

Reference Interval (RI)

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Reference Intervals (RIs) for laboratory test results obtained from healthy reference populations have an important role in diagnosis treatment and monitoring of patients. Careful determination of RIs by a laboratory is very important task [1]. A reference interval is the interval between and including two reference limits. The term "reference range" was rejected because range is the difference between the highest and lowest value in a number set; it is a single value. Reference value is a value expected for a healthy person. They are sometimes called "normal value". By comparing the test results with reference values, your health care provider can determine whether your test results fall outside the range of expected values. Which can provide clues to identify possible conditions or diseases [2]. The term "reference value" was introduced by Nils-Erik Saris and Ralph Grasbeck in 1969 [3]. After seventeen years, between 1987 and 1991, Six guidelines covering different aspect of reference intervals (RIs), were published by International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) recommending that each laboratory produce its own reference interval [4]. According to the directive on in vitro diagnostic medical

devices of the European Union, diagnostic manufacturers are now requested to supply their clients with appropriate RIs for use with their assay platforms and reagents [5], and the International Organization for Standardization (ISO) 15189 standard for clinical laboratory accreditation states that each laboratory should periodically re-evaluate its own RIs [6]. In spite of immense clinical importance, most laboratories across Nepal depends on either kit inserts or scientific literature, which are mostly calculated for western population. Population across the globe differs physiologically, genetically and ethnically, along with differences in lifestyle and diet which have great impact on the various biochemical analytes. Thus, it is inappropriate to use RIs which do not represent the local population. The derivation of RIs by conducting a multicenter study following a common protocol and standard operating procedures (SOPs), for multicenter RI studies [7, 8] is probably the most plausible solution for globally applicable RIs with indication of the utility of a panel of sera for the alignment of test results among laboratories in the multicenter studies [9].

REFERENCES

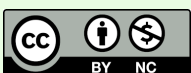
- Horn PS, Pesce AJ. Reference intervals an update. *Clin Chim Acta* 2003; 334:5 – 23
- Graham Jones, Antony Barker. Reference Intervals. *Clin Biochem Rev.* 2008 Aug; 29(Suppl 1): S93–S97. Available online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2556592/>. Accessed August 2015.[3]
- Grasbeck, R. (1969). Establishment and use of normal values. *Scand J Clin Invest*, 110, 1-15.
- Solberg, H. E. (2004). The IFCC recommendation on estimation of reference intervals. The RefVal program. *Clinical Chemistry and Laboratory Medicine (CCLM)*, 42 (7), 710-714.
- Directive 98/79/EC of European Parliament and the Council of 27 October 1998 ON invitro diagnostic medical devices. *Official J Eur Commun* 7 December 1998; L331/1 – L331/37.
- International Organization for Standardization. ISO 15189:2012 Medical laboratories – Requirements for quality and competence, 3rd ed., 2012.
- Ozarda Y, Ichihara K, Barth JH, Klee G, and on behalf of the CRIDL on Reference intervals and Decision Limits, IFCC. Protocol and standard operating procedures for common use in worldwide multicenter study on reference values. *Clin Chem Lab Med* 2013; 51: 1027–40.
- Cerioti F. Prerequisites for use of common reference intervals. *Clin Biochem Rev* 2007;28: 115–21
- Ozarda Y, Ichihara K, Barth JH, Klee G, and on behalf of the CRIDL on Reference intervals and Decision Limits, IFCC. Protocol and standard operating procedures for common use in worldwide multicenter study on reference values. *Clin Chem Lab Med* 2013; 51: 1027–40.

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