Testosterone immunoassays have been on the market for decades providing good clinical performance. Assay performance often relies on the chosen analytical modality. High volume immunoassay analyzers have the advantage of rapid speed and high throughput, while mass spectrometry systems have higher accuracy with much lower throughput. Beckman Coulter's testosterone assay has offered reliable performance in line with other high throughput immunoassay analyzers.

We continuously monitor customer feedback of both positive assay reviews as well as suggestions for improvements. While we cannot speak directly about individual customer feedback, we are dedicated to our processes of continuously evaluating and improving assays for future releases. Unfortunately, we cannot rapidly change claims or performance of our existing assays without thorough development and regulatory clearance process.

Harmonization across modalities is a challenge when considering differences in analytical methods, as well as availability of reference measurement procedures, reference materials and their commutability. There is also regulatory implementation challenges with sometimes contradictory guidance from various government bodies. Currently, Beckman Coulter is involved with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) in standardization activities on procalcitonin, thyroid function, bone metabolism, and cardiac-specific troponin tests. We are not aware of industry harmonization efforts for testosterone testing.