MICROBIOLOGICAL QUALIFICATION OF A ROBOT, KIRO ISOLATOR® (GRIFOLS), FOR THE PREPARATION OF ANTICANCER CHEMOTHERAPIES

institut Curie COM25-43424

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Introduction

Hospital expansion and steady increase in production: 32 800 bags in 2023 vs 35 600 in 2024 → **8% increase**

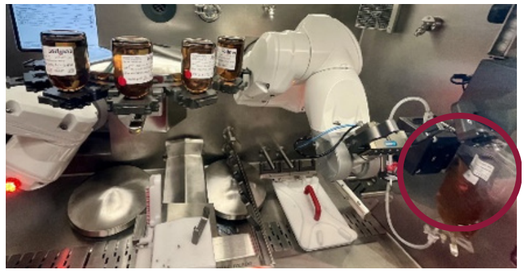
The Kiro Isolator®: an isolator robot capable of handling 10 bags/infusion devices, 8 syringes and 12 vials in the same cycle. 2 arms : 1 for reconstitution and 1 for dosing medications. Gravimetric control is performed at each stage.

Objective: To verify, through microbiological controls, that the Kiro robot's preparation process is carried out aseptically before routine use.

Materials and Method

Training on how to use the Kiro robot → 3 main steps in a cycle :

- **pre-treatment** (weighing empty containers and connecting the tubing to the bag)
- **positioning** containers, solvents and syringes
- **post-treatment** (labelling and weighing containers filled with TSB))



1 cycle of MFT :

2 times per day in 3 days by 3 manipulators

TSB bag → Reconstituted vials

3 10 ml TSB syringes

3 50 ml TSB bags
with total solvent withdrawal

3 infusion devices containing 10 ml of glucose and 50 ml of TSB

Fertility test

Sterilisation of the bag
+
Inoculation of germs
into a TSB bag

Daily sampling: swabbing of handles, contact agar plates on work surfaces, glove prints and active air sampling using an aerobiocolector.

Incubation for 7 days at 20°C, then 7 days at 30°C in an incubator.

Visual inspection of preparations after 14 days to detect any turbidity
Comparison with positive controls

Result

The fertility test proved positive, with microbial growth observed. At the end of the 14-day incubation period, no microbial growth was observed on our 18 bags, 18 syringes and 18 infusion devices prepared by the robot and the various manipulators.

Conclusion

Our results demonstrate that the sterilizing agent does not affect the fertility of the culture medium and that the MFT results are conclusive. The microbiological qualification step of the robot isalidated, as are all stages of the manufacturing process. The robot can now be used routinely for the preparation of anticancer drugs.