

Quality Assurance Program for Neonatal Screening of Glucose-6-phosphate Dehydrogenase Deficiency

Chiang SH¹, Fan CH¹, Wu KF¹, Hsiao KJ^{1,2,3}

Dept. of Medical Research and Education¹, Taipei Veterans General Hospital; Institute of Genetics²,
Genome Research Center³, Yang-Ming University, Taipei, Taiwan

Glucose-6-phosphate dehydrogenase deficiency is the most common enzymopathy, which causes neonatal jaundice if some inducing agents are not avoided. In order to reduce the complications of G6PD deficiency, such as kernicterus, permanent neurological damage, and death, the nationwide neonatal screening of glucose-6-phosphate dehydrogenase (G6PD) deficiency in Taiwan was started on July 1, 1987. At present, the effective collection rate reached 99.7% of all newborns and the overall incidence rate of G6PD deficiency in Taiwan was about 2%. The screening program of Taiwan enrolled 3 screening centers and 18 referral hospitals. An external quality assurance (QA) program for the screening test of G6PD deficiency was developed in 1999 in order to assess the reliability of the screening tests. The quality control materials with different activities of G6PD were prepared from whole blood and spotted onto Guthrie card. Periodically (1-2 month), 10 QC specimens were randomly picked and distributed to each neonatal screening center by speed post delivery. Reports were requested to be returned by fax or e-mail within 3 days for screening centers in Taiwan or 7 days for overseas screening centers. The external QA results were evaluated and compared to the reference values determined by our laboratory. Ten screening centers (3 in Taiwan, 2 in Mainland China, and one each in Philippines, Thailand, Lebanon, Vietnam, and Turkey) participated in this QA program. In addition, one reagent kit producer was also invited to participate in the QA program. From April 1999 to March 2004, 31 QA surveys were performed and 260 reports were received and the reporting rate was 98.5%. One hundred and forty three (143/2,600, 5.5%) abnormal G6PD QA reports were found, of which 32 (32/2,600) were false negative and 111 (111/2,600) were false positive results. This external quality assurance program has been useful for monitoring the performance of G6PD screening tests of the screening centers in the Asian Pacific region, and also provided guidance for correcting analytical errors.