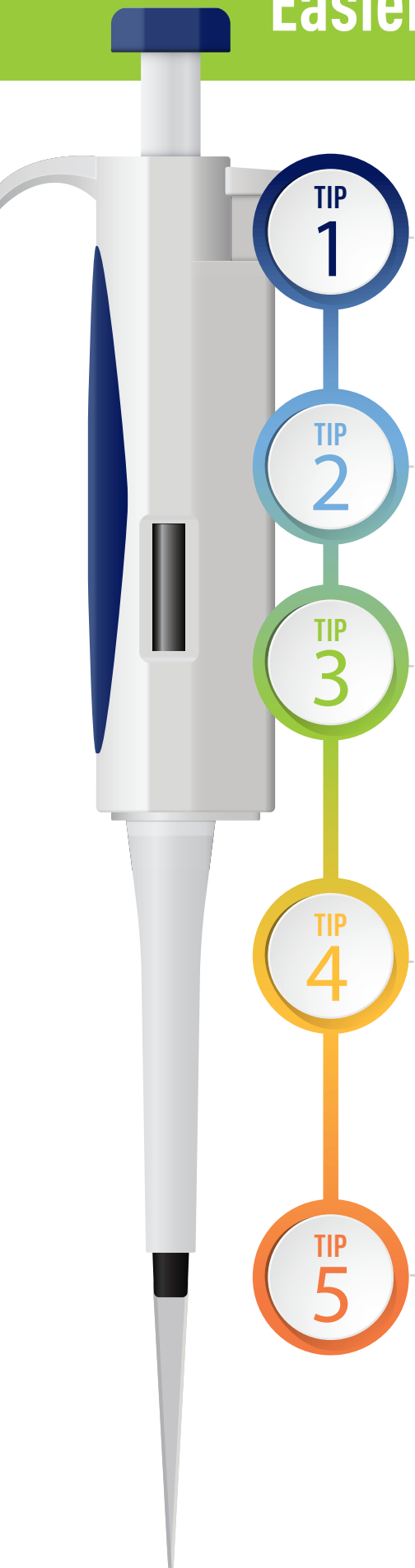
Top 5 Tips for
Easier Bacterial Endotoxin Testing (BET)



TIP 1

Automate where you can

Automating the liquid handling aspects of endotoxin testing can be achieved using microfluidics or robotics. This includes automating the standard curve preparation and positive product controls for every assay. Reducing the amount of interaction needed during the preparation process automatically reduces the chance for errors and contamination.

TIP 2

Utilize support for platform validation

Taking advantage of support offered by the BET platform manufacturer can streamline the validation process and ensure compliance is achieved. It also removes the stress of finding time and designating people to complete the validation. Utilizing the support that is available means you can start seeing the benefits of your new platform quickly.

TIP 3

Set up libraries and templates in your software

Using libraries in the software to build and save products for testing can make for simplified assay template setup. Assay templates can potentially also be built and saved in another library to streamline routine testing.

TIP 4

Avoid compliance concerns

Ensuring that your BET software and instrument are fully validated can help ease compliance concerns. It is important to verify that data integrity and 21 CFR Part 11 guidelines are addressed. These guidelines are usually outlined in the IQ/OQ/PQ documentation and should be easily identifiable within the software. In terms of meeting all requirements of the harmonized global pharmacopoeia, USP <85>, EP 2.6.14 and JP 4.01, you can avoid compliance concerns by using FDA licensed LAL, qualified consumables and reagent water, and including the following: minimum three-point standard curve in duplicate using standardized endotoxin, samples and PPCs in duplicate, negative controls in duplicate, and analyst and lysate lot qualification in triplicate.

TIP 5

Leverage client-server software

Having client-server software installations located on several computers allows for results to be reviewed and signed off on from home, while traveling, or simply from another location in the facility. This means products can be released more quickly and analysis can continue in the lab as needed for other products.

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