

PAL SYSTEM – «IVDready»

- «IVDready»: PALsystem as a part of a dedicated instrument setup is compliant and ready for approval for clinical use / IVD
- Designed, developed, manufactured, tested, and supported under QM-System according to ISO 13485 also covering 21CFR820
- Technical documentation available upon audit request by authorities or notified bodies at CTC Analytics:
 - Risk analysis summary available
 - EMC testing summary available
 - Safety testing summary available
- CTC Analytics supports OEMs in their approval process for clinical diagnostic applications according to the directive 98/79/EC and regulation 2017/746 for Europe and 21CFR807 and 21CFR809 for the United States
- Applies to all PAL3 Systems

EU **Ready** for conformity assessment according to the directive 98/79/EC and regulation 2017/746

Quality Management System (EN ISO13485)

Electromagnetic Compatibility (EN IEC 61326-1 incl. EN IEC 61326-2-6)

Safety (EN IEC 61010-1 incl. EN IEC 61010-2-101)

USA **Ready** to support the listing/approval of such systems by the OEM

Quality Management System (21CFR820)

Electromagnetic Compatibility (FCC)

Safety (UL/ANSI/CSA 61010-1 incl. 61010-2-101)

