

STABILITY STUDY : THERMAL SHOCK VALIDATION

Product : Columbia agar

Reference : 51026: 500g

51280: 1kg

Introduction:

The stability of Columbia agar, reference 51026 and 51280, has been verified by performing real time stability study including thermal shocks sequence to simulate delivery process.

Protocol:

This study is carried out according to the EN 13640 "Stability testing of in vitro diagnostic reagent" recommendations. The storage temperature of Columbia agar is 2-30°C. Therefore, the validated stability trials include tests at 18-25°C and thermal shocks out of temperature specification of 48 hours at < -5°C and 48 hours at 35-39°C. The stability study is realized by family product and the tested reference is 51044, Trypcase-Soy agar. This study supports product performance during shelf life.

Summary of the stability study protocol:

The trials that have been performed consist of verifying the conformity of appearance, pH, fertility, qualitative control and Optochin and Bacitracin tests.

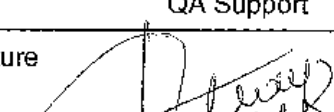
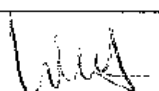
Several points have been tested during the stability study:

T₀ = initial point

T_i = middle point

T_x and T_{x+1} (T_x corresponding to the shelf-life)

The performances are maintained until expiration date.

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August 2006		August 2006	