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The inter-observer reading variability in anti-nuclear antibodies indirect (ANA) immunofluorescence test: a multicenter evaluation and a review of the literature

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Abstract

Recently there has been an increase demand for computer-aided diagnosis (CAD) tools to support clinicians in the field of Indirect ImmunoFluorescence (IIF), as the novel digital imaging reading approach can help to overcome the reader subjectivity. Nevertheless, a large multicenter evaluation of the inter-observer reading variability in this field is still missing. This work fills this gap as we evaluated 556 consecutive samples, for a total of 1679 images, collected in three laboratories with IIF expertise using HEp-2 cell substrate (MBL) at 1:80 screening dilution according to conventional procedures. In each laboratory, the images were blindly classified by two experts into three intensity classes: positive, negative, and weak positive. Positive and weak positive ANA-IIF results were categorized by the predominant fluorescence pattern among six main classes. Data were pairwise analyzed and the inter-observer reading variability was measured by Cohen's kappa test, revealing a pairwise agreement little further away than substantial both for fluorescence intensity and for staining pattern recognition (k=0.602 and k=0.627, respectively). We also noticed that the inter-observer reading variability decreases when it is measured with respect to a gold standard classification computed on the basis of labels assigned by the

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