f14</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f3</td>
<td>Silver Birch</td>
</tr>
<tr>
<td>m2</td>
<td>Cladosporium herbarum</td>
</tr>
<tr>
<td>m1</td>
<td>Grass Myc</td>
</tr>
<tr>
<td>w6</td>
<td>Mugwort</td>
</tr>
<tr>
<td>d2</td>
<td>Dog epithelium</td>
</tr>
<tr>
<td>m6</td>
<td>Alternaria alternata</td>
</tr>
</tbody>
</table>

Test principle.

FastCheckPOC® is an enzyme immunoassay that has been transferred and adapted from laboratory diagnostics to the medical professional’s office for determination of allergen specific IgE in whole (untreated) blood. No extra instrumentation is required to perform the test and to obtain a readout of the result. The evaluation can be made with the naked eye. The test device comprises a membrane card with 12 single allergens or mixtures that are chemically bound within certain areas on the card.

A blood sample (100 µl) from the fingertip or earlobe (or collected from a venous blood sample) is added to the small tube with test solution. The test solution contains an enzyme conjugate that specifically forms complexes to the medical professional’s office for determination of allergen specific IgE in whole (untreated) blood.

Following an incubation period of 15 minutes, all unbound material is washed off using a stringent washing solution.

These complexes are now applied to the membrane card and bound to the allergens on its surface. Sensitisations to the tested allergens are identified by comparing the shape (plus or minus sign) and colour intensity of the symbols with the controls on the membrane card.

Unique products and support services secure an established lead for our commercial customers: profitability, diagnostic and consulting competence with sustainable competitiveness.

Table 1: Current allergen panels used in the fast allergy test for 12 inhalation or food allergens

<table>
<thead>
<tr>
<th>Code</th>
<th>Allergen</th>
</tr>
</thead>
<tbody>
<tr>
<td>t74</td>
<td>Hen egg</td>
</tr>
<tr>
<td>t31</td>
<td>Hazelnut</td>
</tr>
<tr>
<td>f14</td>
<td>Wheat</td>
</tr>
<tr>
<td>t6</td>
<td>Fish Mix</td>
</tr>
<tr>
<td>f11</td>
<td>Peanut</td>
</tr>
<tr>
<td>t31</td>
<td>Carrot</td>
</tr>
<tr>
<td>f9</td>
<td>Soy Bean</td>
</tr>
<tr>
<td>f5</td>
<td>Rye flour</td>
</tr>
<tr>
<td>f85</td>
<td>Celery</td>
</tr>
<tr>
<td>f199</td>
<td>Milk, raw</td>
</tr>
</tbody>
</table>

Maximizing your outcome.

We offer our customers allergens with the highest reactivity and diversity in safe and flexible diagnostic carriers. Our diagnostic concepts enjoy the greatest confidence among experts and beyond.
FastCheckPOC® – PERFORMANCE FOR VALID RESULTS.

The rapid allergy screening test FastCheckPOC® detects IgE antibodies that are freely circulating in the blood stream. When diagnosing allergies, FastCheckPOC® – just as in all other in vitro tests – should be regarded as one part of a diagnostic procedure that includes a complete clinical history and in-depth anamnesis.

Performance characteristics.

- Analytical specificity: cross-reactivity with other immunoglobulin species is not expected
- Correlation w/ ImmunoCAP®: 96 % for positive samples, 98 % for negative samples
- Accuracy: expected values were obtained in all cases
- Reproducibility: 100 % inter-assay
- Repeatability: 100 % intra-assay
- Negative results: < CAP class II
- Detection range CAP class 0/V, class II
- Cut-off/Transition region CAP class II (0.7–3.5 kU/l)
- Positive results ≥ CAP class II

FastCheckPOC® is a qualitative test that correlates well with the ImmunoCAP® system (> 96 %).

The allergens used in FastCheckPOC® are calibrated against the quantitative diagnostic laboratory system ImmunoCAP® by Thermo Fischer.

Illustration 1:
FastCheckPOC® principles

EVERY CONTACT TO DST HELPS YOU.

For more information, please see FastCheckPOC® Package leaflet.

FastCheckPOC®: MEDICAL STUDY AT A GLANCE.

Development and performance evaluation of a visual fast test for the development of specific IgE in capillary blood or heparin blood. We present this study as an abstract in the following.

Are you interested in the complete publication? Or do you have any questions regarding the study or our services? Please do not hesitate to contact us – we will support you directly.

Resumee abstract

The number of allergic patients in industrialized countries has increased over the last 30 years. At present, approximately 30% of the European inhabitants have been affected. According to estimations, only a fraction of patients with respiratory allergy is diagnosed at an early stage and treated correctly. The European Academy for Allergology and Clinical Immunology (EAACI) has, therefore, initiated a campaign focusing on the early diagnosis of allergy. Early diagnosis needs easy screening instruments. Thus, an easy visual allergy test for the fast detection of specific IgE in capillary blood has been developed. This test is based on the ELISA-technique (enzyme-linked immunosorbent assay) and adapted to be carried out at room temperature with a result within 30 minutes using only 2-3 drops of whole blood (100 µl).

Specific IgE for either 12 separate food allergens or 12 separate inhalation allergens can be tested in parallel in one test. The current allergen panel covers approximately 90 % of the relevant inhalant allergens or food allergens for northern and middle Europe.

Allergens on the membrane give a visible sign in the shape of a “+” for positive reactions and a “−” for negative reactions. Correlation of results of the fast allergy test with results of the Pharmacia CAP was shown. In 313 patients the test showed 96 % positive and 98 % negative correlation in average. In conclusion, the test represents a valid method for screening of elevated specific IgE for the most common inhalant and food allergens.

Performance characteristics.

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- Correlation w/ ImmunoCAP®: 96 % for positive samples, 98 % for negative samples
- Accuracy: expected values were obtained in all cases
- Reproducibility: 100 % inter-assay
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FastCheckPOC® is a qualitative test that correlates well with the ImmunoCAP® system (> 96 %).

The allergens used in FastCheckPOC® are calibrated against the quantitative diagnostic laboratory system ImmunoCAP® by Thermo Fischer.

Illustration 1:
FastCheckPOC® principles

Ease-of-use of the fast allergy test was confirmed during the study. The comparison of the results of the fast allergy test and the reference system Pharmacia CAP (Unicap 100) show a good correlation.

The results of comparing the data from 331 patients generated with the fast allergy test and the Uni-CAP 100 laboratory test system are shown below in table 2.1

Table 2: Comparison of results of allergy testing from fast allergy test and laboratory test

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Cap Positive</th>
<th>Fast Test positive</th>
<th>Positive Correlation</th>
<th>Cap Negative</th>
<th>Fast Test negative</th>
<th>Negative Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1 House dust mite</td>
<td>53</td>
<td>38</td>
<td>98.3 %</td>
<td>13</td>
<td>13</td>
<td>98.6 %</td>
</tr>
<tr>
<td>t4 Hazel pollen</td>
<td>24</td>
<td>24</td>
<td>100 %</td>
<td>31</td>
<td>30</td>
<td>96.7 %</td>
</tr>
<tr>
<td>p3 Grass pollen mix</td>
<td>76</td>
<td>75</td>
<td>98.7 %</td>
<td>38</td>
<td>37</td>
<td>97.4 %</td>
</tr>
<tr>
<td>w6 Mugwort pollen</td>
<td>62</td>
<td>60</td>
<td>96.8 %</td>
<td>44</td>
<td>43</td>
<td>97.7 %</td>
</tr>
<tr>
<td>e1 Cat epithelia</td>
<td>33</td>
<td>31</td>
<td>93.9 %</td>
<td>40</td>
<td>40</td>
<td>100 %</td>
</tr>
<tr>
<td>t3 Birch pollen</td>
<td>80</td>
<td>76</td>
<td>95 %</td>
<td>58</td>
<td>56</td>
<td>96.5 %</td>
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<td>f22 Latex</td>
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<td>21</td>
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<td>47</td>
<td>44</td>
<td>93.6 %</td>
</tr>
<tr>
<td>w20 Stinging nettle</td>
<td>15</td>
<td>15</td>
<td>100 %</td>
<td>20</td>
<td>20</td>
<td>100 %</td>
</tr>
<tr>
<td>m2 Cladosporum</td>
<td>4</td>
<td>4</td>
<td>100 %</td>
<td>35</td>
<td>34</td>
<td>97.1 %</td>
</tr>
<tr>
<td>m3 A. fumigatus</td>
<td>4</td>
<td>4</td>
<td>100 %</td>
<td>38</td>
<td>37</td>
<td>91.3 %</td>
</tr>
<tr>
<td>m6 Alternaria alternata</td>
<td>15</td>
<td>14</td>
<td>93.3 %</td>
<td>45</td>
<td>45</td>
<td>100 %</td>
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<tr>
<td>f74 Hen egg</td>
<td>11</td>
<td>11</td>
<td>100 %</td>
<td>20</td>
<td>18</td>
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<tr>
<td>ft73 Meat mix</td>
<td>8</td>
<td>7</td>
<td>87.5 %</td>
<td>31</td>
<td>31</td>
<td>100 %</td>
</tr>
<tr>
<td>f24 Shrimps</td>
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<td>9</td>
<td>90 %</td>
<td>26</td>
<td>25</td>
<td>96.2 %</td>
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<tr>
<td>f17 Hazelnut</td>
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<td>30</td>
<td>90.9 %</td>
<td>34</td>
<td>34</td>
<td>100 %</td>
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<tr>
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<td>19</td>
<td>86.4 %</td>
<td>24</td>
<td>24</td>
<td>100 %</td>
</tr>
<tr>
<td>f14 Soy bean</td>
<td>14</td>
<td>13</td>
<td>92.8 %</td>
<td>23</td>
<td>23</td>
<td>100 %</td>
</tr>
<tr>
<td>f5 Rye flour</td>
<td>11</td>
<td>11</td>
<td>100 %</td>
<td>18</td>
<td>18</td>
<td>100 %</td>
</tr>
<tr>
<td>f24 Wheat flour</td>
<td>18</td>
<td>18</td>
<td>100 %</td>
<td>21</td>
<td>21</td>
<td>100 %</td>
</tr>
<tr>
<td>f31 Carrot</td>
<td>17</td>
<td>16</td>
<td>94.1 %</td>
<td>18</td>
<td>18</td>
<td>100 %</td>
</tr>
<tr>
<td>f85 Celery</td>
<td>21</td>
<td>21</td>
<td>100 %</td>
<td>28</td>
<td>28</td>
<td>100 %</td>
</tr>
<tr>
<td>f199 Milk</td>
<td>15</td>
<td>14</td>
<td>93.3 %</td>
<td>38</td>
<td>36</td>
<td>94.7 %</td>
</tr>
</tbody>
</table>

Results of the study4

Heparin blood, capillary blood and blood serum samples were concurrently drawn from the patients. For the Uni-CAP 100 laboratory test only serum was used (as this system requires serum), while capillary blood, heparin blood or serum were used with the fast allergy test.

The results of 331 patients were finally included in the evaluation. For the inhalation panel, the correlation of positive results (see legend table 2) was between 93.3 % and 100 % while the correlation of negative results was between 93.6 % and 100 %.

Smaller sample volumes (50 µL) lead to results that differed from laboratory test results. Sample volumes of 200 µL or 400 µL did not differ from the results obtained using a sample volume of 100 µL.1

Discussion
Type 1 allergies are widely spread in Europe, but only few patients are diagnosed early and receive appropriate treatment, because allergy expertise and immediate access to reliable diagnostic tools are limited particularly in primary care in Europe.

For an early-on diagnosis in disease development a fast allergy screening test represents a simple and effective tool for determination of type I sensitisations. The qualitative results render the fast screening test a useful tool to confirm anamnesis with regard to the presence of an allergic condition. The simultaneous testing of 12 allergens lower total cost of the test and speed it up. Positive results should be confirmed by quantitative in vitro testing, skin test or provocation test if indicated, to ensure an adequate therapy. If negative results occur while the symptoms still persist a visit with an allergologist is strongly recommended. 

Are you interested in the complete publication? Or do you have any questions regarding the study or our services? Please do not hesitate to contact us – we will support you directly.

EVERYTHING’S VALID.
EVERYTHING’S POSSIBLE.

DST specialises in diagnostic solutions for allergies, food intolerances and professional diet optimisation. We stand for concentrated competence and experience under one roof: science, R&D, consultation, support, allergen production. Our allergen extract production has one of the largest offers in the market: 600 allergens with valid results – fast and reliable.

DST is certified by TÜV Rheinland.