Current reliability of the Immulite® assay for measurement of serum IGF-1 in the Brazilian adult population

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DEAR EDITOR,

The Immulite® assay, the test most commonly used for IGF-1 measurement by clinical laboratories in Brazil, recently had supply problems (1) and temporarily ceased to be used. Earlier, the assay had been reported to overestimate IGF-1 concentrations (1-3). Many laboratories are now returning to use the Immulite® assay for IGF-1 measurement. This test will therefore continue to be used in Brazil, at least in the short and medium term, although it does not meet the current recommendation of calibration against the World Health Organization (WHO) International Standard (IS) 02/254 (4). Another assay (Liaison®), calibrated against IS 02/254, is available in Brazil. However, IGF-1 reference values obtained with this assay have not been established in studies including a sufficient number of individuals and following current recommendations (4). With the return of the Immulite® assay, it is necessary to confirm that the current lots no longer overestimate IGF-1. This confirmation is necessary since the information was only provided by the manufacturer (1), but so far there are no published data that prove this. Furthermore, the causes of the problem and the respective technical adjustments to solve it were not clarified (1).

The characteristics of the population studied have been published previously (5). Briefly, volunteers of both genders (500 women and 500 men) from the metropolitan region of Belo Horizonte, ranging in age from 21 to 70 years, with a body mass index ≥ 18.5 and ≤ 30 kg/m^2 were selected. The subjects were apparently healthy and were not taking any potentially interfering medications. Ten groups divided according to age (5-year intervals) were defined, with 100 subjects (50 men and 50 women) per group. The study was approved by the Ethics Committee of the Institution.

The samples were centrifuged immediately after collection, divided into aliquots, and stored at -80°C. The aliquots used in this study remained frozen. In the previous study (5), the measurements were made before the period in which overestimated IGF-1 values began to be observed (1-3). In the present study, the measurements were made in June 2014 using lots that, according to the manufacturer, are in alignment with the medians of the reference range data published in the Instructions For Use (1).

Comparing the IGF-1 concentrations obtained in this study with those of the previous study (5), we observed a variation of - 3% to + 7%. The variation in serum IGF-1 levels was ≤ 7% in all samples and ≤ 5% in 90% of the samples. The correlation coefficient between the first and second measurement of IGF-1 was 0.98 ($p < 0.001$). In view of the high reproducibility of the results, the reference values established previously (5) and in this study were very similar. There was also complete overlap of the median IGF-1 concentrations (in the 10 age groups).

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The results obtained now in 2014 were very similar to those found in 2009 (5), with complete overlap of median values, a finding permitting two conclusions. First, the current lots of the Immulite® assay probably do no longer overestimate IGF-1, at least so far. Second, the previously published reference values (5) can be used today by the laboratories that return to measure IGF-1 with this assay. However, since the cause of the overestimated IGF-1 values has not been established (1-3), it is not possible to ensure that this and other problems do not occur in future lots. Furthermore, we emphasize that problems with the assay may occur progressively, with small lot-to-lot variation, until the cumulative difference becomes noticeable (2). Likewise, we highlight the importance of physicians for informing the laboratories about unexplainable IGF-1 results or variations and results that are incompatible with the clinical history.

The short-term perspective is that the use of assays not only calibrated against IS 02/254, but also employing adequately obtained reference values (6), will significantly minimize the problems related to serum IGF-1 measurement.

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