



## Guide to Skin Testing For Sensitivity to Diphtheria Antitoxin

### Rationale for Guide:

You have received,

- 1.) Diphtheria Antitoxin with package. These vials contain the amount needed for all skin tests and therapeutic administration.
- 2.) 1 vial of Histatrol (histamine phosphate 2.75 mg/mL for percutaneous testing) with package insert.

Diphtheria antitoxin is a horse serum product. Because a small (< 1%) proportion of patients are allergic to horse products, it is recommended that patients be tested for this allergy by skin test before the therapeutic horse serum is administered. This additional 5-page, step-by step illustrated instructional insert is intended to help guide proper execution of the skin testing procedure and interpretation of results. **These instructions supercede all instructions in the Diphtheria Antitoxin package insert and the Histatrol<sup>®</sup> package insert.** This guide includes an overview of the skin testing procedure (p.1-2), photographs illustrating positive and negative skin tests (p. 3), detailed skin testing instructions (p. 4), and a flow chart of the procedure (p. 5).

### Definition of Terms:

Negative Control: Control illustrating non-reaction

Positive Control: Control illustrating a positive (acute allergic) reaction

Diphtheria Antitoxin: Equine origin antibody preparation for treatment of diphtheria

Histatrol (histamine phosphate): a reagent that produces acute allergic reaction on skin testing; serves as a positive control illustrating what an allergic reaction would look like when testing for sensitivity to diphtheria antitoxin.

Normal Saline: Reagent that produces no allergic reaction on skin testing; serves as a negative control illustrating what a skin test with no reaction would look like when testing for sensitivity to diphtheria antitoxin. (Normal saline is not included in package.)

### Overview of Skin Testing Procedures:

Epinephrine Hydrochloride Solution (1:1000) and other appropriate agents must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs. In addition, the patient should be placed in a comfortable position during the tests and the test areas should be cleaned with alcohol before testing.

You will perform skin tests using the left arm for the controls (saline and histamine phosphate) and the right arm for the test (Diphtheria Antitoxin):

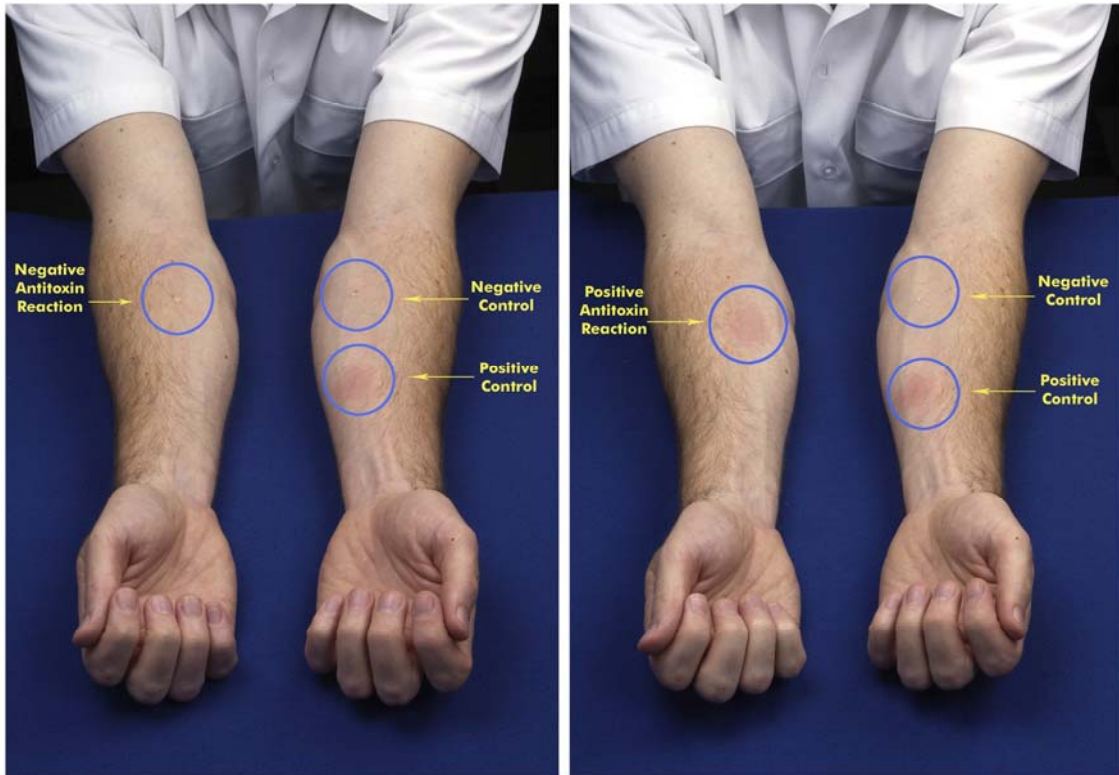
1. Normal saline as the negative control (left arm)
2. Histamine phosphate 2.75mg/mL as the positive control (left arm)
3. Diphtheria Antitoxin at 1:100 dilution (right arm)  
(prepared by diluting 0.1 mL antitoxin serum in 10mL normal saline)

Tests are performed by making a small scratch in the skin and placing a small drop of the solution to be tested on the site of the scratch.

**Interpretation of Results:**

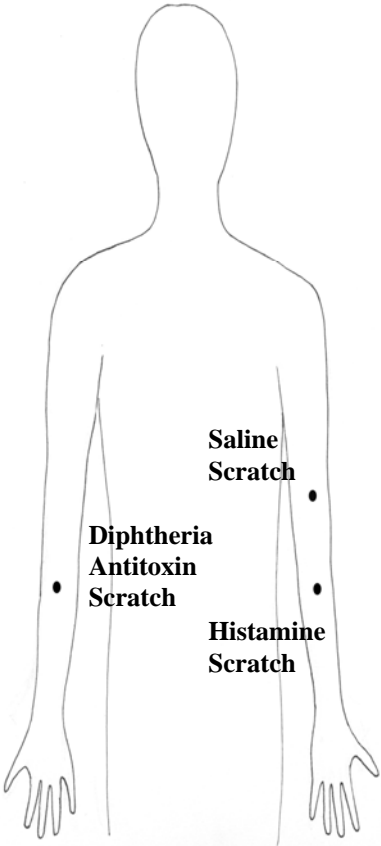
Photographs are provided in this guide (p. 3) to assist with interpretation of the results.

- If the test arm (right arm) reaction looks like the negative control (normal saline), then the patient has no allergic reaction to the Diphtheria Antitoxin and may be treated.
- If the test arm (right arm) reaction looks like the positive control (Histamine Phosphate), then the patient is allergic and must undergo desensitization before treatment. (See package insert for desensitization protocol.)



**Negative Skin Test**

**Positive Skin Test**

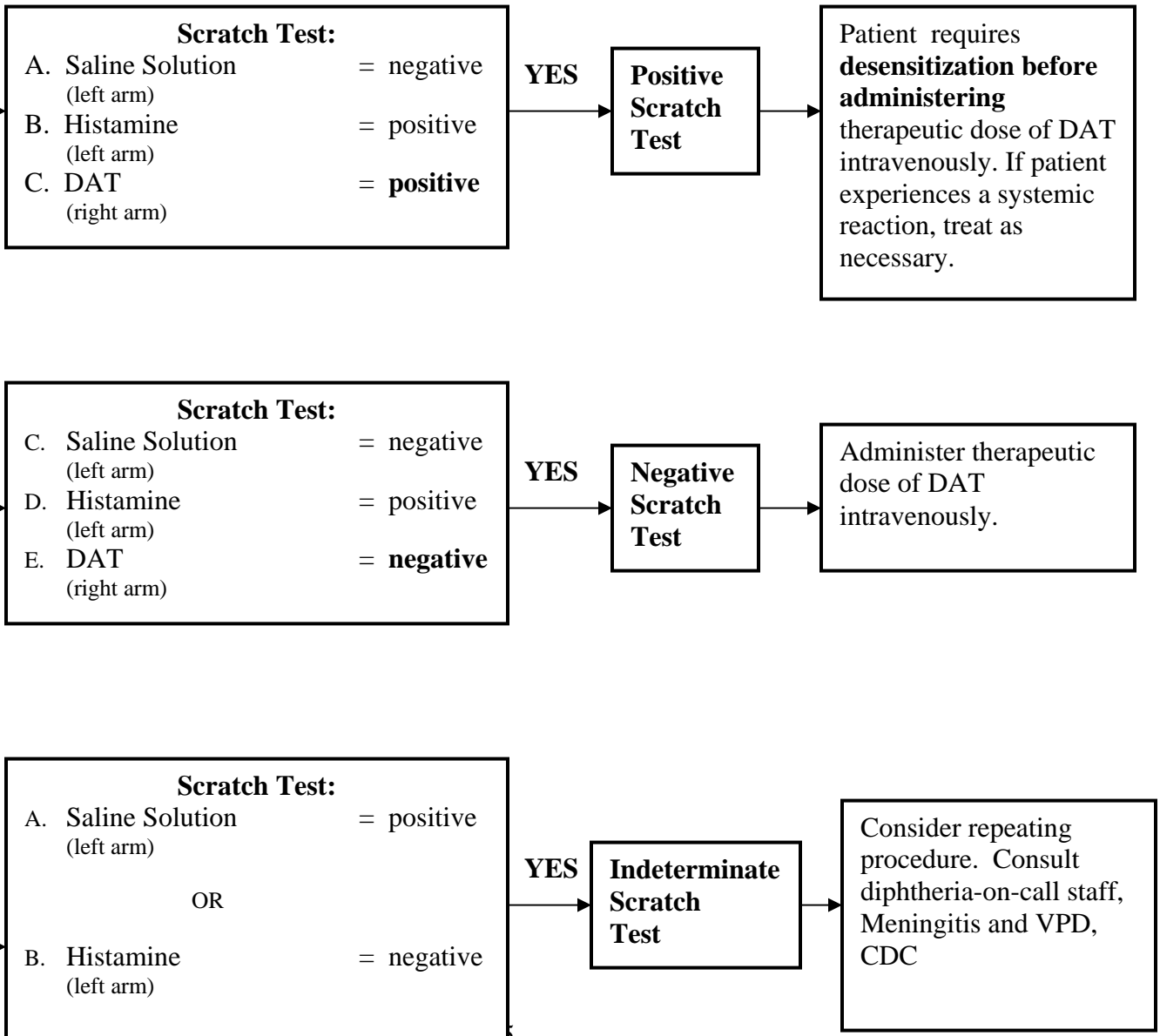
STEP	PROCEDURE	ILLUSTRATION
	<b>SCRATCH TEST:</b>	
A.	<p><b><u>Negative Skin Test Control—Saline Solution (left arm)</u></b></p> <ol style="list-style-type: none"> <li>Carefully scratch the skin approximately 2mm-4mm in length with a sterile needle (27 gauge) without drawing blood.</li> <li>Place a small drop of normal saline on the site of the scratch.</li> <li>Read the test at 15 minutes; no reaction should occur</li> </ol>	
B.	<p><b><u>Positive Skin Test Control- Histamine (Histatrol) (left arm)</u></b></p> <ol style="list-style-type: none"> <li>Choose a site on the arm at least 5 cm from any other test site. Carefully scratch the skin approximately 2mm-4mm with a sterile needle (27 gauge) without drawing blood.</li> <li>Using dropper from Histatrol vial (Histamine Phosphate 2.75 mg/mL for <u>percutaneous</u> testing), place a small drop of Histatrol on the site of the scratch.</li> <li>Read the test at 15 minutes; <u>if a large wheal reaction occurs before that time, the test site should be wiped free of histamine</u></li> </ol>	
C.	<p><b><u>Diphtheria Antitoxin Types A &amp; B Testing (right arm)</u></b></p> <ol style="list-style-type: none"> <li>Dilute 0.1 mL diphtheria antitoxin in 10 mL normal saline to make a <u>1:100</u> dilution of Diphtheria antitoxin serum.</li> <li>Choose a site on the arm at least 5 cm from any other test site. Carefully scratch the skin approximately 2mm-4mm in length with a sterile needle (27 gauge) without drawing blood.</li> <li>Place a small drop of a <u>1:100</u> dilution of the Diphtheria antitoxin serum in normal saline on the site of the scratch.</li> <li>Read the test at 15 minutes; no reaction should occur. A reaction indicates the patient is allergic and requires desensitization.</li> </ol>	
<p><b>EXPLANATION OF RESULTS</b></p> <p>If the patient has a <b>negative</b> skin test (Diphtheria Antitoxin test site on right arm looks like the Saline Solution test site on left arm), Diphtheria antitoxin can be administered to the patient.</p> <p>If the patient has a <b>positive</b> skin test (Diphtheria Antitoxin test site on right arm looks like the Histamine (HISTATROL) test site on left arm), <b>patient requires desensitization before administering dose of antitoxin</b>. If patient experiences a systemic reaction (e.g., hypotension, respiratory distress, generalized rash) administer epinephrine as necessary. See package insert for desensitization protocol.</p>		

## Flow Chart Insert for Diphtheria Antitoxin Administration

Perform scratch test as described in text:

- |                    |             |
|--------------------|-------------|
| A. Saline Solution | - left arm  |
| B. Histamine       | - left arm  |
| C. DAT             | - right arm |

### Result



This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/vpd-vac/diphtheria/dat/downloads/skintest-guide.pdf>