

DESCRIPTION

GREER® Pick® is a sterile, single-use (single-site) disposable skin testing system designed to aid in the determination of specific allergen sensitivity in suspected allergic individuals. The system is designed to be used by allergy practitioners who are trained in the administration and interpretation of allergy skin tests, and are trained to provide emergency treatment in the event of a life-threatening reaction. Before using the system, allergy practitioners should be completely familiar with the instructions in this Directions for Use and any applicable prescribing information for allergenic extracts and control solutions.

GREER Pick is a skin testing system used to administer allergenic extracts or control solutions using the prick or puncture skin testing technique. The system is fully compliant with Occupational Safety and Health Administration (OSHA) bloodborne pathogen standards¹ and includes the following components:

1. GREER Pick is supplied in sterile pouches of 42 picks (Figure 1) and is designed to apply allergenic extracts or control solutions to the skin and serves as a cap to the GREER® Pick® Well™ when not in use. Each GREER Pick is a self-loading, six-tine, single-site skin test applicator with a molded plastic grip (Figure 1).

Figure 1



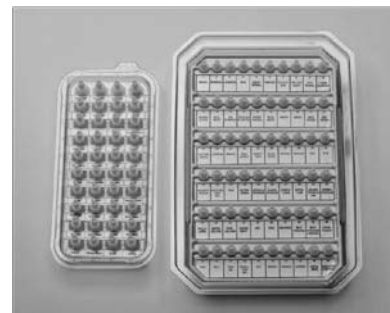
2. The GREER Pick Well (Figure 2) is supplied in sterile pouches of 24 wells, which are intended to contain the allergenic extracts or control solutions for skin testing. The GREER Pick Well is transparent to permit viewing of the level of the allergenic extract or control solution.

Figure 2



3. The GREER® Pick® Tray™ (Figure 3) is available in two sizes to hold GREER Pick Wells for 40 or 60 allergenic extracts and control solutions for testing. The trays are transparent for inspection of extract or control solution levels.

Figure 3



The 40-well GREER Pick Tray comes with a lid and is designed to permit stacking for testing and storage flexibility (Figure 4). A separate lid is available for the 60-well GREER Pick Tray, which also permits stacking of the tray. Each GREER Pick Tray provides ample space for extract labeling.

Figure 4



PREPARING THE GREER PICK SYSTEM FOR USE

Prior to setting up the GREER Pick skin testing system, determine which allergenic extracts and control solutions will be used for testing.

Each GREER Pick Tray is supplied with customizable self-adhesive labels to be used to identify the allergenic extracts and control solutions in the tray (Figure 5). Make a record the lot numbers and expiration dates of the allergenic extracts and control solutions contained in the wells.

Figure 5



Once the trays are labeled, open the GREER Pick Well pouch and firmly press each well into the position of the tray that will be filled with the allergenic extract or control solution for testing. (Figure 6).

Figure 6



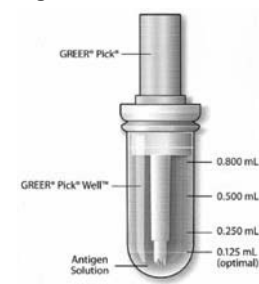
Fill each GREER Pick Well with approximately 0.125 mL (Figure 7) of the appropriate allergenic extract or control solution taking care not to touch nearby wells or the inside wall of the well. Ensure that the allergenic extracts and control solutions in the wells correspond with the labels on the tray. It is recommended that glycerinated extracts containing a phenol preservative be used to inhibit microbial growth.

Figure 7



When the GREER Pick Well is filled with 0.125 mL of glycerinated allergenic extract, approximately 1,800 tests can be performed from one 5 mL vial (Figure 8).²

Figure 8



Once each well is filled with the appropriate allergenic extract or control solution, remove a GREER Pick from the sterile pouch. Handle the GREER Pick without touching the testing tines to avoid contamination or damage. Immediately insert one GREER Pick into each labeled well containing allergenic extract or control solution (Figure 9). This serves to minimize the potential for contamination, evaporation, and the likelihood of spills. Once the GREER Pick Tray is labeled, the wells filled with allergenic extracts or control solutions and GREER Picks are inserted, the skin test system is ready for use. When not in use, store the skin

test system in the refrigerator at 2 to 8°C to maintain potency of the allergenic extracts and control solutions.

Figure 9



The GREER Pick is a single-use device and should be discarded after one use. The wells are disposable and can be replaced and filled with the appropriate fresh allergenic extracts and control solutions regularly. This practice will help to ensure allergen potency. Each GREER Pick Well can be replaced individually by simply lifting the well upward and discarding. Empty wells can be identified by viewing through the transparent GREER Pick Tray.

SKIN TESTING PROCEDURE

The GREER Pick is indicated for use in prick or puncture testing. Skin tests can be performed on the upper back or volar surface of the forearm.³ It is recommended that approximately 2 to 2.5 cm of space be left between each applied allergenic extract or control solution, and that tests should not be placed within 5 cm of the wrists or within 3 cm from the antecubital fossae.³ Skin tests should not be performed on areas with active dermatitis or severe dermatographism.³ Prior to testing, clean the skin test area with alcohol and allow to dry. Mark the skin using a marking pen for placement of the allergen (Figures 10A and 10B).

Figure 10A

Figure 10B



Prick Testing Method

Remove a GREER Pick from the prepared tray by lifting it vertically, being careful not to touch the tip against the side of the well. Inspect the tip of the device to ensure that a small droplet of allergenic extract or control solution is present (Figure 11).

Figure 11



Hold the GREER Pick at approximately a 45-degree angle to the skin at the test site. Bring the tip of the GREER Pick in contact with the superficial skin maintaining a 45 degree angle (Figure 12) and press gently. Withdraw the GREER Pick with a slight lifting of the skin. This should not induce bleeding. Discard the used GREER Pick in a biohazard container.

Figure 12



Figure 13



Puncture Testing Method

Remove a GREER® Pick® from the GREER® Pick® Well™ by lifting it vertically, being careful not to touch the tip against the side of the well. Inspect the tip of the device to ensure that a small droplet of allergenic extract or control solution is present (Figure 11).

Hold the GREER Pick perpendicular to the test site. Press the tines firmly against the superficial skin. Withdraw the GREER Pick from the skin. This should not induce bleeding. Discard the used GREER Pick in a biohazard container.

A small imprint of the device should remain at the test site, indicating that a correct amount of pressure was applied (Figure 13). Repeat these steps with remaining extracts and control solutions until testing is complete. Following the instructions should produce uniform skin tests without inducing bleeding.

Storage and Disposal

Once skin testing is completed, place a new GREER Pick into the GREER Pick Well for each allergenic extract or control solution used. Store the covered GREER® Pick® Tray™ at 2 to 8°C until the next use.

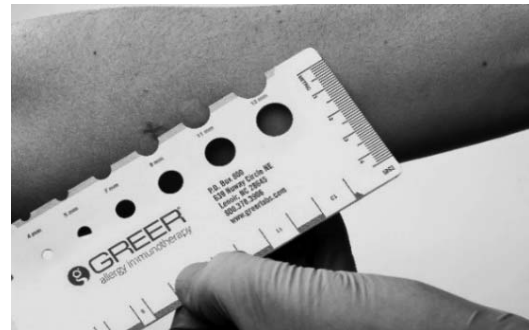
GREER Pick is a disposable, single-use device and should be discarded after one use in a biohazard container in accordance with OSHA standards to prevent the transfer of bloodborne diseases. Do not reuse GREER Picks.

GREER Pick Wells should be replaced regularly. If a used GREER Pick is mistakenly placed back into a well, discard the entire well and its contents in a biohazard container and prepare a new well for the next use.

Reading Skin Test Reactions

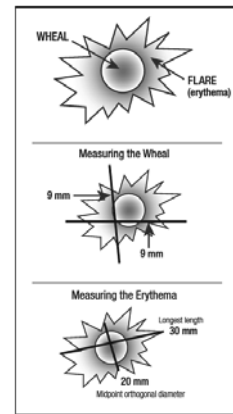
Allergic individuals may differ widely in their response to allergenic extracts or control solutions. Evaluate the results of allergy skin tests in relation to both the positive and negative control tests (Figure 14). The patient history, current allergen exposure, and any recent use of interfering drugs, such as antihistamines or beta blockers, should be considered when evaluating the patient's response.

Figure 14



Test sites should be read approximately 15 to 20 minutes after administration of the test allergenic extract or control solution.³ The wheal (edema) and flare (erythema) reactions should be measured and recorded (Figure 15).

Figure 15



A skin test wheal response less than 3 mm larger than the size of the negative control test done at the same time is considered a negative reaction. A skin test wheal response at least 3 mm larger than the negative control done at the same time is considered a positive reaction.³ Individual patient reactivity can vary with time, allergen potency, drug therapy, and/or immunotherapy, as well as testing technique. The most reliable method of recording a skin test reaction is to measure the largest diameter of both wheal and erythema, as well as the diameter of the reaction perpendicular to the largest reaction diameter. The results are used to calculate the approximate area for both wheal and erythema. While some correlation exists between the size of the skin test reaction and the degree of sensitivity, other factors should be considered in the diagnosis of allergy to specific allergens.

Various methods are in use for grading skin test reactions to allergens. Grade the response as defined in the applicable allergenic extract prescribing information.

HOW SUPPLIED

- Item # GP-1C GREER Pick Single-Site Skin Testing Devices (case), 2,100 GREER Pick devices (50 sterile pouches of 42)
- Item # GW-2 GREER Pick Well
1 sterile pouch containing 24 wells
- Item #GY-40 40-Well GREER Pick Tray with lid
- Item #GY-5 60-Well GREER Pick Tray
- Item #GY-LD 60-Well GREER Pick Tray Lid
- Item# GP-10 40-Well GREER Pick Evaluation Package
1 40-well GREER Pick Tray with lid
1 set of 40 labels
420 GREER Pick devices (10 sterile pouches of 42)
48 GREER Pick Wells (2 sterile pouches of 24)
1 GREER Pick skin testing instructional DVD
1 skin reaction guide
1 GREER Pick sample skin testing sheet
1 GREER Pick practical guide

- Item# GP-11 60-Well GREER Pick Evaluation Package
1 60-well GREER Pick Tray
630 GREER Pick devices (15 sterile pouches of 42)
72 GREER Pick Wells (3 sterile pouches of 24)
1 GREER Pick skin testing instructional DVD
1 Skin Reaction Guide
1 GREER Pick sample skin testing sheet
1 GREER Pick practical guide

REFERENCES

1. U.S. Department of Labor Occupational Safety and Health Administration. Potential for occupational exposure to bloodborne pathogens from cleaning needles used in allergy testing procedures. Available at: https://www.osha.gov/dts/hib/hib_data/hib19950921.html Published September 21, 1995. Accessed February 03, 2016.
2. Data on File, Evaluation of Allergenic Extract Consumption for the GREER Pick and GREER Pick Well Skin Test Device Components. GREER Laboratories, Inc. June 10, 2004.
3. Bernstein IL, Li JT, Bernstein DI, et al. Allergy diagnostic testing: an updated practice parameter. *Ann Allergy Asthma Immunol.* March 2008;100 (Suppl 3):S1-S148.

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Single-Site Allergy Skin Test System Directions for Use

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