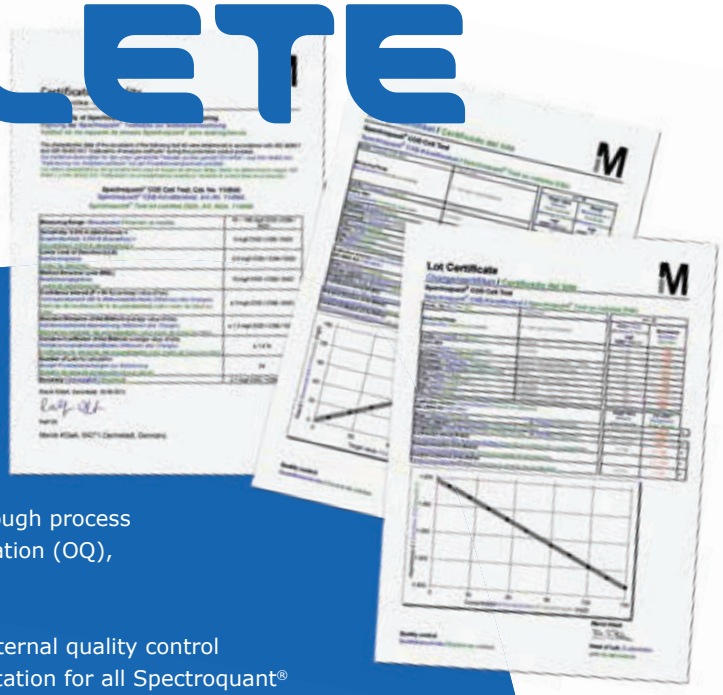
# Spectroquant®
# Analytical Quality Assurance

# SIMPLY COMPLETE



**Analytical Quality Assurance [AQA]** is the practice of ensuring that your results are reliable and conform with Good Laboratory Practice (GLP) guidelines. This thorough process includes installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).

**The Spectroquant® AQA concept** covers all stages of internal quality control (IQC). We also provide complete IQ, OQ and PQ documentation for all Spectroquant® instruments. Target values and tolerances are either supplied in certificates or pre-programmed in the instruments.

**Installation Qualification [IQ]** aims to verify that instrument delivery matches the purchase order, and to assure that it is installed correctly.

## AQA 3 steps to great quality

1 **PHOTOMETER CHECK:** Operational qualification (OQ)
Easy to perform with certified color standards, or Certipur® UV/Vis standards

2 **SYSTEM CHECK:** Performance qualification (PQ)
Recovery measurement using CombiCheck standard solution, certified reference material (CRM) standard solutions, or Certipur® standard solutions

3 **MATRIX CHECK:** Performance qualification (PQ)
One-time spiking with CombiCheck R-2 solution, or multiple dilution/spiking with certified reference material (CRM) standard solutions or self-prepared solutions.

# PHOTOMETER CHECK

AQA 1

### Operational qualification (OQ) – Checking the instrument

The aim of OQ is to assure the instrument's functionality over the entire operating range, according to defined procedures.

### Photometer Check

All Spectroquant® instruments are checked using certified color standards, or Certipur® UV/Vis standards.

### Spectroquant® NOVA and Spectroquant® Prove photometers

These photometers offer an instrument-supported AQA concept that combines the three essential components of quality control. For effortless, accurate AQA – **target values and tolerances are on the certificate, and can be stored and used for further checks.**

| Photometer Check | Information | Content | Ord. No. | Prove | NOVA | Move 100 \| 300 \| 600 | Move 30 \| 60 \| 60A | Move 100 | Multy $Cl_2/O_3/ClO_2/CyA/pH$ |
|---|---|---|---|---|---|---|---|---|---|
| **Spectroquant® Zero Cell** | We recommend replacing the zero cell every 2 years. | • One 16-mm cell filled with distilled water | **1.73503.0001** | ■ | ■ | | | | |
| **Spectroquant® PhotoCheck** | Secondary standards are compliant with ISO 9001, ISO 14001 and ISO 17205 guidelines, and calibrated with instrument qualified with NIST standards. | • Check solutions for 3 different wavelengths<br>• 2 zero cells<br>• 2 cells for checking the bar-code reader (only for Spectroquant® NOVA photometers) | **1.14693.0001** | ■ | ■ | | | | |
| **Spectroquant® Verification Standards** | Standards are supplied in sealed vials, which are individually calibrated on instruments traceable to NIST SRM 2032, 935a. | • 1 zero standard<br>• 6 cells for checking 6 different wavelengths of the instrument | **1.19302.0001** | | | ■ | | | ■ |
| **Spectroquant® Reference Standards** | Standards are supplied in sealed vials, which are individually calibrated on instruments traceable to NIST SRM 2032, 935a. | • 1 zero standard<br>• 3 cells for checking 3 different concentrations for chlorine, chlorine dioxide and ozone method in the instrument | **1.19301.0001** | | | | | ■ | |
| **Spectroquant® PipeCheck** | For checking pipettes and documenting results, without the need for a precise balance. | • 24 cells with check solutions<br>• 4 cells with corresponding reference solutions | **1.14962.0001** | ■ | ■ | ■ | | ■ | ■ |

# Spectroquant®
# Analytical Quality Assurance

## Certipur® UV/Vis standards

Certipur® UV/Vis standards can be used to verify the consistent and correct operation of your UV/Vis spectrophotometer.
The solutions are suitable for checking the following parameters as per Ph Eur:

- Absorption
- Stray light
- Wavelength accuracy

Operations as per GLP, GMP, USP and ISO 9001 or ISO 45001 demand these regular controls.
All standards are traceable to NIST.

| Designation | Content | Ord. No. | Prove 100 | Prove 300 | Prove 600 |
|---|---|---|---|---|---|
| UV/Vis Standard 1 | Potassium dichromate solution for absorbance acc. to DAB and Ph Eur Certipur® 2 x 10 mL $K_2Cr_2O_7$ – 60.06 mg/L in $H_2SO_4$ – 0.01 N and 6 x 10 mL $H_2SO_4$ – 0.01 N | 1.08160.0001 | ■ | ■ | ■ |
| UV/Vis Standard 1A | Potassium dichromate solution for absorbance at 430 nm acc. to DAB and Ph Eur Certipur® \| 2 x 10 mL $K_2Cr_2O_7$ – 600.06 mg/L in $H_2SO_4$ – 0.01 N and 6 x 10 mL $H_2SO_4$ – 0.01 N | 1.04660.0001 | ■ | ■ | ■ |
| UV/Vis Standard 2 | Sodium nitrite solution for stray light testing acc. to DAB and Ph Eur Certipur® 3 x 10 mL $NaNO_2$ – 50 g/L in $H_2O$ | 1.08161.0001 | ■ | ■ | ■ |
| UV/Vis Standard 3 | Sodium iodide solution for stray light testing acc. to DAB and Ph Eur Certipur® 3 x 10 mL NaI – 10 g/L in $H_2O$ | 1.08163.0001 | | | ■ |
| UV/Vis Standard 4 | Potassium chloride solution for stray light testing acc. to DAB and Ph Eur Certipur® \| 3 x 10 mL KCl – 12 g/L in $H_2O$ | 1.08164.0001 | | | ■ |
| UV/Vis Standard 5 | Toluene solution in n-hexane for testing the resolution power acc. to DAB and Ph Eur Certipur® \| 2 x 10 mL 0.02 % (v/v) toluene and 6 x 10 mL n-hexane | 1.08165.0001 | | | ■ |
| UV/Vis Standard 6 | Holmium oxide solution reference material for wavelength testing acc. to DAB and Ph Eur Certipur® \| 3 x 10 mL $Ho_2O_3$ – 40 g/L in $HClO_4$ (10 % v/v) | 1.08166.0001 | ■ | ■ | ■ |

# SYSTEM CHECK AQA 2

**Performance qualification [PQ] – Checking the complete system and sample matrix**
Verifying product-related functionalities is the most comprehensive step in the process, and involves the measurement of both method-specific standards and real samples. PQ consists of two components: System Check and Matrix Check.

**System Check**
System Check covers all components of the analysis (instrument, test kit, standard, pipette and/or cell, and operator).


▸ **The recommended standard solutions for each Spectroquant® test kit are listed on page 92 – 97.**
▸ **Spectroquant® CombiCheck** — **Product information see page 98 – 101**
▸ **Standard solutions (CRM) for photometric applications** — **Product information see page 102**
▸ **Certipur® standard solution** — **Product information see page 106**

# MATRIX CHECK

# AQA 3

**What:** Matrix Check, identifies measurement errors due to interferences from foreign substances in the sample. As they can significantly interfere with results, various foreign substances have been investigated to define the maximum concentration at which they may be present in samples without causing errors. These limits are stated in the package insert of each Spectroquant® test kit.

**Why:** For samples with very complex or unknown compositions, interferences can be analyzed based on recovery rates, and rectified through appropriate countermeasures, such as sample pre-treatment.

**How:** Depending on the sample concentration, there are two methods to choose from:

**1. One-time standard addition (spiking) with CombiCheck R-2 addition solution**

▸ **Spectroquant® CombiCheck** **Product information see page 98 – 101**

**2. Multiple dilutions or spiking with self-prepared spiking solutions**

To avoid changing the sample matrix, spiking solutions should be highly concentrated standards, and used in small quantities relative to the sample portion.

▸ **Standard solutions (CRM) for photometric applications** **Product information see page 102**

▸ **Certipur® standard solution** **Product information see page 106**

Comprehensive quality assurance using IQ, OQ, and PQ documents will transform your measurements into proven, verifiable analytical results. **Please contact your local Merck representative to learn more about our quality assurance service.**

# PROTECT YOUR DATA

**Password-protected control of the complete system**

- Ensure AQA intervals are observed by issuing a password (NOVA photometers), or defining hierarchical user groups (Prove spectrophotometers)
- Measurements and methods are only possible if quality control checks and intervals are adhered to
- Documentation of AQA results are provided in the final report, proving GLP compliance and ensuring that the system is tested