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Using the *In Vitro* Pyrogen Test in the Validation of Depyrogenation Process by Dry-Heat

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SUMMARY. **In the present study, the feasibility to employ the *in vitro* pyrogen test (IPT) in the validation of depyrogenation process is presented. As one of the main advantages of IPT is its ability to determine pyrogen absorbed to the container surface, direct incubation of diluted whole blood with the endotoxin indicator was first attempted. It was not possible to quantify the endotoxin in control indicators due to the high content, which is discussed. However, it was possible to demonstrate that indicators subjected to the depyrogenation process were indeed pyrogen free, a quality that is difficult to assure when the LAL assay is employed in extract of indicators or medical devices. On the other hand, IPT performed as well as LAL when endotoxin was previously extracted from the indicator surface. Finally, some conditions for incubation of whole blood with the test surface and to dilute the supernatant obtained from the incubation are presented.**

KEY WORDS: Depyrogenation, Endotoxin, *In vitro,* Pyrogen, Validation, Whole blood.

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