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Interlaboratory Surveys of the Determination of Tumour Markers Scatter and Repeatability of the Results

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Summary: Data collected between 1983 and 1991 in interlaboratory surveys of the determination of tumour markers are used to show the magnitude of the scatter of results from different laboratories for the analysis of a single quantity in a given matrix. These data also show that the varying specificity of different reagent combinations appears to make a considerable contribution to this scatter, and that the used reagent combinations were not of uniform quality over a relatively extended period. The results for the following tumour markers were studied: α -fetoprotein (AFP), carcinoembryonic antigen (CEA), human chorionic gonadotropin (hCG), human chorionic gonadotropin + β -subunit (hCG + β -hCG), tissue polypeptide antigen (TPA), carbohydrate antigen 19-9 (CA 19-9), cancer antigen 15-3 (CA 15-3), cancer antigen 125 (CA 125), prostatic acid phosphatase (PAP) and prostate-specific antigen (PSA).

Introduction

During the last decade, in the field of tumour diagnosis, many more quantitative determinations for tumour markers have become available, and the number of these determinations requested and performed has also markedly increased. The determination methods are based exclusively on immunochemical principles, whose complex procedures are more subject to systematic and random errors, compared with many procedures of more traditional clinical chemical analysis.

Soon after the introduction of the determination of tumour markers, the necessity arose to test the reliability of the analytical results in collaborative interlaboratory surveys, as far as this was possible under the preconditions laid down for such tests (1). Since 1981, regular interlaboratory surveys of tumour markers have been carried out in collaboration with the German Society for Clinical Chemistry. The first interlaboratory surveys were conducted on three tumour markers: α -fetoprotein, carcinoembryonic antigen and human chorionic gonadotropin (2). By 1991 the

number of tumour markers under survey had increased to 10 and, by the end of 1991, the number of participating laboratories to 430.

More thorough investigations were promoted by the survey results of 1991, which revealed an especially wide scatter for certain analytical quantities.

The way in which the concept of the surveys is put into practice provides no basis for a detailed criticism of methods. Rather, these investigations had the following two-fold aim: on the one hand they sought to establish the magnitude of the scatter of results from different laboratories for individual tumour markers during an extended observation period. On the other hand, it was of interest to determine whether any characteristic differences existed between results obtained with different reagent combinations (kits). The results from the most frequently determined tumour markers, carcinoembryonic antigen and α -fetoprotein, provide the most comprehensive data for the discussion of this problem. It therefore seemed reasonable to base a more detailed study on these two analytical