Ns. Rif. RAQ031_06/2017

TO WHOM IT MAY CONCERN

Pero, 08/06/2017

SUBJECT: Chromosome Kit and Chromosome Medium P Stability tests under boundary conditions

Hereby, Euroclone S.p.A., as Chromosome Kit and Chromosome Medium P manufacturer, declares that a risk analysis was performed to identify boundary conditions for stability tests reflecting specific Device intended use and stated shelf life, according to "TGS 2 Establishing stability of an in vitro diagnostic medical Device for WHO". Some results are listed below, but other tests are running on.

1. **Tests on thaw-freeze cycles.**

Chromosome Kit and Chromosome Medium P maintain specific quality performances up to expire date if no more than two thaw-freeze cycles occur before use.

2. **Storage at different conditions from -22°C/-18°C.**

Chromosome Kit and Chromosome Medium P maintain specific quality performances also stored at +4°C up to 14 days. During this period, use the Device. Don't freeze again.

3. **Testing time.**

Chromosome Kit and Chromosome Medium P can be maintain at room temperature (+20°C/+25°C) till 3 hours to set up the test.

4. **Stability test after transport validation**

Chromosome Kit and Chromosome Medium P maintain specific quality performances up to expire date if received both completely frozen or partially thawed. In the second case, freeze immediately or aliquot as convenience. So a shipping delay doesn't compromise quality performance if the Device is properly stored.

5. **Long-Term Stability**

Quality Control lab preliminary data demonstrate that if Device is stored in proper conditions, performances are maintained up to 15 months after production.

Our quality control lab preliminary data demonstrate that if Device is stored in proper conditions, performances are maintained up to 15 months after production. Additional tests are planned in order to verify a possible shelf life extension. At date, the IVD Device shelf life is 12 months from production.

Best regards.

Dr. ssa Monica Munaro
QA/RA Supervisor

EUROCLONE S.p.A. - Sede legale: Via Spezia, 1 - 20142 Milano (Italy)
Sede amministrativa:Via Figino, 20/22 - 20016 Pero (MI) Italy - Ph. +39 02 38195.1 - Fax +39.02 38101465 - www.euroclone.it - info@euroclone.it
C.F. P.IVA e n°Registro Imprese Milano 08126390155 – REA Milano 1208538 - Cap. Soc. Euro 3.000.000,00 i.v.