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Biostatistician Review Report

This study aimed to evaluate the diagnostic performances of a new point of care test based on detection of anti-deamidated gliadin peptides for the screening of celiac disease. For this purpose, we used standard statistical tools: receiver operating curve, sensitivity, specificity and likelihood ratios (positive and negative). The counts of patients are detailed for each analysis and the 2*2 tables used for assessment of sensitivities and specificities are shown. The ROC curve and its area under the curve were obtained by the non parametric approach proposed by Delong EM (reference 13 of manuscript). The 95% confidence intervals (obtained by the same approach) are systematically reported. 95% confidence intervals, obtained by the exact method of Clopper-Pearson, are also reported for proportions (sensitivities and specificities). The inter-rater agreement was assessed using the Kappa coefficient, reported with its standard error. The 95% confidence intervals for the Kappa coefficients and the likelihood ratios were obtained by exact methods using software StatXact-8 All statistical methods used in the analyses are described in the section Statistical analysis of Methods. No statistical tests were performed. The characteristics of patients were described in Table 1 of the manuscript. The median was used to describe the age of patients, and the minimal and maximal values are also reported. The counts of missing data are also reported. All analyses were performed using STATA v11, except for assessment of 95% confidence intervals for likelihood ratios and Kappa coefficients, which were obtained using StatXact-8.

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