Are Rapid Over The Counter Allergy Tests Accurate and Safe?

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Food Allergy in SA?

- 34% of the population “think” they have a food allergy
  - 22% will avoid certain foods
  - Only 1-6% objectively tested as allergic

- Allergy prevalence higher in children
  - peaks in first 2 yrs of life then decreases as tolerance develops
  - SA Food Sensitisation & Food Allergy (SAFFA) study
    - Point prevalence 12-36 mo SA children 11.6%
    - Mild to mod AD prevalence 40%
    - 5% prevalence in unselected Xhosa teens
Food Allergy

• Occurs within 2 hrs of ingestion
  – GIT, urticaria, rhinitis, wheezing, anaphylaxis

• Tolerance > 70% by 16 yrs
  – allergy march

• Adult spectrum of allergies different to those in children and usually persistent
  – nut allergies, shell fish, drugs, preservatives
Laboratory Testing for Food Allergy

• Most tests measure if the person has sensitisation to a particular allergen
  – May or may not react clinically to that allergen

• Tests for specific IgE to a particular food
  – Skin prick tests
  – Specific IgE immunassays (RAST)
  – Specificity of these tests are very important
    • Higher in person with clinical symptoms

• Gold standard is a food challenge
  – Risk of severe reactions
# SPT’s vs Specific IgE Tests

**How does the skin-prick test compare with the specific IgE test in allergy testing?**

<table>
<thead>
<tr>
<th>Skin-prick test (<em>in vivo</em> test)</th>
<th>Specific IgE (RAST) (<em>in vitro</em> test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inexpensive</td>
<td>More expensive</td>
</tr>
<tr>
<td>Rapid: results within 15-20 minutes</td>
<td>Safe</td>
</tr>
<tr>
<td>Patient involvement . . educational</td>
<td>No need to withdraw medication</td>
</tr>
<tr>
<td>Sensitive (especially for foods)</td>
<td>Not influenced by skin disease (e.g. eczema)</td>
</tr>
<tr>
<td>Antihistamines withdrawn for 72 hours</td>
<td>Larger range of allergens</td>
</tr>
<tr>
<td>Needs to be performed on ‘normal skin’</td>
<td>Result delayed</td>
</tr>
<tr>
<td>Small risk of anaphylaxis: trained personnel and resuscitation equipment necessary</td>
<td>Lends itself to over testing (knee-jerk ticking of request form)</td>
</tr>
<tr>
<td>Reporting needs to be standardised in mm (positive result = 3mm&gt; negative control)</td>
<td></td>
</tr>
<tr>
<td>Dermatographism: false positives</td>
<td></td>
</tr>
</tbody>
</table>
ALLERGY OR INTOLERANCE?
NOT SURE? TEST NOW

In today’s world there is an increasing need for rapid diagnostic tests.
MILKCHECK
Milk allergy home-test kit that detects high levels of milk allergy antibodies (IgE)
Easy, simple and safe finger prick blood test
Helps to find the cause of symptoms such as abdominal pain, nausea, vomiting and diarrhoea
*Rapid results within 15 minutes
*High accuracy of 97.14%

To Buy Online
CLICK HERE

FERTIQUICK
Easy, simple and safe male fertility home test
The test is suitable for men of proactive age who have doubts about their fertility.
*Rapid results within 7 minutes.
*High accuracy of 95.10%

ALLERGOCHECK
Convenient home-test kit for the detection of raised levels of allergy antibodies (IgE)
Helps to find the cause of symptoms such as sneezing, stuffy or runny nose, irritated watery eyes and asthma.
Easy, simple and safe finger prick blood test
*Rapid results within 15 minutes
*High accuracy of 94.77%

To Buy Online
CLICK HERE

GLUTENCHECK
Gluten Intolerance home-test kit is used as preliminary diagnosis of celiac disease.
Helps to find the cause of symptoms such as diarrhoea, vomiting, stomach pain, bloating blockage and fatigue.
Blood test to detect the presence of IgA tissue transglutaminase (anti-ITG IgA) antibodies.
Easy, simple and safe finger prick blood test
*Rapid results within 10 minutes.
*High accuracy of 98.00%
Objectives

• How do food allergy POC tests work?
• Are the POC allergy tests accurate compared to the gold standard specific IgE?
• What is the comparison of costs?
• Are there any advantages or disadvantages?
Methods

• 10 Eggcheck® and 10 Milkcheck® (Nano Repro) rapid allergy tests from one commercial pharmacy OTC

• Blood specimens randomly selected over one week with high, medium and low specific IgE (KU/L) for egg and milk (Immunocap®, Thermofischer).

• Specimens were stored at the same temperature (2-8 °C) until testing

• All rapid allergy tests were performed by one operator on the same day as per the manufacturer’s instructions in the included package insert.
# Descriptives

<table>
<thead>
<tr>
<th></th>
<th>Egg</th>
<th>Milk</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>10</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7 (70%)</td>
<td>4 (40%)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>Male</td>
<td>3 (30%)</td>
<td>6 (60%)</td>
<td>9 (45%)</td>
</tr>
<tr>
<td><strong>Age group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 yr</td>
<td>1 (10%)</td>
<td>2 (20%)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>1-4 yrs</td>
<td>2 (20%)</td>
<td>4 (40%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>5-19 yrs</td>
<td>3 (30%)</td>
<td>3 (30%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>&gt;20 yrs</td>
<td>4 (40%)</td>
<td>1 (10%)</td>
<td>5 (25%)</td>
</tr>
<tr>
<td><strong>Phadia IgE Level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate +ve</td>
<td>6 (60%)</td>
<td>5 (50%)</td>
<td>11 (55%)</td>
</tr>
<tr>
<td>High +ve</td>
<td>2 (20%)</td>
<td>5 (50%)</td>
<td>7 (35%)</td>
</tr>
<tr>
<td>Very High +ve</td>
<td>2 (20%)</td>
<td>0 (0%)</td>
<td>2 (10%)</td>
</tr>
</tbody>
</table>
Food Allergy Testing

MilkCHECK®
Milk Allergy? Test yourself at home now!
Rapid test for the detection of allergy antibodies to milk

INSTRUCTIONS FOR USE

OBTAINING THE BLOOD DROP

This is simple and causes little discomfort. Only a small drop of blood is required.

Do not use the lancet if its blue tab (marked "New") is missing.

Using gentle pressure, massage the fingers from the sample to be taken (the middle or ring finger is the best) by gently pressing the thumb of your hand up to the tip of the finger several times.

Twist and pull off the blue tab from the lancet to reveal the spring-loaded white contact piece beneath.

Holding the indented side grips of the lancet between the thumb and forefinger of your free hand press the white contact piece firmly against the soft pad of your finger tip until a click is heard.

The needle immediately retracts into the lancet for safe disposal and cannot be reused. Using a dry tissue, wipe away the first sign of blood from the fingertip.

Contact your local distributor/retailer if you have difficulty using the lancet or in obtaining a satisfactory amount of blood. It is important to press the lancet very firmly against the fingertip otherwise the skin will not be punctured.

ADDITIONAL MATERIALS

Test cassette in a sealed pouch and a 0.5 ml syringe with a needle or a reproducibility test cassette.

RETAIN THE TEST CASETTE

ADDITIONAL DEVELOPER SOLUTION

Carefully unscrew the cap from the developer solution bottle and pour all the contents of the bottle into the large well just below the blood well. Then wait exactly 15 minutes. Do not move or pick up the test cassette once you have added the developer solution. If the developer solution bottle is not completely filled with blue liquid, contact your local distributor/retailer.

PULLING THE SLIDER

Only after waiting exactly 15 minutes pull up the test cassette, keeping it horizontal, and pull the blue slider until you feel it click into place. The test working indicator will change from blue to white.

If you have very high levels of IgE antibodies you may see a positive result within 15 minutes. However, it is necessary to wait 30 minutes after pulling the blue slider to confirm a completely negative result.

Validation:

If you are satisfied with the results of your test, you can contact your local distributor/retailer for further information.

For self-testing:

Control line: A pink or red line opposite the symbol indicates that the test has worked correctly. No line should be visible opposite the symbol.

Positive: Read the result after waiting exactly 15 minutes. A pink or red line opposite the symbol indicates that the test has worked correctly. You should be able to see a positive result within 15 minutes. However, it is necessary to wait 30 minutes after pulling the blue slider to confirm a completely negative result.

Negative: To confirm a completely negative result, you should wait 30 minutes after pulling the blue slider.

Invalid:

If there is no line opposite the symbol opposite the symbol, you should be able to see a positive result.
Results
Results
Positive Agreement at Different IgE Levels
- Egg & Milk Combined

<table>
<thead>
<tr>
<th>IgE Level</th>
<th>15 MINS</th>
<th>30 MINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>71.4%</td>
<td>100.0%</td>
</tr>
<tr>
<td>High</td>
<td>63.6%</td>
<td>70.0%</td>
</tr>
<tr>
<td>Moderate</td>
<td>57.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Total</td>
<td>45.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
Positive Agreement for Different Allergens

<table>
<thead>
<tr>
<th>Allergen</th>
<th>RAPID @ 15 MINS</th>
<th>RAPID @ 30 MINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg</td>
<td>30,0%</td>
<td>70,0%</td>
</tr>
<tr>
<td>Milk</td>
<td>60,0%</td>
<td>70,0%</td>
</tr>
<tr>
<td>Total</td>
<td>45,0%</td>
<td>70,0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RAPID @ 15 MINS

RAPID @ 30 MINS
# Positive Agreement by Gender & Age Group

- Egg & Milk Combined

<table>
<thead>
<tr>
<th>Gender</th>
<th>Positive Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rapid @ 15 mins</td>
</tr>
<tr>
<td>Female</td>
<td>45.5%</td>
</tr>
<tr>
<td>Male</td>
<td>44.4%</td>
</tr>
<tr>
<td>Total</td>
<td>45.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age group</th>
<th>Positive Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rapid @ 15 mins</td>
</tr>
<tr>
<td>&lt;1 yr</td>
<td>0.0%</td>
</tr>
<tr>
<td>1-4 yrs</td>
<td>83.3%</td>
</tr>
<tr>
<td>5-19 yrs</td>
<td>50.0%</td>
</tr>
<tr>
<td>&gt;20 yrs</td>
<td>20.0%</td>
</tr>
<tr>
<td>Total</td>
<td>45.0%</td>
</tr>
</tbody>
</table>
Costs

• Specific IgE tests Immunocap/Thermofischer
  – Single allergen = R 310
  – Pooled test (FX5) = R 620

• POC
  – EggCheck® = R 706
  – MilkCheck® = R 751
Summary Results

• Intensive instructions to operator, most likely self/parent or dietician or GP
  – Difficult to read results

• Poor agreement at 15 min, better at 30 mins
  – Worse at moderate/high levels IgE
  – Milk is better than egg
  – Uncertain in < 1 yr olds

• POC not cheaper than formal specific IgE
Regulation of Medical Devices

• Gaps/inconsistencies in health care regulation left medical diagnostic devices in limbo

• Capacity constraints previously but now new regulations will allow in vitro diagnostic devices (IVDS)

• Minister of Health in the Government Gazette on 9 December 2016
  – in force after years of uncertainty
POC testing in Pathology

• The Good
  – External and internal quality checks
  – Calibration, SOP’s
  – Maintenance, Record keeping
  – Moderation of quality

• The Bad
  – Correlation with the truth
    • Sensitivity
    • Specificity
    • Clinical significance

• The Ugly
  – High differential between results
  – Can the patient be seriously misled
  – May be unaware of real allergy/cholesterol level/glucose