

COMPARABILITY OF PEDIATRIC CLINICAL CHEMISTRY REFERENCE INTERVALS AS MEASURED BY THE ROCHE HITACHI 704 AND BECKMAN SYNCHRON LX20

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NHANES 1999-2000 and NHANES 2001-2002 are subsets of the 1999-2004 National Health and Nutrition Examination Survey which was conducted on civilian noninstitutionalized individuals. Approximately 1500 (1999-2000 study) and 1600 (2001-2002 study) individuals, ages 12 to 18 y had their blood drawn after fasting. The Roche Hitachi 704 (Roche Diagnostics, Indianapolis, IN) and the Beckman Synchron LX20 (Beckman-Coulter, Fullerton, CA) were used in the 1999-2000 and the 2001-2002 studies, respectively. Our objective was to derive clinically robust pediatric reference intervals and to assess the comparability of the Hitachi and LX20 reference intervals. The NHANES data were abstracted with Microsoft Access and analyzed with Microsoft Excel. To determine health-associated reference intervals, we used the following exclusion criteria: pregnancy, obesity (BMI >30), diastolic blood pressure > 100mmHg, creatinine exceeding 2.5 mg/dL and glucose exceeding 126mg/dL. Each population set was separated into four categories, Males 12 to 15y and 16 to 18y, Females 12 to 15y and 16 to 18y. The 2.5th, 50th and 97.5th percentiles were determined for each analyte / category class. We used visual inspection to assess the closeness of the Hitachi and Beckman reference limits. In addition, we calculated the % differences between the Hitachi and Beckman 50th percentiles: $[100 \times (\text{Beckman value} - \text{Hitachi value}) / \text{Hitachi value}]$ and compared them to the medically allowable bias. Visually and clinically, 14 analytes have comparable reference values. The Table shows the Beckman and Hitachi reference intervals for these 14 analytes as well as the combined instrument reference intervals for the 12 to 15 y girls (n=872) and the 16 to 18 y girls (n=528). The reference limits of the other analytes are not interchangeable: albumin, ALP, bilirubin, cholesterol, creatinine, LD and phosphate. The clinical laboratory industry needs to expend far more effort before the reference intervals of even common analytes are transferable.