A Sysmex Group Company

CytoCell® Stability Statement

To whom it may concern,

OGT's range of CytoCell liquid FISH probes, DAPI Antifade, and Hybridisation Solutions are manufactured in our Cambridge UK facility under a Quality Management System (QMS) that has been certified as compliant to ISO 13485:2016, ISO 9001:2015, and the full MDSAP audit criteria.

CytoCell IVDs are CE marked in accordance with the applicable European In Vitro Diagnostic Medical Devices legislation:

- FISH Probe Kits - Directive 98/79/EC (General IVDs placed on the market under the transitional provisions listed in Article 110(3) of Regulation (EU) 2017/746, as amended by Regulation (EU) 2022/112).
- DAPI Antifade ES - Regulation (EU) 2017/746 (Class A IVD accessory).

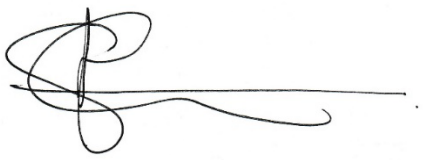
In addition, OGT have (where applicable) developed verification procedures based on BS EN ISO 23640:2015 and CLSI EP25-A to determine or transfer the shelf life of CytoCell products and their stability during storage and transportation.

Further data supporting the stability of a product is gathered when testing retain samples during any post-production investigations or complaint investigations.

Therefore, the data on file indicates the following, regarding the stability of CytoCell products:

> Our CytoCell liquid FISH probes, DAPI Antifade and Hybridisation Solutions can be shipped at ambient temperature (up to 40°C) for up to a total maximum of 14 days (including shipping to distributors and onward shipping to customers) with no detrimental effect on their stability. The products should then be stored at their relevant recommended temperature on arrival at their destination.
>
> The shelf life of our CytoCell liquid FISH probes, DAPI Antifade and Hybridisation Solution I can be supported up to 24 months (2 years) from date of manufacture (when stored as indicated on the labelling).
>
> The shelf life of our Hybridisation Solution B can be supported up to 30 months (2.5 years) from date of manufacture (when stored as indicated on the labelling).

Signed for and on behalf of Cytocell Limited and OGT on 06 July 2022 by:



Steve Chatters, DipRCPath
Executive VP of Regulatory, Medical, and Quality Affairs, OGT

Cytocell Limited, OGT
418 Cambridge Science Park, Milton Road, Cambridge, CB4 0PZ, UK
T: +44 (0)1223 294048 F: +44 (0)1223 294986 E: probes@cytocell.com W: ogt.com

CytoCell