

Reallocation of sterile injectable preparations : what is the microbiological risk?

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BACKGROUND

A risk assessment of the reallocation process at Avicenne Hospital identified 17 preventive measures to improve its safety, including performing the procedure **within an isolator** and implementing **analytical testing prior to reallocation**.

OBJECTIVE: To assess the **risk of microbiological contamination** of unused preparations returned from clinical wards and its **potential impact on the microbiological control of isolators**.

MATERIALS & METHODS

1. Simulation of storage under uncontrolled environmental conditions



12 bags filled with tryptic soy broth*



4 storage conditions

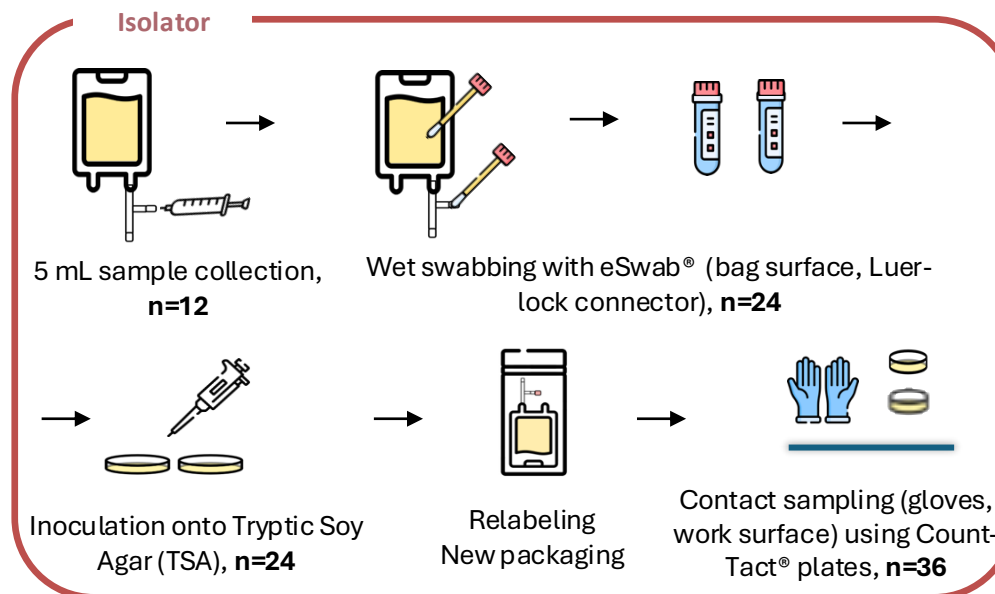


Duration : 24 hours

Group	Storage condition	N
C1	Kept in the sterile zip-lock bag** closed	3
C2	Kept in the sterile zip-lock bag open	3
C3	Removed from the sterile zip-lock bag and handled with gloves	3
C4	Removed from the sterile zip-lock bag and handled without gloves	3

2. Simulation of reallocation in a sterile isolator and sampling

- Start of active air sampling inside the isolator (n=4)



- Incubation **> 30 °C, 72 h**
- Visual inspection of the broth, colony counting on agar plates

RESULTS

- Bag contents: **0 contamination**
- Isolator environment: **0 airborne or surface contamination**
- Bag surfaces: **1 positive sample, smooth external surface** (third bag, group C3)

CONCLUSION & DISCUSSION



Limited microbiological risk associated with reallocation, under the conditions studied



Small sample size
Experimental nature of the study

Product reallocation within a sterile isolator was considered acceptable under the following conditions :

- < 24 h outside a controlled environment
- Storage in the sterile packaging
- Strict acceptance criteria and rigorous traceability

* Tryptic Soy Broth (STBMTS12, Merck), ** Sterile UV-protective overwrap bags (SLB over pack) 150 × 220 mm