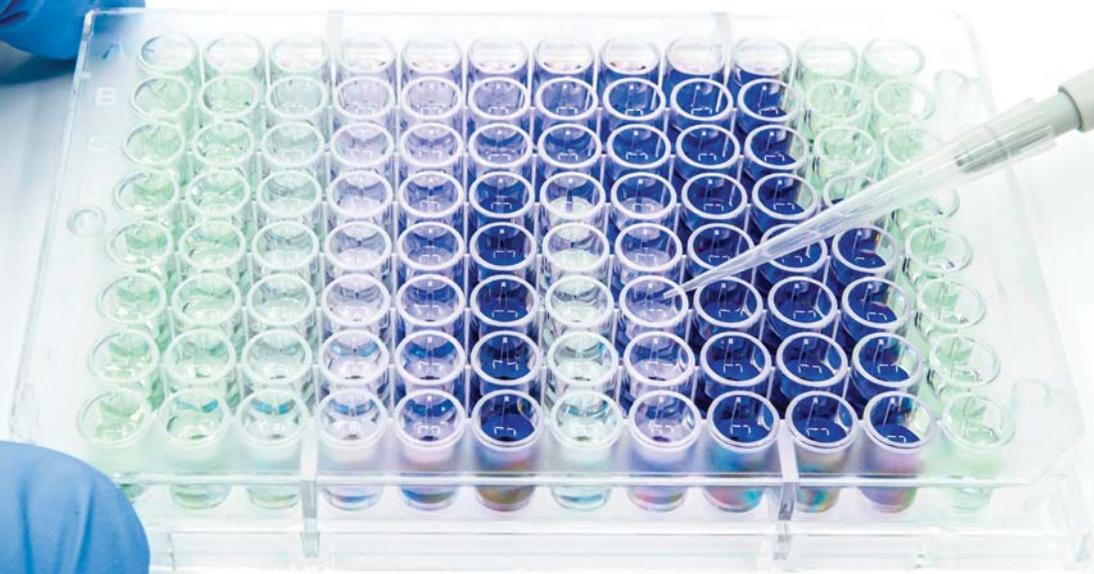


CONCLUSIONS FROM RECENT PyroSmart NextGen® rCR comparability studies

- ▶ **ACC's PyroSmart NextGen® rCR's final endotoxin results in both ACC and end user studies are equivalent to LAL reagents (chromogenic or turbidimetric) within the tested sample sets**
 - *With a higher slope of linear regression and higher rate of valid relative recoveries than when comparing LAL vs. LAL within the ACC water study*
- ▶ **Based on the advantages of PyroSmart NextGen® and the equivalency shown, we concluded that PyroSmart NextGen® is a suitable candidate for early in-house implementation**
- ▶ **We continue to look for more guidance from the regulatory agencies:**
 - *The choice of samples?*
 - *How to evaluate the comparability data sets?*
 - *How many samples are needed to declare comparability of rCR to LAL?*



Visit acciusa.com to view the full webinar on
Comparisons of Traditional LAL to Recombinant Reagents