

Product: pH validation dish
Catalogue No.: 16452
Lot No.: E1-P8-1706-1
Manufactured: June 2017

We hereby confirm that the LOT indicated above will be validated in accordance with the following tests. Before final release for distribution the product has to pass all tests with acceptable results:

pH equilibration	3 mL sample of un-equilibrated G-TL media (pH >8.2) equilibrates to a stable pH 7.30 ± 0.10 when incubated at 37°C in 6 % CO ₂ atmosphere for 8 hours. The pH remains stable for up to 24 hours.
Evaporation	Evaporation of 3 mL media in a non-humidified incubator at 37°C is < 2 % after 24 hours.
Leakage	Weight difference before and after leakage test < 0.05g No physical spillage seen.
Embryo toxicity	Presence of pH validation dish with silicone lid and attached label does not adversely affect embryo development in adjacent culture dishes as assayed by 1-cell mouse embryo assay giving ≥ 80 % expanded blastocysts after 96 hours in a closed environment. The embryo toxicity test is a release test and the product will only be sold if it has passed satisfactorily.

The product is not a medical device according to EU directive 93/42/EEC and may NOT be used to cultivate human embryos. .

Quality assurance of the product is performed in accordance with the requirements of the Quality Management System DS/EN ISO 13485:2012, "Medical devices - Quality management systems - Requirements for regulatory purposes".



Torben Christian Christensen
 QC&RA Manager