P-237 - EXTERNAL QUALITY ASSESSMENT FOR TSH ON DRIED BLOOD SPOTS: INFLUENCE OF RESULTS’ EXPRESSION ON SCREENING INTERPRETATION.

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Proficiency testing is required for certification/accreditation as part of the quality management system of clinical laboratories and is a powerful tool for methods’ evaluation. Our EQAS (ProgBA) provides laboratories dried blood spot materials that mimic newborn specimens, monthly statistics and cumulative reports to help participants maintain accurate and reliable testing practices. Newborn screening analytes (TSH, 17OHProgesterone, Phenylalanine, Immunoreactive Trypsin, Galactose, Biotinidase) are under the scope of ISO/IEC17043: 2010 since 2014. TSH results are expressed in serum equivalent or whole blood units. Different cutoffs are used by individual labs, triggering difficulties in interpretation. We present data for TSH. ProgBA distributed 12 samples prepared out of 7 pools to 50 laboratories (2017-2018 surveys); target values for interpretation were assigned as > 80% consensus. Homogeneity and stability of samples were checked before distribution. Results were evaluated using measured concentrations, cutoffs informed by each participant lab, expressed in whole blood or serum equivalent units, and positive ratio (PR) values and interpretation (recall patient or not). Major methods for TSH used were ELISA (MP-Biomedicals, n=48 (39%); Tecnosuma, n=31 (25%); BioRad, n=3 (2%); Monobind, n=14 (11%)) and DELFIA (PerkinElmer®, n=26 (21%)). TSH results (Median [interquartile ranges] in mUI/mL and median PR) for a positive sample, >80% general and within-method consensus, were: MP-Biomedicals 80 [60-91], 4.4; Tecnosuma 65 [49-77], 6.5; BioRad 49 [45-58], 4.5; Monobind 48 [45-57], 3.2; Delfia 64 [57-67], 6.8. Results for a TSH borderline sample (47% general consensus) were (Median [interquartile ranges] and median PR): MP Biomedicals 18 [15-24], 0.98; Tecnosuma 7.4 [4.6-9], 0.68; BioRad 16 [15.6-17], 1.5; Monobind 11 [9.4-13], 0.74; Delfia 11 [10.7-12.7], 1.25. %Concordance with positive screening obtained for this sample was: Delfia 76%, BioRad 83%, Monobind 12%, MP-Biomedicals 47%, Tecnosuma 18%. Cutoffs used (mUI/mL) by Labs were for: Delfia=8 (35%), 9 (18%), 10 (35%), 15 (12%), BioRad=10 (67%), 20 (33%), Monobind=15 (92%), 25(8%), MP-Biomedicals=10(16%), 15(6%), 20(78%), Tecnosuma=8(29%), 9(12%), 10 (53%), 15 (6%). Within-method differences in %concordance may be due to the use of different individual cutoff values and use of blood or serum equivalent units. Harmonization of results’ expression is of outmost importance to get comparable results in newborn screening.