

Screening Processor; and hemoglobin by Bio-Rad Variant nbs System. Due to the prevalence of homocystinuria, all newborns are also screened for homocysteine. Second tier tests for methylmalonic, methylcitric and ethylmalonic acids are performed to reduce false positive rates. The Laboratory participates in the Collaborative Laboratory Integrated Reports database for population comparison and cutoff adjustments. The Laboratory is accredited by the College of American Pathologists. In 2018, a total of 22 confirmed positive screens were detected for amino acids and acylcarnitines. No false negative screens were identified and a total of 91 false positive screens were reported. Positive screens included: PKU (3), TYR II/III (1), HPRO (1), ASA (1), CUD (2), MCAD (2), 3MCC (5), GAI (1), MMA/PA (5) and B12 (1). The most frequent false positive screens included: PKU (5), TYR II/III (7), CIT (8), MSUD (7), NKHG (6), CUD (13), 3MCC (8), GAI (5), SCAD (6) and MMA/PA (3). Review of false positive screens showed greater reliance of interpretation on second tier results would significantly lower the false positive rate. Also, plasma amino acid analysis for all 7 suspected MSUD screens showed that the false positive screens were due to an increased hydroxyproline. A second tier screen that detects hydroxyproline on dried blood spot has the potential to further reduce the false positive rate. The Metabolic Laboratory in Qatar seeks ways to improve newborn screening by reliable detection of affected newborns and by reducing false positive screens.

P143. Accreditation of Newborn Screening Centers in the Philippine Setting

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Background: As stated in the Republic Act 9288 or the Newborn Screening Act of 2004, Newborn Screening Centers shall be established strategically and be duly accredited by the Department of Health. Currently, there are six NSCs in the Philippines. Each NSC is required to provide laboratory and follow-up services to all Newborn Screening Facilities (NSFs) within their service area. Before a NSC can begin formal operation, it is required to successfully undergo an initial accreditation. Once licensed, the NSC must undergo reaccreditation every three (3) years.

Objective: This presentation reviews the accreditation process among Newborn Screening Centers (NSCs) in the Philippines.

Method: The process of NSC Accreditation for the past 8 years was reviewed.

Results and Discussion: The accreditation process includes satisfactory completion of requirements outlined in a published DOH Checklist. The Philippine Performance Evaluation and Assessment Scheme (PPEAS) was developed to aid in determining readiness. Over time and with use, this tool and has been updated so that it remains current. PPEAS addresses in some detail the various components of the NBS system. Periodically, outside reviews by a team comprised of selected NSC members takes place to augment the 3-year formal review cycle and help prepare for the formal review. As part of the formal DOH review, foreign experts experienced in such accreditation reviews have been included as members of the accreditation team.

Accreditation reviews consist of two parts. The first involves service delivery, technical operations and information management, which includes the international experts. The second focuses on education and regulation, human resource, administration and financing linkages and facility management. All findings and recommendations are discussed with the NSC management and require compliance before issuance of an operating license. The accreditation process has facilitated harmonization of newborn screening in the Philippines.

P144. Internal Quality Control for Newborn Screening by Tandem Mass Spectrometry

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Background: Expanded newborn screening by tandem mass spectrometry (TMS) has been adopted for many newborn screening laboratories worldwide in past decade. Many analytes, including amino acids (AA) and acylcarnitines (AC), could be analyzed concurrently in a single test from dried blood spot sample. However, most TMS reagent kits do not provide the control sample for all the analytes intended to be determined. An internal quality control (QC) is developed to assist the screening laboratory carrying out routine daily quality assessment independent of reagent kit.

Materials & Methods: QC materials were obtained from spotting bloods spiked with different levels of target analytes, including 10 AA and 28 AC (C0–C26), on newborn sample collecting filter paper (Whatman 903) by a GMP manufacture (ISO 13485 certified). Three newborn screening centers, one used derivatized method, one used non-derivatized method, the other used both methods, have evaluated these QC samples. QC results were reported via TMS IQC MIS System online. Real time statistic and control chart were shown on web for QC assessment.

Results: The between QC samples variations were less than 10% (CV). After package opened, the QC samples were stable at 4 degree C for intended daily use in one week. Two levels (low and high) of QC samples were included in routine analytical runs in each of the newborn screening laboratories. More than 3,000 set of results have been reported since January 2018. The within laboratory variations (CV) for most items were

P145. Comparison of the TSH and OHP Values Between the Initial Contaminated and the Repeat Acceptable NBS Samples

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Background: A very important quality indicator of an effective newborn screening system is a good quality of dried blood spot sample. Poorly collected samples are labeled unsatisfactory and are not fit for testing because of risk of giving inaccurate results. One type of unsatisfactory specimen is a contaminated sample. There are many causes of contamination and newborn screening coordinators are encouraged to submit acceptable samples at all times.

Objective: This study aims compare the TSH and OHP values between the initial contaminated and the repeat acceptable newborn screening samples, to determine if contaminated samples will give erroneous laboratory NBS results for the metabolites for CH and CAH and to determine if there is a need to change the protocol in testing contaminated samples

Methods: All initial NBS samples that were received at the NSC Mindanao from October 1, 2013 to July 7, 2017 and that were labeled as having contaminated dried blood spot were tested for the six-test NBS disorders. Following the usual protocol of NSC Mindanao, babies with contaminated samples were actively recalled by the NSCM Follow up Nurse to ask for an urgent repeat collection. Repeat acceptable samples were tested for the 6-tests. Retrospectively, values of the TSH and OHP for each sample were compared to the values detected in the initial contaminated samples.

Results: From October 1, 2013 to July 10, 2017, there were 4,558 initial contaminated samples received at NSC Mindanao. Only 75% submitted a repeat acceptable sample. Overall results for TSH and OHP screening revealed that TSH and OHP values for both initial and repeat cards were positively skewed and showed significant difference on its mean values.

Conclusion: There were significant differences in the TSH and OHP values of contaminated and acceptable NBS samples leading to false positive NBS screening for CH and CAH.