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CLSI-based transference of the CALIPER database of pediatric reference intervals from Abbott to Beckman, Ortho, Roche and Siemens Clinical Chemistry Assays: Direct validation using reference samples from the CALIPER cohort

Mathew P. Estey [a,b], Ashley H. Cohen [a], David A. Colantonio [a,b], Man Khun Chan [a], Tina Binesh Marvasti [a], Edward Randell [c], Edgard Delvin [d], Jocelyne Cousineau [d], Vijaylaxmi Grey [e], Donald Greenway [f], Qing H. Meng [g], Benjamin Jung [h], Jalaluddin Bhuiyan [h], David Seccombe [i], Khosrow Adeli [a,b,*]

[a] CALIPER Program, Department of Pediatric Laboratory Medicine, The Hospital for Sick Children, Canada
[b] Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, ON, Canada
[c] Eastern Health, St. John's, NL, Canada
[d] Sainte-Justine Hospital, Montreal, QC, Canada
[e] McMaster Children Hospital, Hamilton, ON, Canada
[f] The Ottawa Hospital, Ottawa, ON, Canada
[g] Royal University Hospital, Saskatoon, SK, Canada
[h] BC Children's Hospital, Vancouver, BC, Canada
[i] CEQAL, Vancouver, BC, Canada

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ABSTRACT

Objectives: The CALIPER program recently established a comprehensive database of age- and sex-stratified pediatric reference intervals for 40 biochemical markers. However, this database was only directly applicable for Abbott ARCHITECT assays. We therefore sought to expand the scope of this database to biochemical assays from other major manufacturers, allowing for a much wider application of the CALIPER database.

Design and methods: Based on CLSI C28-A3 and EP9-A2 guidelines, CALIPER reference intervals were transferred (using specific statistical criteria) to assays performed on four other commonly used clinical chemistry platforms including Beckman Coulter DxC800, Ortho Vitros 5600, Roche Cobas 6000, and Siemens Vista 1500. The resulting reference intervals were subjected to a thorough validation using 100 reference specimens (healthy community children and adolescents) from the CALIPER bio-bank, and all testing centers participated in an external quality assessment (EQA) evaluation.

Results: In general, the transferred pediatric reference intervals were similar to those established in our previous study. However, assay-specific differences in reference limits were observed for many analytes, and in some instances were considerable. The results of the EQA evaluation generally mimicked the similarities and differences in reference limits among the five manufacturers' assays. In addition, the majority of transferred reference intervals were validated through the analysis of CALIPER reference samples.

Conclusions: This study greatly extends the utility of the CALIPER reference interval database which is now directly applicable for assays performed on five major analytical platforms in clinical use, and should permit the worldwide application of CALIPER pediatric reference intervals.

Introduction

Clinical interpretation of laboratory test results is heavily dependent on the availability of reliable reference intervals. In simplistic terms, reference intervals represent the range of results that are commonly observed in a population of healthy individuals. More specifically, current guidelines define a reference interval as the range that encompasses the central 95% of the distribution of test results from reference individuals sampled from a healthy reference population [1]. Comparison of a given test result to an appropriate reference interval gives meaning to that result, enabling proper clinical assessment and patient care. The process of establishing accurate and reliable reference intervals is complex, and highly dependent on selecting an appropriate reference population [2]. Factors such as age, sex, sexual development, ethnicity, and geographic location may profoundly affect the reference concentration of a given analyte. As a result, partitioned reference intervals accounting for the influence of these covariates are required for

Abbreviations: CALIPER, Canadian Laboratory Initiative in Pediatric Reference Intervals; CLSI, Clinical Laboratory Standards Institute; Q–Q, quantile–quantile; EQA, External quality assessment; CEQAL, Canadian External Quality Assessment Laboratory.

* Corresponding author at: Clinical Biochemistry Division, DPLM, The Hospital for Sick Children; 555 University Avenue; Toronto, Ontario, Canada; M5G 1X8.
E-mail address: khosrow.adeli@sickkids.ca (K. Adeli).

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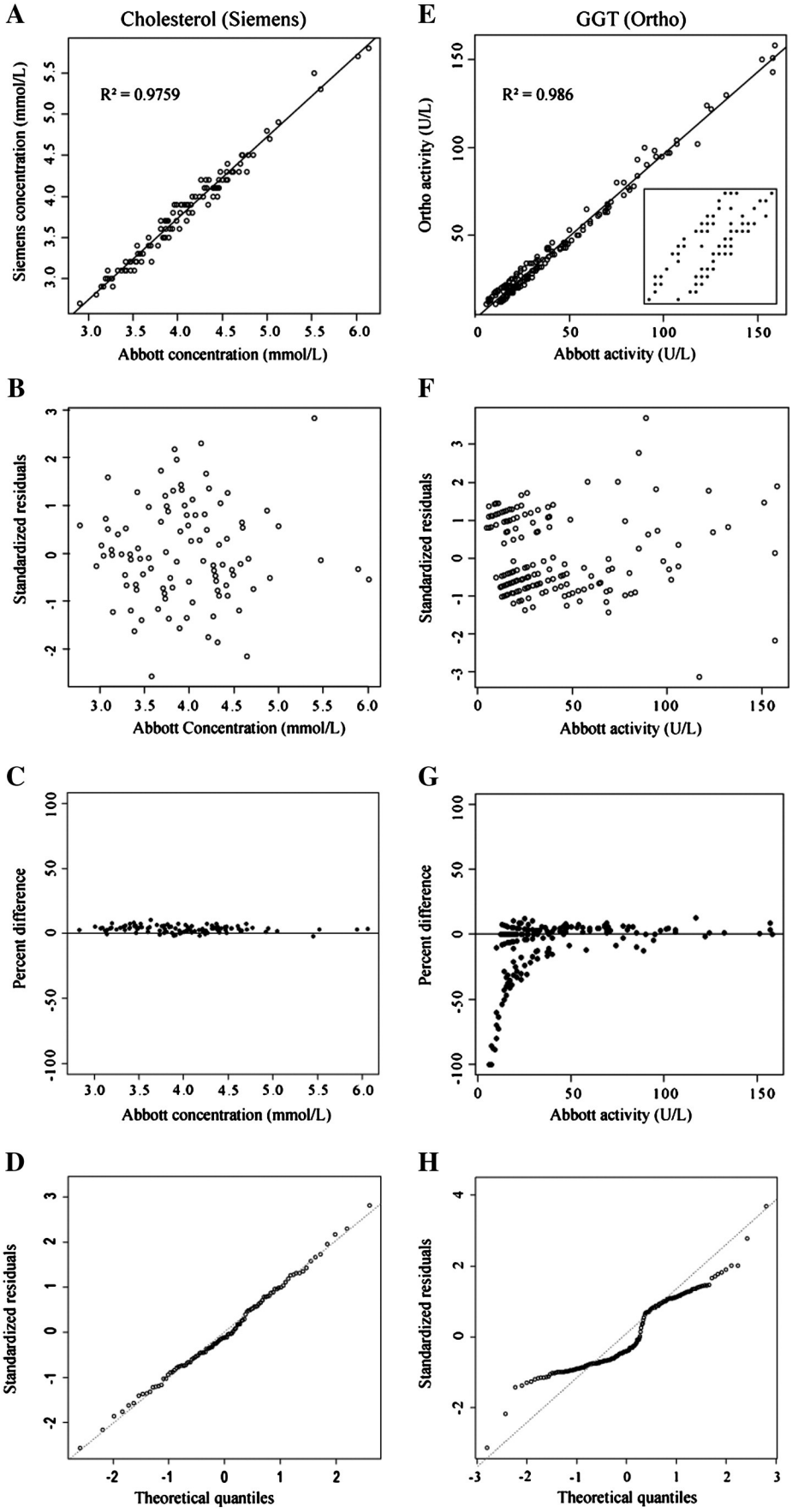

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