

LETTER TO THE EDITOR

ALL FILTER UNITS ARE NOT ALIKE: REPORT OF A PROBLEM ENCOUNTERED DURING PREPARATION OF INDIUM-111 CAPROMAB PENDETIDE

To the Editor: Preparation of recently marketed radiolabeled antibody products involves filtration of the final product during withdrawal from the reaction vial into the administration syringe. This filtration serves to: (a) assure the sterility of the final product; and (b) remove any protein aggregates that may have formed in the reaction vial (1). Filtration problems previously reported include excessive negative (back) pressure in the reaction vial (which may lead to difficulty in removing the entire volume from the vial) (2), foaming of the solution if manipulations are not performed smoothly (which may lead to difficulty in removing the entire volume from the vial) (1), and not keeping the needle opening below the liquid level at all times (which may result in air-locking of the filter) (1-3).

Another filtration problem was encountered recently at our institution. The product was prepared and quality control tested without problem. When the filter unit package was opened for attachment of the filter unit to the administration syringe, the

sterile filter unit was dropped accidentally (contaminated). Concerned about potential compromise of sterility, a different filter unit was used to withdraw the product from the vial into the syringe. None of the filtration problems noted above were encountered. However, upon assaying the syringe in the dose calibrator, it was observed that only a very small amount of radioactivity was present. Assay of the filter unit indicated that >90% of the radiolabeled antibody was retained in the filter unit. Attempts to recover the product from the filter unit were unsuccessful and the patient was rescheduled.

A Millex® GV (Millipore, Bedford, MA) filter unit is included in the antibody kit, and the manufacturer's instructions include the statement, "Aseptically attach the 0.22- μ m Millex GV sterile filter (provided) and a sterile hypodermic needle to a 10 ml sterile disposable syringe and withdraw the contents of the reaction vial through the filter into the syringe" (3). In the case reported here, a 0.22- μ m Millex GS sterile filter unit was used inadvertently.

Materials used for construction of filter membranes include mixed cellulose esters, polyethersulfone, polytetrafluoroethylene, polyvinylidene

fluoride, cellulose nitrate, polycarbonate and nylon (4). These materials vary markedly in characteristics such as hydrophilicity, chemical reactivity, flow rate, particle retention and protein binding (4). The 0.22- μ m Millex GV sterile filter provided in the kit has a polyvinylidene fluoride membrane, and is used because it exhibits the lowest protein binding. The 0.22- μ m Millex GS sterile filter that was inadvertently used in this case has a mixed cellulose ester membrane which exhibited high protein binding.

This case illustrates the importance of using the appropriate filter unit. Problems encountered during filtration of radiolabeled antibody products may result in an inadequate preparation for the patient procedure, which in turn results in wastage of an expensive product and a delay before the procedure can be rescheduled.

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References

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