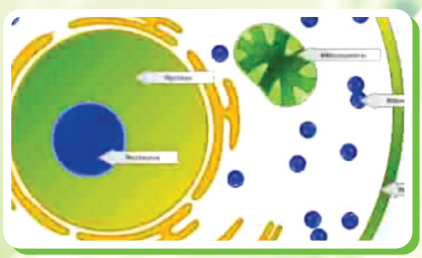

PAKCURE Pharma

The only Pharmaceutical Company in Private Sector to manufacture Anti Allergy Vaccine, Approved and Licensed by Drug Regulatory Authority of Pakistan (DRAP) Ministry of Health Sciences, Regulations and Coordination Government of Pakistan, Islamabad

ALLERGY DIAGNOSIS AND TREATMENT

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GUIDELINES FOR PERFORMANCE OF SKIN PRICK TEST FOR ALLERGY

1. PERFORMANCE OF SKIN PRICK TESTS:

- Use standardized extracts only.
- Include a negative control solution.
- Perform tests on normal skin.
- Evaluate the patient for dermographism.
- Determine and record medications taken by the patient and time of last dose.
- Record the reactions after 15-20 min.
- Measure the longest wheal diameter.

2. COMMON ERRORS IN SKIN PRICK TESTS

- Tests are placed too close together (less than 2 cm), and overlapping reactions cannot be separated visually.
- Induction of bleeding, leading possibly to false-positive results.
- Insufficient penetration of skin by puncture instrument, leading to false-negative results. This occurs more frequently with plastic devices.
- Spreading of allergen solutions during the test or when the solution is wiped away.

3. WHAT IS THE RECOMMENDED SKIN PRICK TEST TECHNIQUE?

The modified SPT introduced by Pepys is the current reference method, which involves passing a fine metal needle through a drop of allergen extract after wiping the skin with alcohol with little pressure. Puncture tests with various devices can decrease SPT variability. A different needle or puncture test should be used for each test. For allergens, the peak of the skin wheal is reached around 10–20 min after the test, and a reading of the largest diameter of the skin wheals after 15 min is recommended.

4. WHICH TREATMENTS SUPPRESS SKIN TESTS?

Drugs can suppress skin tests; therefore it is always necessary to ask patients about the medications they have taken in the preceding days. This is particularly true for oral H_1-antihistamines, but also for other drugs which are not necessarily used for the treatment of allergic diseases such as anxiolytics, but not antidepressants. Topical skin corticosteroids may alter skin reactivity.

5. WHICH DISEASES AFFECT SKIN TESTS?

Prick testing can only be performed on healthy skin. Patients with widespread urticaria or eczema (e.g. atopic dermatitis) cannot be tested in areas of affected skin. Neurological disorders as well as infectious disease (e.g. leprosy) can lead to false-negative SPTs.

6. AFTER THE TEST:

Monitor for signs of anaphylaxis. If the patient complains of runny nose, facial itching or Short of Breath, those may be early signs of anaphylaxis, and treatment with Cortisone should be considered.
If local itching at the site of the allergen pricks is very troublesome to the patient, a steroid cream or spray can be prescribed. A dose of oral antihistamine can also be given.Topical skin corticosteroids may alter skin reactivity.

Pharmacological Classification: Allergenic Proteins
Pharmacological Action of the Extract: Immuno-Stimulant.

7. INDICATIONS:

Allergic rhinitis, allergic conjunctivitis, and allergic asthma and hay fever due to inhalant allergens; provided the allergy to the allergen in question has been proven by skin prick test.

8. CONTRA-INDICATIONS:

- **Do not give** specific immunotherapy (SIT) to patients with serious immunological diseases.
- **Do not give** specific immunotherapy (SIT) to patients on treatment with beta -adrenergic blockers. They may be more reactive to allergens given for treatment and unresponsive to the usual doses of adrenaline used to treat allergic reactions.
- **Do not give** specific immunotherapy (SIT) to patients with diseases in which adrenaline is contra-indicated such as coronary artery disease, hypertension and hyperthyroidism.
- **Do not give** specific immunotherapy (SIT) during pregnancy or lactation. If a patient becomes pregnant during treatment, then stop injections. Immunotherapy should be avoided in patients with a bleeding tendency.
- It is uncertain whether specific immunotherapy (SIT) can exacerbate autoimmune diseases, therefore allergen injections should be given cautiously to patients with autoimmune diseases and only if the risk from allergen exposure is greater than the risk of exacerbating the autoimmune disease.

9. SPECIAL PRECAUTIONS:

- Injections must be given subcutaneous under the supervision of registered medical practitioner at a clinic or hospital with an emergency set up.
- Emergency equipment and personnel trained in its use should always be available.
- Patients should be kept under medical observation for at least 30 minutes after testing and treatment.
- Cortisone injection should be at hand and may be given if considered advisable to control anaphylactic shock.
- Adrenaline or Dexamethazone injection should always be available in the emergency set up and should be given if any untoward reaction occurs.

11. WARNINGS:

- **Do not** rub the site of injection.
- **Do not** inject into a blood vessel or intramuscularly.
- **Stop** Specific Immunotherapy (SIT) in patients with severe reaction.

12. SIDE EFFECTS:

Local and/or systemic reactions may occur. Injections of Allergex-Px1 may be associated with some itching and redness at the injection site. Prolonged pain, or pain radiating up the arm is usually the result of intramuscular injection. Local reaction includes swelling at the injection site.

Mild systemic reactions: itching of the eyes, nose, throat or skin, or localized urticaria.

Severe systemic reactions: Generalized urticaria, asthma, anaphylactic shock. Should an anaphylactic reaction occur immunotherapy should be discontinued. The patient should be treated with adrenaline/corticosteroids and antihistamines.

13. DOSAGE AND ADMINISTRATION:

As a result of determination of type of allergy through tests, the appropriate Vaccine, from the products listed in Guidelines, is to be administered as per the following schedule and dosages: **[Interval between doses 01 week (7 days)]**

DOSAGE SCHEDULE:		Date:
1st week	0.10 ml	
2nd week	0.15 ml	
3rd week	0.20 ml	
4th week	0.25 ml	
5th week	0.30 ml	
6th week	0.35 ml	
7th week	0.40 ml	
8th week	0.45 ml	
9th week	0.50 ml	
10th week	0.55 ml	
11th week	0.60 ml	
12th week	0.70 ml	