Statement of quality

cGMP manufacturing and TaqPath qPCR master mixes

Thermo Fisher Scientific is dedicated to quality and operational excellence in everything we do—from how we manage our core quality processes, to our facility investments and our risk management systems. As a part of this commitment to quality, all Applied Biosystems™ TaqPath™ qPCR master mix products are manufactured in an ISO 13485–certified and FDA-registered facility, which adheres to the principles of current good manufacturing practices (cGMP).

cGMP principles for these products include, but are not limited to:

- ISO 13485:2016 certification at all manufacturing sites in which TaqPath qPCR master mix products are produced
- Complaint handling, surveillance, deviation investigation, associated corrective and preventive actions, and a risk management system compliant with ISO 13485 and United States 21 CFR Part 820 requirements
- Established change control and notification processes
- Supplier qualification and raw material quality control (QC) procedures
- Traceability, handling, and controlled storage of raw materials through to finished product
- Documented and validated manufacturing and QC methods
- Suitable process and production controls with defined batch release specifications and records
- Product stability programs
- Well-educated and trained personnel with documented training records
- Documentation controlled through an electronic document management system (EDMS)
- Environmental controls, and cleaning and monitoring procedures, for equipment and facilities
- Qualified, and routinely calibrated and maintained, critical manufacturing and QC equipment—installation qualification, operational qualification, and performance qualification (IQ/OQ/PQ)

Learn more at **thermofisher.com/taqpath**