

Our objective was to study the stability of CK-MM and sources of variation in DBS samples of a prototype automated immunoassay, which is currently under development for the GSP[®] system from PerkinElmer to measure CK-MM from dried blood spots.

Sources of variation were characterized by using a panel of DBS and liquid samples prepared from human whole blood and spiked with purified human CK-MM. We also studied the stability of CK-MM in DBS samples stored at different temperatures and humidity.

Punches from the edges of DBS showed higher variation than the punches from the middle of the DBS spot. These results suggest that CK-MM analyte might not be evenly distributed in DBS. Humidity and temperature had a significant effect on the stability of CK-MM in DBS samples. For long-term storage, DBS samples should be stored frozen to ensure the stability of CK-MM.

P45. Newborn Screening for Critical Congenital Heart Diseases (CCHD) in a Remote County of Shanghai, China

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Critical congenital heart diseases (CCHD) are severe and life-threatening diseases requiring surgical or catheter intervention within first year of life. Recently, pulse oximetry (POxS) was adopted for newborn screening of CCHD. A community-based newborn CCHD screening program was developed for Chongming Island, which is a remote county located in Shanghai, China. The birthing facilities on the Island are located about 90 km (~2 h traffic time) from the city referral medical centers and without any pediatric cardiologist on the Island.

Two birthing facilities were participated in this program between August 2014 and December 2015. At the age of 24–36 h, POxS tests were performed. A result decision chart and a CCHD Screening Assistant App <cchd.pmf.tw> were provided to assist result decision at bedside. If the newborn failed the screening test, after clinical examination the newborn was referred for an echocardiography by a local ultrasonographer immediately. The echocardiographs were reviewed by a pediatric cardiologist of the referral medical center via free WeChat App remotely.

Of 3303 live births on the island during the period, 98.2% underwent POxS. Five (0.15%) newborns had failed the screening test. All the screen failed cases were referred and confirm diagnosed before 48 h after birth. Four of them were confirmed as CCHD, 3 IAA and 1 single ventricle, one of them had diagnoses solely attributable to the CCHD screening. The other referred case was diagnosed with pulmonary dysfunction.

This efficient and effective community-based newborn CCHD screening program in Chongming Island successfully integrated screening and referral systems which provided a scheme for implementation of the newborn CCHD screening program in remote area without local pediatric cardiologist in China.

P46. Global Update of Critical Congenital Heart Disease Newborn Screening Using Pulse Oximetry

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Background: Congenital heart disease (CHD) is the most prevalent birth defect in newborns and is the leading cause of death prior to one year of age. Screening asymptomatic newborns for critical congenital heart disease (CCHD) has become the standard of care in several developed countries. National and multi-center pilot projects are well underway and will add to our ability to refine existing protocols. In the United States, an estimated 98% of births or more are currently being screened for CCHD.