P-210 - CUT-OFF LEVELS FOR THE IMMUNOREACTIVE TRYSIN TEST IN A MEXICAN POPULATION OF NEWBORNS

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INTRODUCTION: Cystic Fibrosis (CF) is a genetic, chronic disease that affects multiple organs, a diagnosis of CF has lifelong implications for affected individuals; consequently a timely diagnosis needs to be accurate. CF neonatal screening in Mexico is based on the immunoreactive trypsin (IRT) assay as primary screening. However, if only a single specimen is routinely collected, use of an IRT/IRT algorithm would require for a second dried blood spot specimen at two weeks old approximately. At this age, elevated IRT values are more specific for CF because IRT values decrease in infants. OBJECTIVES: To present the first IRT cut-off point defined for newborns from two to five days old, and the second cut-off defined for newborns from 15 to 30 days old calculated in order to ensure that any newborn get an equitatable test. METHOD: To calculate first cut-off 500 samples from newborns between two and five days old were analyzed, and using a data set demographic characteristics, specific birth weight, health condition and term infants were examined. The second cut-off was calculated from 133 samples of babies between 15 and 30 days old. Samples were processed with NEONATAL IRT Screening ELISA Kit (Zentech, S.A.), an enzyme linked immunoassay. Assays were read on a spectrophotometer and results concentration of each sample were analyzed in statistical software in order to calculate the cut-off's. RESULTS: For the first cut off, the result for 99.5th percentile was 85.2 µg/L, and the mean concentration of this population was 38.9 µg/L. The second cut off was 74.5 µg/L. It is important to establish our own cut off points periodically to reduce false positives and negatives, when more newborns are tested. CONCLUSIONS: These cut off values have been set in an attempt to maximize sensitivity and positive predictive value. Although the initial cut off for IRT/IRT decreased over time from 85.2 µg/L to 74.5 µg/L, in attempts to decrease false negative results in the IRT/IRT, method all abnormal results from the second test it is verified by sweat test.