

0164 - INDIRECT APPROACH TO ESTABLISH REFERENCE INTERVALS FOR THYROID HORMONES IN INFANTS UNDER ONE YEAR OF AGE

Mode: Research paper

Thematic Unit: Thyroid

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Background/Objectives: Thyroid hormones are essential for neonatal brain development, growth, and metabolism. The diagnostic value of laboratory tests depends on interpreting results within reference intervals (RIs) that account for physiological variability. Indirect methods are especially useful in pediatrics, where recruiting healthy subjects is challenging and age-specific partitioning is frequently required. This study aimed to establish and verify RIs for TSH, free T4 (FT4), total T4 (TT4), and total T3 (TT3) in infants under 1 year of age using an indirect approach aligned with CLSI EP28-A3c.

Methods: Retrospective analytical study of data collected between 2008 and 2025 from two laboratory information systems. Data corresponded to apparently healthy infants under 12 months who underwent outpatient thyroid testing by electrochemiluminescence immunoassays; patients with known endocrine or genetic disorders were excluded. Age groups analyzed were 1–15 days (d), 16–30d, 31–60d, and 2–12 months (m). Age partitioning was assessed using Kruskal–Wallis and Mann–Whitney U tests and confirmed by the Harris–Boyd method. Outliers were excluded using Tukey’s method and clinical judgment. Reference intervals (RIs) were calculated and verified following CLSI EP28-A3c. Verification used 20 healthy infants per RI and was accepted if $\geq 80\%$ of the results fell within established limits. The study was approved by the Institutional Ethics Committee.

Results: The initial database included 1,682 thyroid tests, of which 98 were excluded. Infants aged 1–30d showed higher TSH concentrations (RI: 1.55–12.7 $\mu\text{IU/mL}$), with a significant decline thereafter (31–60d: 0.71–10.2 $\mu\text{IU/mL}$; 2–12m: 0.59–7.8 $\mu\text{IU/mL}$; p

Conclusion: The RIs obtained were consistent with the physiological thyroid hormone secretion described in the literature for infants under 1 year of age. Following the CLSI EP28-A3c guideline recommendations, the verified RIs enable accurate interpretation of thyroid function during early life, supporting timely diagnosis of thyroid disorders in infants. Altogether, they provide a robust framework that strengthens pediatric endocrinology practice

