This Lab Medicine serves to address several questions from clinicians interpreting the new beta-hCG test.

1. What is the reference range for a female up to and including 17 years of age? The manufacturer of the new test platform did not perform a statistically valid reference range study for this age group nor does the World Health Organization propose one. The following comment from the manufacturer regarding this issue is as follows: "Healthy, nonpregnant individuals typically have low (<5 mIU/ml) to undetectable hCG. hCG results between 5 mIU/ml and 25 mIU/ml may be indicative of early pregnancy but should be interpreted in light of the total clinical presentation of the patient". A comment reflecting this will be reported along with the numeric result to aid in interpretation. It is reasonable to follow serial quantitative values over time in equivocal cases.

2. What is the correlation of the new test results to gestational age? Again, the manufacturer of the assay does not provide data or graphs to address this question. For a rough rule of thumb, our own validation data suggests that there can be an up to 10-20% increase in beta hCG levels relative to the old method.