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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 double-blind 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 \pm 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 ≥ 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.

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