preferable to use Heparin as the anticoagulant. Our results have demonstrated no adverse effects even when using much higher than recommended concentrations of Heparin (10). The observations by Porter et al. (17) do not directly relate to our particular kit system.

REFERENCES


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REPLY: Wilson and Hung point out that the package insert of the recently approved in vitro red blood cell labeling kit, UltraTag® RBC, does not detail the amount of heparin or ACD to be used as anticoagulants when collecting the blood sample for labeling.

The language in the package insert was both reviewed and approved by the FDA and reflects the variety of different forms of ACD and heparin that are commercially available. The USP XXII describes two forms of ACD, formula A and formula B, and there are at least two modified formulas of ACD commercially available. Heparin is also supplied by a number of manufacturers, both in different formulations, and over a wide range of concentrations. It would be impractical and confusing to list all of the available forms of these anticoagulants, with associated recommendations for the amount of each to be used to collect a blood sample, and thus the package insert does not do so.

In Wilson and Hung’s experiments, both ACD and Heparin were diluted to 1 ml with 0.9% NaCl. The initial (0 min) labeling efficiencies (LE) with both heparin and ACD are slightly lower than expected, but at the 30-min time point they have improved to typically expected values which approach 100%. The slightly lower than expected 0 min LEs, may have resulted from the dilution of the anticoagulant with 0.9% NaCl. Expected LEs were obtained for both anticoagulants with eluates obtained from generators which had been eluted 24 hours previously (24-hr ingrowth eluates). When 72-hr ingrowth eluates were used, depressed LEs were obtained with ACD, while expected LEs were obtained with heparin.

This latter observation is of particular interest since it suggests that ACD does not perform equally to heparin in all situations. To assess this possibility, Mallinckrodt Medical, Inc. has taken a number of actions. First, all clinical studies have been thoroughly reviewed. Sixty patient studies were performed using ACD, formula A, or Mallinckrodt’s Modified ACD anticoagulants at ratios of 0.15 ml per ml of blood. The average LE was above 97%, but information on the ingrowth time of the generator eluates had not been recorded. Next, an experiment was carried out wherein blood samples collected from volunteers were labeled using five varieties of commercially available ACD, at ratios of 0.17-0.18 ml per ml of blood. LE was nearly quantitative in all cases. Even holding the samples for several hours (between collection and labeling) did not produce any negative effect on LE. In another experiment, the blood samples were collected using an excess of ACD and were labeled with #Tc obtained from a 72-hr ingrowth generator. LE was excellent at the recommended levels of ACD (1), but LE was observed to decrease with increasing excessive amounts of ACD. We have also confirmed the results of Wilson and Hung reported for 12-hr old technetium eluates obtained from a 72-hr ingrowth generator. Using heparin, LE was consistently greater than 97%, while LE with ACD was suboptimal (57%-72%). Mallinckrodt Medical, Inc. currently has in progress a number of additional evaluations of the effect of anticoagulant on UltraTag® RBC labeling. Further action, as warranted, will be based on these more detailed examinations. Please address any questions on the use of this product to Mallinckrodt’s Technical Service Department at 1-800-325-3688.

REFERENCES


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