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Neurochemical Dementia Diagnostics – Interlaboratory Variation of Analysis, Reference Ranges and Interpretations

Hansotto Reiber[1]*, Peter Lange[2] and Inga Zerr[2]

[1]*Soc. for Advancement of Quality Assurance in Medical Laboratories, INSTAND, Düsseldorf, Germany*
[2]*Neurochemistry Laboratory, Department of Neurology, University Medical Center, Georg August University Göttingen, Germany*

Abstract

Purpose: Dementia marker analysis requests the control of analytical reliability.

Method:
system [EQAS] for dementia marker analysis. Stabilized CSF samples are analyzed with a reference range-related evaluation and a differential diagnostic interpretation of combined parameters [total Tau protein, phospho Tau protein and Amyloid-ß-peptide Aß1-42].

Results:
range: the highest value was 10-fold higher than the lowest for Aß42 [69-771 pg/ml], 4-fold higher for Tau [315-1292 pg/ml and twofold for pTau [53-83 pg/ml]. With a success range of median ± 25% the fraction of outliers were up to 31% [Aß42] or 13-15% [Tau] and 3-11% for pTau in the N= 6 surveys. B) For evaluation [normal /pathological/border line] participants used a huge range of individual cut-off values: Tau [150-540, median 450 pg/ml], pTau [35-85, median 61 pg/ml] and Aß1-42 [205-600, median 500 pg/ml] with serious consequences for the differential diagnosis. C) In case of a sample with normal median values [e.g. Tau = 381 pg/ml and Aß= 748 pg/ml] 45% of participants regarded their values as pathological with a stunning interpretation of combined Tau and Aß1-42 data: 29% of the participants found this data combination compatible with an Alzheimer's disease, 29% reported this as a normal sample, and 42 % regarded an interpretation as not possible.

Conclusions: Up to 31% outliers are a source of serious diagnostic errors. The unacceptable large variation of the laboratory own cut-off values leads to false negative and false positive diagnostic interpretations. This questions the practical relevance of dementia marker analysis. The calculation of mathematical formulas or ratios of the analytical parameters is not improving the discriminative sensitivity due to the error propagation in mathematical
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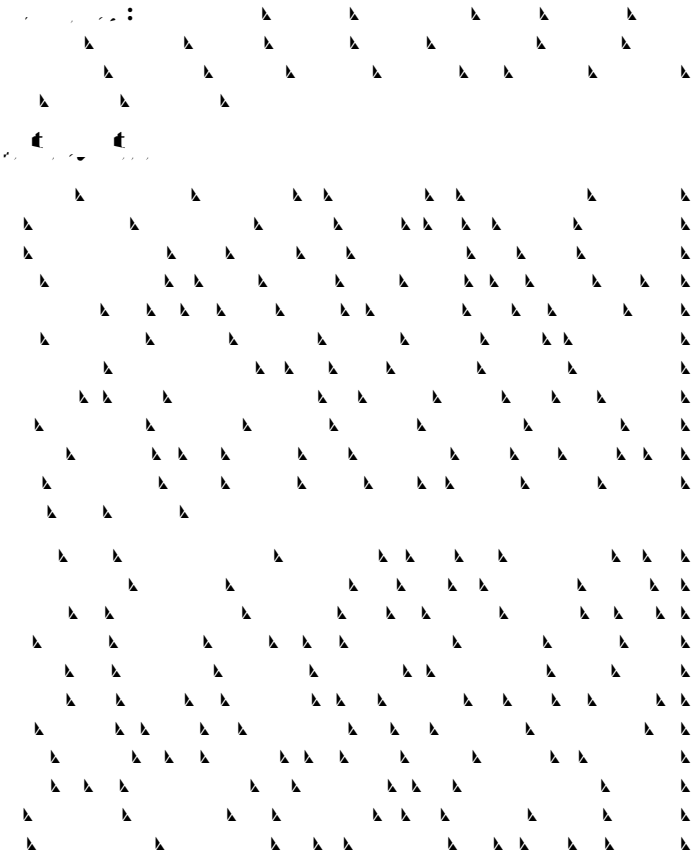

***Corresponding author:** Hansotto Reiber, Soc. for Advancement of Quality Assurance in Medical Laboratories, INSTAND, Düsseldorf, Germany, Tel: 005511982787549; E-mail: ho@horeiber.de

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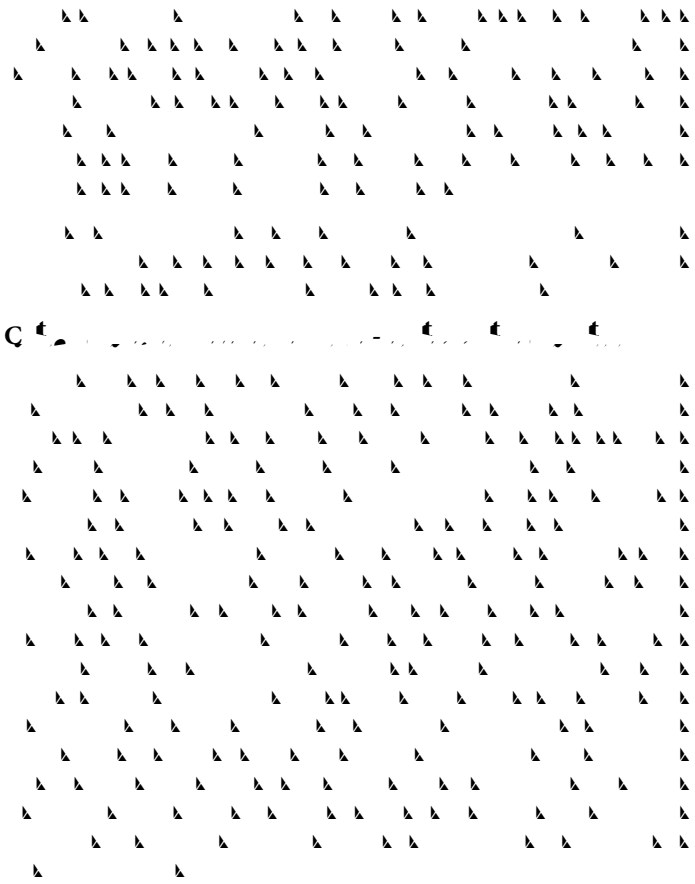

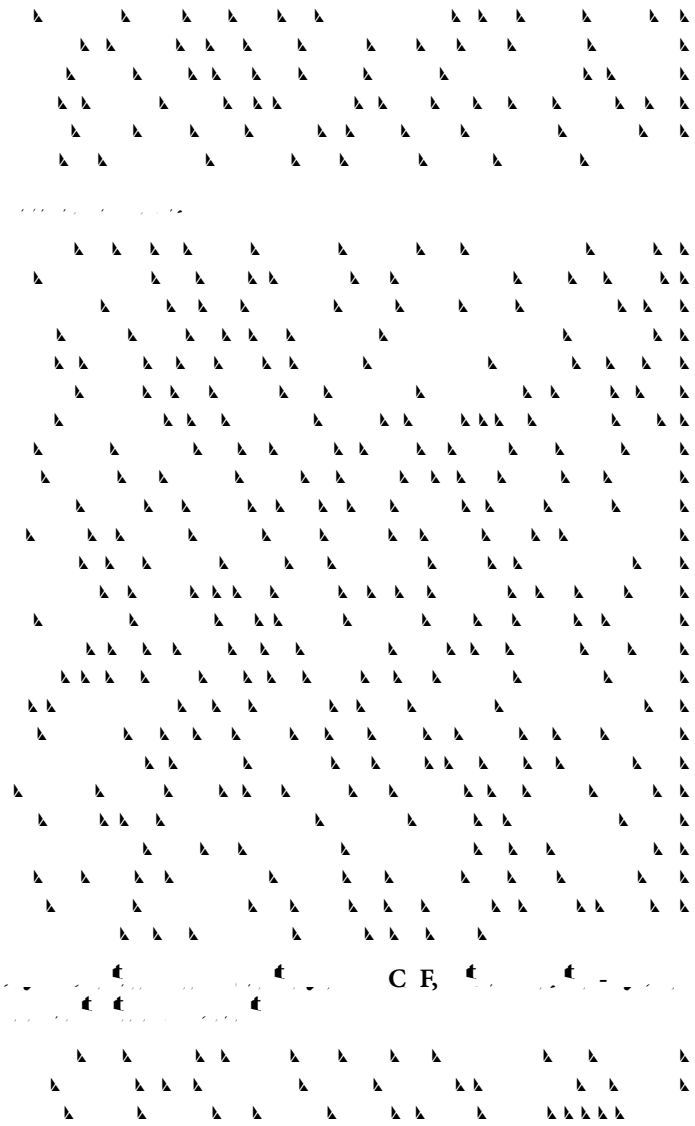

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