

# Qualification of thermostatic air oven

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### Introduction

BioMérieux is an international company specialized in the in vitro diagnostics for medical and industrial applications. On Marcy l'Etoile's site, there are metrological controls of thermal probes used for checking out the temperature of the storage zones such as incubators or freezers. The thermal probes are standardized every six months for the most critical zones and once a year for the others. This standardization was carried out in a thermostatic air oven with a reference probe. This air oven has a temperature range between  $-25^{\circ}\text{C}$  and  $56^{\circ}\text{C}$ . The metrological department needed to increase this temperature range to  $-31^{\circ}\text{C}$  and  $80^{\circ}\text{C}$ . and realize this qualification for a thermostatic air oven.

### Experimental methods

For the qualification of the new area of use, it was not necessary to re-do an installation qualification since no aspect of the actual installation was modified. Only the operational qualification was realized. It aimed at verifying that the equipment worked in accordance with the specifications. It was made up of several processes.

The first process was to check the documentation relating to post description and operator's training.

The second process consisted in verifying the interface man/machine worked well. In summary the operator had to check the fonctions of the programme.

The last process was the study of the temperature homogeneity in the thermostatic air oven on totality of measurement point :  $-31^{\circ}\text{C}$ ,  $-25^{\circ}\text{C}$ ,  $2^{\circ}\text{C}$ ,  $8^{\circ}\text{C}$ ,  $22^{\circ}\text{C}$ ,  $37^{\circ}\text{C}$ ,  $56^{\circ}\text{C}$ ,  $80^{\circ}\text{C}$ . Nine Kaye probes were used and were strategically arranged in the air oven. Kaye probes measured and stored the temperature every minute during the cycle. These measures were compared with the reference probe of the air oven. The following tests were realized : vacuum (limit  $\pm 2^{\circ}\text{C}$ ), in the oil (limit  $\pm 0.5^{\circ}\text{C}$ ) and in the plexiglas (limit  $\pm 0.5^{\circ}\text{C}$ ).

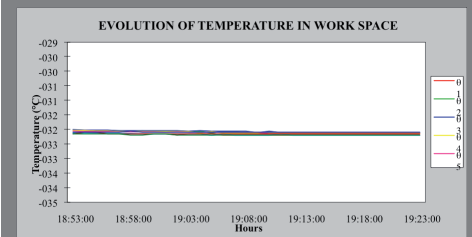
### Results and discussion

- First process : All the required documentation existed and was up to date.
- Second process : Following the test of the interface man/machine a difference file\* was emitted. After modification in the « graph set » the test results were in accordance with the requirements, consequently the difference file\* was closed.
- Third process : All the results of the homogeneity test were in accordance with the requirements. All homogeneities measured were lower than the criteria of acceptance. For exemple in the oil at  $-31^{\circ}\text{C}$  the homogeneity was  $0.23^{\circ}\text{C}$ .

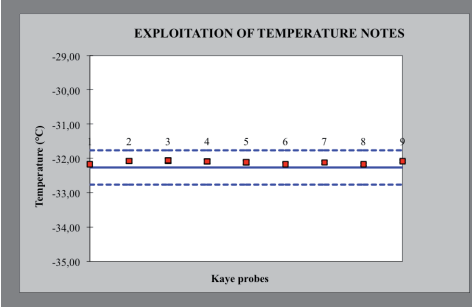
Graph 1 represents the stability of every Kaye probes during the cycle (29 hours). Graph 2 shows the average values (red square) and limit values of acceptance (blue dotted line) and wanted / desired temperature (blue line).

Study of temperatures measured on 30 minutes

Graph.1



Graph.2



### Conclusion

The results were in accordance with the requirements. The range  $-31^{\circ}\text{C}$  +  $80^{\circ}\text{C}$  was qualified, and a certificate of qualification was written. The metrological department can use this temperature range. The data file was re-issued and new calculations were carried out in order to specify the right zone within the area of use. These new calculations avoided the taking out of the thermal probe which is correct in the thermal zone of utilisation even if the result is not totally complying with the demand in the work area. For exemple thermal probe for the freezer must be in accordance with the temperature range  $-25^{\circ}\text{C} \pm 6^{\circ}\text{C}$  so the accordance with the other temperature are not taken into account.

\*Difference file : report of non-compliance