

Are you worried about noncompliance?

Companies in the pharmaceutical, applied testing, and molecular diagnostics industries are regularly challenged to meet rising standards of quality and comply with regulatory requirements (e.g., GLP, GCP, GMP, ISO 17025, ISO 15189, US FDA 21 CFR Part 11, CLIA, CAP). The process can be time consuming if there is a lack of expertise or support to accelerate the in-house validation and accreditation process. Accreditation to international standards demonstrates competencies of the laboratory and brings extra revenue to the business. **Noncompliance can be expensive!**



QIAGEN Service Solutions helps you to achieve cost-effective compliance:

- Maximum instrument uptime
- Quality of test results assured
- Secure inspection/maintenance schedule
- Onsite user training with certificates
- Installation qualification/operational qualification
- LIMS Integration to support Computer System Validation
- Comprehensive documentation/calibration reports to be integrated into QA management system

Valuable services for your peace of mind:

Service Option	Preventive Maintenance/ Inspection Service	On-site response time*	Hotline Priority	Repair parts, labor, travel	IQ/ OQ	Application Training	Service Documentation	Proactive Contract Renewal	LIMS Integration Service
PM/Inspection Service	✓						✓	✓	
Basic Agreement	✓	5 days	Medium	✓			✓	✓	
Full Agreement	✓	48 hours	High	✓			✓	✓	
Premium Agreement	✓	24 hours	Highest	✓			✓	✓	
IQ/OQ Service					✓		✓		
Application Training						✓	✓		
QIAlink™							✓		✓

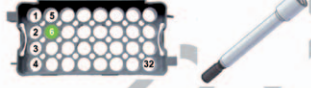

* On-site response time: subject to local terms and conditions.



QIAcube		QCU0069			
Item		Check		D #	
SAP	Name	Quantity	Passed	Failed	
Instrument and Accessories					
9001202	QIAcube (110V)	1	<input type="checkbox"/>	<input type="checkbox"/>	
9001203	QIAcube (230V)	1	<input type="checkbox"/>	<input type="checkbox"/>	
9017847	Shaker Rack	1	<input type="checkbox"/>	<input type="checkbox"/>	
9017848	Rotor	1	<input type="checkbox"/>	<input type="checkbox"/>	
9017849	Swing-out Buckets	12	<input type="checkbox"/>	<input type="checkbox"/>	
9017851	Labware Tray	1	<input type="checkbox"/>	<input type="checkbox"/>	
9017852	Rotor Nut	1	<input type="checkbox"/>	<input type="checkbox"/>	

Tab. 2.5-2 List of accessories and supplies

SPQCU001A, Rev. 1.0 Installation Qualification 12

QIAcube		QCU0069			
Test/Requirements	Accept. Criteria	Passed	Failed	Comment	D #
Tip check sensor test CAUTION: Remove the bottle rack for this test! This test requires the usage of the tip check sensor test adapter included in the IQ/OQ Tools kit. QIAC (9018578). Load the tool equipped with the 1000 µl bit in position 6 of an empty 1000 µl tip rack, load the tip rack on the labware tray.					
					
Start the test: 'IQ/OQ → 1. IQ/OQ QIAcube → 7. Tip check sensor test → 1. 1000 µl Tip width test' CAUTION: The test adapter cannot be disposed of as a normal tip. To avoid damage to QIAcube, prepare to cancel the run as soon as QIAcube has picked the test adapter. Press "Cancel" followed by "OK" to confirm as soon as the adapter has passed the tip check sensor. Turn OFF QIAcube, remove the tip check sensor test adapter from the tip adapter manually. Turn ON QIAcube and download the logfiles to the USB stick. Check in the logfile that the correct width has been measured.					
Value:	95 - 155	<input type="checkbox"/>	<input type="checkbox"/>	Discrete value	
Load the tool equipped with the 200 µl bit in position 6 of an empty 200 µl tip rack, load the tip rack on the labware tray.					
					
Start the test: 'IQ/OQ → 1. IQ/OQ QIAcube → 7. Tip check sensor test → 2. 200 µl Tip width test' CAUTION: The test adapter cannot be disposed of as a normal tip. To avoid damage to QIAcube, prepare to cancel the run as soon as QIAcube has picked the test adapter. Press "Cancel" followed by "OK" to confirm as soon as the adapter has passed the tip check sensor. Turn OFF QIAcube, remove the tip check sensor test adapter from the tip adapter manually. Turn ON QIAcube and download the logfiles to the USB stick. Check in the logfile that the correct width has been measured.					
Value:	10 - 50	<input type="checkbox"/>	<input type="checkbox"/>	Discrete value	
Tab. 3.5-2 Qualification tests					
SPQCU001A, Rev. 1.0		Operational Qualification		40	

Sample documentation of Installation Qualification and Operational Qualification.

The IQ/OQ Services provides documented verification that your systems are installed and functioning according to manufacturers' specifications. Comprehensive user trainings are provided to certify the quality of your laboratory personnel. Routine inspections and preventive maintenances help you to ensure highest quality of patient results. All services are provided by experienced and highly qualified QIAGEN specialists.

For detailed information and availability of service products, please contact your regional sales manager or email: service_sales_eu@qiagen.com.

Customer has the sole responsibility to ensure that QIAGEN and/or its affiliate(s) products and services, including but not limited to qualification and validation, are adequate to meet customer's own regulation, certification, and other requirements.

QIAGEN Service Solutions is intended as a general-purpose device for laboratory use. No claim or representation is intended for its use to identify any specific organism or for clinical use (diagnostic, prognostic, therapeutic, or blood banking).

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Austria ■ 0800-281011
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