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INTERLABORATORY QUALITY SURVEY FOR MATERNAL BLOOD SCREENING OF DOWN SYNDROME IN TAIWAN

K. J. Hsiao[1,2], S. H. Chiang[2]

Institute of Genetics[1], National Yang-Ming University

Dept. of Medical Research[2], Veterans General Hospital-Taipei; Taipei, Taiwan. R.O.C.

To assess the quality of the screening result, an interlaboratory quality survey for Down syndrome screening was developed in Taiwan. There are thirteen laboratories participated in the survey. Periodically, 4 specimens (2 lyophilized quality control sera and 2 sera from pregnant subjects) kept in dry ice were sent to each of the laboratories by speed post delivery. From Jan. 1995 to June 1996, six surveys were performed. Three different kinds of AFP kits, one hCG kit and one freeβ-hCG kit, were used by the participants. Seven obvious error results were found from 99 data reported and were excluded from statistical analyses. The interlaboratory imprecision (CVs) for the concentrations (AFP, hCG and free β-hCG) determined by all the kits and the same kit within a survey were between 5.0~34.8% and less than 10%, respectively. In most of laboratories, the run-to-run CVs for the determination of the concentrations of three markers were all less than 5%. Conversion of the concentration into multiples of the median (MoM) did not improve the precision of interlaboratory results. CVs of the Down's risk values calculated from AFP MoM & hCG MoM (group A laboratories, n=8) and AFP MoM & free β-hCG MoM (group B laboratories, n=5) were between 23~137%. Discordance of the final decision results was found in 5 samples from four surveys (positive/negative; 3/7, 2/8, 4/9, 5/8, 1/12). The results indicated that the precision of marker concentration determined by the screening laboratories in Taiwan is within acceptable range, but the quality of data conversion to the Down's risk value needs to be improved.

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