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## A PORTABLE TEST SYSTEM (PTS) FOR DETERMINATION OF BAC RIAL ENDOTOXINS IN 18F-FDG RADIOPHARMACEUTICAL.

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**Introduction:** Pyrogens include any substance capable of elicitin febrile response upon injection or infection. Endotoxin is a type of p gen that is strictly of gram-negative origin, a natural complex o popolysaccharide ocurring in the outer layer of the bilayered gram-ne tive bacterial cell. An automated portable test system (PTS) has b developed for determination of bacterial endotoxins in water, in-p cess and end-products using the Limulus amebocyte lysate (LAL) netic chromogenic test. The aim of this work was to validate this met for 18F-FDG radiopharmaceutical. **Materials and methods:** Exp ments were performed in three batches of 18F-FDG produced at IP CNEN/SP in a portable test system (PTS) from Endosafe, Inc.TM, Char ton, SC. Single polystyrene cartridges containing dry LAL-reagents, c trol standard endotoxin (CSE) and synthetic color substrate were us The LAL sensitivity was 0.05 EU mL-1. 25 $\mu$L samples of the produc serial dilutions were pipetted into the cartridge wells and the temp ture of the reaction was 37 ± 1 °C. Results were obtained for the dotoxin concentration in samples by interpolation of an archived st dard curve (5.0; 0.5 and 0.05 EU mL-1) at OD (optical density) 4 nm, after 20 minutes. **Results:** The maximum valid dilution was cal lated to establish the extent of dilution to avoid interfering test co tions (MVD = 500). The endotoxin concentration was lower than lowest concentration of the standard curve in all samples, and the rameters of coefficient correlation (R) ≤ 0.980, recovery of posi product control (RPPC) 50-200% and coefficient variation (CV) of samples < 25% were satisfied from 1:5 until 1:50 dilution factor. D **cussion/conclusion:** The PTS is a new kinetic chromogenic techni for bacterial endotoxin determination. Especially for short-li radiopharmaceuticals, it trends to be the method of choice. The te nique showed to be simple, easy, fast and accurate and the validat was successfully performed.