DISCLOSURE

The authors declare no conflict of interest.

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Response to Drábek and Cereda

To the Editor: We appreciate the letter by Drs. Drábek and Cereda[1] regarding our article "Informatics-Based, Highly Accurate, Noninvasive Prenatal Paternity Testing".[2] We at Natera wholeheartedly agree with the authors that established standards are critical to minimize the possibility that a commercially available paternity test could return a false result. To put their letter into proper context, it is important to note that conventional paternity test methodologies rely on the availability of pure child DNA, which is appropriate for postnatal testing as well as for prenatal testing, in which child DNA can be obtained through an invasive procedure. Unfortunately, invasive procedures carry a risk of miscarriage, and women have traditionally had no risk-free prenatal paternity testing options.

Fortunately, the recent discovery that maternal blood contains fetal cell-free DNA has opened the door to noninvasive prenatal paternity testing. However, the fetal cell-free DNA found in maternal plasma is mixed in with a much larger amount of maternal cell-free DNA and cannot be separated, precluding the use of traditional paternity testing methods. To overcome this challenge, we developed a new analytical method appropriate for performing paternity testing on fetal–maternal DNA mixtures.

In keeping with our common desire to establish standards that ensure accuracy of new paternity testing methodologies, we are working with several nationally recognized organizations to this end. Our noninvasive prenatal paternity test has been approved by the New York State Department of Health, and a review of our test methodology and analytics by the American Association of Blood Banks' Relationship Testing Standards Committee has found them to be appropriate for relationship testing.

In response to specific comments by Drs. Drabek and Cereda, we believe that they have conflated the projected accuracy of the test and the observed accuracy in the study cohort. Our claim that the method determined paternity with 100% accuracy in a trial with 36,400 paternity tests with known results is correct. Moreover, although the method suggested by Drs. Drabek and Cereda is appropriate when pure fetal DNA has been isolated, as stated above, it is not currently possible to use this method prenatally in a noninvasive manner.

DISCLOSURE

All authors are employees of Natera, with stock or options to hold stock in the company.

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