

■ Appendix: Recommendation for testing the environmental conditions in a RUMED

Zones:

- Packing zone
- Sterilization zone

Surfaces:

- Critical surfaces
 - Worktops in the packing zone (packing table, heat sealer station)
 - Hand-touch surfaces/sites in both zones (e.g. mouse, touch screen, magnifying lamp, pistol handle, ...)
 - Storage surfaces in both zones
- Non-critical surfaces
 - Surfaces not coming into contact with re-processed MDs (e.g. MD consignment store, MD release site, thermal protection glove, etc.)

Test material:

- Rodac plates
 - TSA agar or TSA with neutralizer
 - 25 cm², round, rigid, with lid

Scope:

- All packing tables/heat sealer stations with at least 3 contact plate samples from:
 - Worktops and
 - Hand-touch surfaces
- At least, 5 contact plate samples from non-critical surfaces in the packing zone
- At least, 5 contact plate samples from critical + non-critical surfaces in the sterilization zone

Frequency intervals:

- Frequency intervals must be specified within the respective establishment.
- Quarterly tests are recommended; less frequent test intervals can be used if the results are normal

Conduct:

- Sampling is done in workflow
- Clearly label the underside of plates with water-proof pen
 - Record date, time, room + sampling site in the accompanying document/protocol
- With disinfected hands, remove the lid of the Rodac plate without touching the nutrient medium
- Applying gentle pressure, press the nutrient medium to the test surface for around 5 – 10 seconds
- Replace the lid without contaminating the nutrient medium

Evaluation:

- Total CFU per Rodac plate
- Differentiation at species level, including quantitative specification per Rodac plate of Gram-negative rods, *S. aureus*, *enterococci*, *streptococci*
- Differentiation of spore-forming from vegetative microorganisms
- Differentiation of other microorganisms as needed for further evaluation (e.g. coagulase-negative *staphylococci*, *micrococci*, moulds, *Candida* spp.)

Limit values:

- Critical surfaces:
 - ≤ 20 CFU/Rodac plate
- Non-critical surfaces:
 - ≤ 25 CFU/Rodac plate
- The following applies for both surfaces: no evidence of
 - *S. aureus*
 - Humidophilic microorganisms
 - Pathogenic microorganisms

Limit value overshooting:

- Repeat test at unsatisfactory site
- In addition, test four similar sites
- If the threshold value is exceeded again in the repeat test, documented analysis of the causes must be conducted and remedial action taken.

TEST LOCATION

MATERIAL + SCOPE

CONDUCT

EVALUATION

LIMIT VALUES

YOU FIGHT FOR PATIENT SAFETY



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