The sera that were distributed for establishing the functional sensitivity, and the pools that had been exposed to a defined period of preanalytical temperature, were shipped frozen for analysis. Because surface mail is a standard method of transporting sera to be analyzed for stable analytes such as TSH, and because the goal of our study was a realistic assessment of method performance in clinical practice, both the US and UK pools were distributed by surface mail without refrigerant, although pools were first frozen before mailing. We decided not to add azide to the US pools, to better reflect the routine transportation of clinical specimens. We do not know whether the addition of azide would have changed the US data; however, pools were mailed to all laboratories on the same day, and the pool values reported were generally concordant with the established pool values and functional sensitivities for most of the methods.

Most clinical laboratories strive to select the most appropriate methods for their local needs, and maintain high quality in their clinical results. However, conditions are not always optimal in a busy clinical laboratory. Instruments malfunction occasionally, calibrations drift, reagents age, personnel do change, and human error cannot always be avoided. Probably many factors are responsible for the discrepancy between the manufacturer's performance and that of the clinical laboratories. It was not possible to evaluate all possible factors, but the effects of preanalytical temperature provide a cautionary note that should prompt further studies of this and other variables. It is the responsibility of the manufacturers to focus on the reasons for loss of performance in clinical practice and to improve the robustness of their methods. We hope that our study leads to the practice of realistically determining functional sensitivity and that other independent studies of the reliability of subnormal range measurement will be made.

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Factitious Additional Band Simulating Bence Jones Protein Caused by Contamination from Face Plate for Ureterostomy

To the Editor:
In our laboratory the screening for urinary monoclonal components, notably Bence Jones proteins, is performed by electrophoresis on cellulose nitrate and gold staining (Dasit, Milano, Italy) (1).

We recently observed two specimens which, when examined by the above-mentioned method, showed a band in the γ-globulin zone. Using the Hydragel kit Sebia for immunofixation (Ciampolini, Florence, Italy) for both samples, we were unable to immunoprecipitate the band: We also used antisera to IgG, IgA, IgM, IgD, IgE, lysozyme, and cystatin-C (Dako, Copenhagen, Denmark), and antisera to bound and free κ and λ chains (Atlantic Antibodies, Stillwater, MN).

Both specimens showed an abundance of sticky sediment; moreover, in both cases, the band didn't appear in the acid-violet-stained immunofixation reference electrophoresis gel, which clearly showed an albumin band.

Further investigations revealed that both specimens were collected from urinary pouches of ureterostomized outpatients. These pouches normally adhere to a face plate, which has a central hole and in turn adheres on the other side to the patient's abdomen. These pouches and their face plates come from the same commercial source (ConvaTec Division, Bristol-Myers Squibb, Rome, Italy).

The possibility of contamination was suggested. We were able to retrace one patient who volunteered a specimen of his pouch and face plate for ureterostomy. Monoclonal-component-negative urines kept at 37°C overnight in this pouch remained negative; when the face plate was used (as happens in vivo, where the urines come into contact with the inner face of the face plate), they developed a band in γ-globulin zone, as we had supposed (Fig. 1).

This experiment yielded the same results with urines of various pH (alkaline, acid, and neutral).

We also observed that small parts (1 cm²) of the face plate surface kept in 100 mL of saline solution or distilled water at 37°C for several hours visibly melted, yielding sediment and a band simulating a monoclonal component on gold-stained electrophoresis gels.

The composition of the face plate

Additional Band Forming on Gold-Stained Electrophoresis Gels Due to Contamination from Face Plate for Ureterostomy

In Situ PCR Amplification of Guthrie Card DNA to Detect Cystic Fibrosis Mutations

To the Editor:
Guthrie card bloodspots provide a valuable source of DNA for detection of genetic diseases (e.g., cystic fibrosis [CF] (1), phenylketonuria (2), sickle cell anemia (3)) by polymerase chain reaction (PCR). Molecular amplification of whole blood poses considerable technical obstacles, owing to the impurity of DNA (quantity and quality) and the presence of natural PCR inhibitors (4–6). Because of these complications, investigators have resorted to a variety of purification