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### Faecal elastase-1 (EL-1) in pediatric patients with cystic fibrosis

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Dear Editor,

I have read the recent publication on faecal elastase-1 (EL-1) in pediatric patients with cystic fibrosis with great interest.<sup>1</sup> Gonzales et al. concluded that "The test was standardized, is easy to execute, and can be used to assess the pancreatic status of patients with cystic fibrosis."<sup>1</sup> There are, however, some concerns. First, no complete study on the diagnostic properties (sensitivity, specificity, predictive value, etc.) of the test has been reported. In addition, there is no evidence to support the conclusion on the standardization and easy-to-use property of the test. Second, it should be noted that a special diet or known disease (gastrointestinal disease, surgery, diabetes mellitus, etc.) can alter test results.<sup>2</sup>

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No conflicts of interest declared concerning the publication of this letter.

#### References

1. Gonzales AC, Vieira SM, Maurer RL, E Silva FA, Silveira TR. Use of monoclonal faecal elastase-1 concentration for pancreatic status assessment in cystic fibrosis patients. *J Pediatr (Rio J)*. 2011;87:157-62.
2. Herzig KH, Purhonen AK, Räsänen KM, Idziak J, Juvonen P, Phillips R, et al. Fecal pancreatic elastase-1 levels in older individuals without known gastrointestinal diseases or diabetes mellitus. *BMC Geriatr*. 2011;11:4.

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### Authors' reply

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Dear Editor,

We agree that a comparison with a gold standard test was not performed. This point was therefore reported as one limitation of our study. However, the extensive literature on the comparison of faecal elastase-1 with other tests reveals high levels of sensitivity (90-100%) and specificity (93-98%) for pancreatic insufficiency in cystic fibrosis patients with an age distribution similar to that of our sample.<sup>1-6</sup> This allows us to draw conclusions about diagnostic properties. In addition, we followed the European Cystic Fibrosis Society Guidelines on the Early Management of Infants Diagnosed with Cystic Fibrosis Following Newborn Screening. The guidelines recommend that: "at diagnosis, infants must have pancreatic function assessed clinically and by measuring stool fecal elastase. Repeated assessment of pancreatic status is essential during the first year of life if elastase is normal at diagnosis."<sup>7</sup>

It should be remembered that the purpose of our study was to compare the concentration of faecal elastase-1 among patients with mutation  $\Delta F508$ .

The second reference cited by Professor Viroj Wiwanitkit (Herzig et al.) is of great interest, but it refers to 159 patients, 66.7% of them aged over 60 years and without cystic fibrosis. Our patients, aged 4 months to 17 years, showed no diabetes mellitus, previous surgery, alcohol intake, Shwachman-Diamond syndrome, celiac disease, irritable bowel syndrome, or inflammatory bowel disease. In addition, patients taking drugs to regularize bowel habits and patients with liquid stool three or more times a day during the 2 weeks preceding the examination were excluded from the study.

Finally, regarding the fact mentioned by the author that a special diet could alter faecal elastase-1 test results, it is worth noting that our patients, due to the severity of the disease, were given a high-calorie/high-protein diet suitable for their age.