DMSc PROFICIENCY TESTING PROGRAM FOR α-THALASSEMIA 1 DIAGNOSIS: 13 YEARS EXPERIENCE IN THAILAND

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Abstract. Precise and accurate molecular diagnosis of α-thalassemia 1 allele is one of the key factors for successful prevention and control of Hb Bart's hydrops fetalis (homozygous α-thalassemia 1) in Thailand. Since 2004, the Department of Medical Sciences (DMSc), Ministry of Public Health has established a DMSc proficiency testing program for molecular diagnosis of α-thalassemia 1. The program evaluates clinical laboratory performance based on pre-established criteria in comparison with other member laboratories. Enrollment in the DMSc program expanded from 13 laboratories in 2004 to 44 by the end of 2016. Four blind DNA samples were tested triennially and each laboratory performance at the end of each test cycle were distributed to all participating laboratories. Overall analytical accuracy (99.5%), analytical sensitivity (99.2%) and analytical specificity (99.7%) indicated excellent performance. Only 11/44 participating laboratories in 39 test cycles failed to correctly genotype the samples. Ten of the eleven laboratories resolved the problem by the end of the following test cycle and all within three cycles. The DMSc proficiency testing program will be expanded to cover other molecular genetic tests, such as β-thalassemia, Down syndrome and cancer biomarkers, to ensure the quality of these tests in clinical laboratories throughout Thailand.

Keywords: genetic test, proficiency testing, thalassemia, Thailand.

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