



**RE: Concerns About T.R.U.E. TEST® (Allergen Patch Test) application in children**

Dear Health Care Professional:

Thank you for your recent request for information regarding the T.R.U.E. Test® Allergen Patch Test. We hope the following provides you with the information you require.

The Product Information (Product Package Insert) for T.R.U.E. Test states that the safety and effectiveness for pediatric use has not been established. Therefore, the application of T.R.U.E. TEST in children is currently considered an off-label use in the United States even when supported by current medical care guidelines.

However, physicians in the United States do patch test children using T.R.U.E. TEST. Postmarketing surveys have shown that of 3,200 reports filed in a two-year period, 19 were for patients under the age of 13, and 74 were for patients between the ages of 13 and 19. In addition, published clinical studies of patch testing in pediatric patients report the use of T.R.U.E. TEST in patients ranging from 6 months to 14 years of age.

Overall, positive reactions to T.R.U.E. TEST allergens have occurred at rates similar to previously published pediatric studies that used conventional patch tests and Finn Chambers®. These pediatric studies with T.R.U.E. TEST have also reported doubtful or transient positive reactions, irritant reactions to the tape, and localized discomfort during patch testing.

- Johnke et al. (2004) reported on the use of T.R.U.E. TEST in infants up to 18 months of age. Of the 543 infants tested, 8.6% had positive nickel reactions. However, of these only one was considered clinically relevant. These investigators also cautioned that the adult level of nickel allergen in T.R.U.E. TEST (0.2 mg) might elicit more transient false positive reactions in infants.
- Mortz et al. (2002) used T.R.U.E. TEST panels on 1,146 schoolchildren in the 8th grade. Tests adhered well most patients, and only 2% experienced tape reactions. In this pediatric population, 15% tested positive to one or more T.R.U.E. TEST

allergens. However, many of these schoolchildren had a history of atopy or hand dermatitis.

- Bruckner et al. (2000) patch tested 85 children from 6 months to 5 years of age using T.R.U.E. TEST. They reported the overall prevalence of contact allergies in these children at 24.5%. Irritant reactions to the tape were reported in 7.4% of the tested children, and 6% removed the patches early due to discomfort.

- Romaguera and Vilaplana (1998) patch tested 141 children with T.R.U.E. TEST. Of these, 45% were determined to have allergic contact dermatitis, most commonly to nickel, cobalt, mercurials, fragrance and rubber-based chemicals.

Post Marketing Clinical Trials of T.R.U.E. TEST with children and adolescents ages 6-18 are in the developmental stages and were completed in 2010.

The information in this communication is only educational and is not intended to advise medical professionals to use T.R.U.E. TEST in a manner inconsistent with product labeling.

Please let us know if we can provide any further information about patch testing with T.R.U.E. TEST that may be helpful to you or your patients.

Sincerely,



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References:

- (1) Product Information for T.R.U.E. TEST. Allerderm Laboratories, Inc. (T.R.U.E. TEST package insert)
- (2) T.R.U.E. TEST Study Group. Comparative multi-center studies with T.R.U.E. TEST and Finn Chambers in eight Swedish hospitals. *J Am Acad Dermatol* 1989; 21:846-849.
- (3) Ruhnek-Forsbeck M, Fischer T, Meding B, *et al.* Comparative multi-center study with T.R.U.E. TEST and Finn Chamber patch test methods in eight Swedish hospitals. *ActaDerm Venereol (Stockh)* 1988; 68:123-128.
- (4) Wilkinson JD, Bruynzeel DP, Ducombs G, *et al.* European multi-center study of T.R.U.E. TEST, Panel 2. *Contact Dermatitis* 1990; 22:18-225.
- (5) Rietschel RL, Fowler JF. *Fisher's contact dermatitis*, 5th ed., Lippincott Williams and Williams, Philadelphia, 2001.