

**The efficacy of Immunochromatographic strip test for screening of  $\alpha$ -thalassemia 1 carriers at  
community hospitals and referral laboratory centers**

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**Objective:**  $\alpha$ -thalassemia 1 gene is the severe form of  $\alpha$ -thalassemia. Couples with either of this gene are at risk for fetus development that is not compatible with survival and their maternal often suffer from complications such as pre-eclampsia and postpartum hemorrhage. Presently, it has been demonstrated that  $\alpha$ -thalassemia immunochromatographic strip test ( $\alpha$ -Thal IC strip, i+Med Laboratories Company Limited) might be an attractive alternative to identify carriers of  $\alpha$ -thalassemia 1 due to convenience to use, cheap and less-time consuming. However, none of previous studies has been tested in the primary health care setting and the referral laboratory centers. The objective of this study was to determine the accuracy of  $\alpha$ -Thal IC strip for screening  $\alpha$ -thalassemia 1 carrier at 5 community hospitals and 5 the Regional Health Promotion Centers, Department of Health by using polymerase chain reaction (PCR) for  $\alpha$ -thalassemia 1 (SEA and THAI type) as a gold standard.

**Materials and Method:** The study was divided into two protocols. The first protocol, the total of 601 blood samples of pregnant women and their partners who attained antenatal care clinic during September to October 2014 at 5 community hospitals, were screened  $\alpha$ -thalassemia 1 carrier with the  $\alpha$ -Thal IC strip by technicians of community hospitals within 24 hours after blood sample collection. After that, all of them were transferred to the Regional Health Promotion Center 5, Nakhon Ratchasima for confirmation by PCR

technique. The second protocol, the blood samples consisted of 2,027 samples with positive results by the screening tests during the prevention and control program were referred from community hospitals to the 5 Regional Health Promotion Centers, Department of Health between January to August, 2014. The samples were transferred on various means of transportations and were then tested  $\alpha$ -thalassemia 1 carrier with the  $\alpha$ -Thal IC strip and DNA analysis by PCR technique. The two tests of each sample were separately and blindly performed by the two technicians.

**Results:** The sensitivity, specificity and accuracy of the  $\alpha$ -Thal IC strip for screening  $\alpha$ -thalassemia 1 carriers by the technicians at the 5 community hospitals were 100, 75.0-87.0, and 76.3-87.4, respectively. On the other hand, the sensitivity, specificity and accuracy with the same test that was performed by the technicians at the 5 Regional Health Promotion Center, Department of Health were 76.2-100, 68.3-87.2, and 72.2-88.7, respectively. It was found that the screening at the Regional Health Promotion Center, Department of Health had false negative results. It might be used old blood samples and most of them were not handled appropriately due to transportation by mail without ice.

**Conclusion:** The study showed that the  $\alpha$ -Thal IC strip could be used for screening  $\alpha$ -thalassemia 1 carriers in large populations due to very sensitive, no false negative results, simple protocol and less-time consuming. However, the blood samples should be tested within 24 hours after collection. Although the  $\alpha$ -Thal IC strip could minimize the need for PCR in diagnosis of  $\alpha$ -thalassemia 1 carriers but it could not reduce the total cost of laboratory testing when it is routinely used in the national prevention and thalassemia control program.