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## Proposed Tuberculin PPD-S2 as Reference Standard

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Since 1951, the tuberculin PPD-S1 has been used to standardize commercial PPD reagents and perform special tuberculin surveys. PPD-S1 is now in short supply, and a new standard (PPD-S2) has been manufactured. To determine if PPD-S2 is equivalent and can replace PPD-S1, Villarino and coinvestigators from the CDC; the FDA; Seattle-King County Health Department, University of California, San Diego; University of Arizona, Tucson; Emory University, Atlanta, Georgia; Marion County Health Department, Indianapolis, Indiana; and

Denver Public Health Department, Denver, Colorado, conducted a doubleblind clinical trial. Between May 14 and October 28, 1997, 69 subjects with a history of culture-proven TB (TB patients) and 1,189 subjects with a very low risk for TB infection were enrolled, received four skin tests (with PPD-S1, PPD-S2, and one each of the commercially available PPDs), and had reactions measured by two trained observers. Among the TB patients, there was statistically indistinguishable immunogenicity (mean reaction size±standard deviation): 15.6±6.6 mm for PPD-S1 and 14.8±5.6 mm for PPD-S2. Among low-risk subjects, the tests had equally high specificities (PPD-S1, 98.7%; PPD-S2, 98.5%), using a 10-mm cutoff. The number of discordant (negative vs positive) interpretations for PPD-S2, assuming that low-risk subjects who had a  $\geq$ 10 mm reaction to PPD-S1 were truly infected, was low (0.5%) and indistinguishable from the rate of discordant interpretations of the same test when read by two different observers (0.8%).

The study results indicate that PPD-S2 is qualified to be used as the new US reference standard for PPD tuberculin.

FROM: Villarino ME, Brennan MJ, Nolan CM, Catanzaro A, Lundergan LL, Bock NN, et al. Comparison testing of current (PPD-S1) and proposed (PPD-S2) reference tuberculin standards. *Am J Respir Crit Care Med* 2000;161 (4 part 1):1167-1171.