

Nitrite Spectroquant® Test Kits Equivalency Checklist for Laboratories

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Introduction

This report lists the requirements for documentation and quality control required by the current 2012 promulgated 40 CFR part 136.6 that a laboratory must have onsite to establish method equivalency for the Spectroquant® Nitrate Test Kits.

Laboratory Requirements for Equivalency Documentation

This checklist applies to current Merck KGaA, Darmstadt, Germany, Spectroquant® Nitrate Test Kits:

1. 1.00609
2. 1.14547
3. 1.14776

The laboratory check list in Table 1 should be used to provide equivalency documentation for laboratory result users and regulatory auditors. Copies of the reports “*Equivalency of Spectroquant® Nitrite Method Azo Dye Test Kits Nitrite Method Iron Redox Test Kit Reactions and Photometry*” and “*Nitrite Spectroquant® Test Kits Equivalency Checklist*” along with the “*Nitrite Spectroquant® Analytical Test Kit Method*” can be obtained from <http://www.emdmillipore.com/USEPA>

Initial and ongoing quality control (QC) as required both in 40 CFR part 136.6(b)(2)(i)(A) and 40 CFR part 136.7 is detailed in the “*Nitrite Spectroquant® Analytical Test Kit Method*”. When developing an in-lab Standard Operating Procedure (SOP) care must be taken to not leave out any of the QC requirements in the method as this will not meet the requirements of Method Equivalency as outlined in 40 CFR part 136.6(b)(2)(i)(A).

The laboratory must refer to the current promulgated 40 CFR part 136 for updated equivalency requirements.

Additional information can be obtained at <http://www.emdmillipore.com/USEPA>

| Table1: Laboratory Method Equivalency Checklist | |
|--|---------------------------|
| Item from Reding Memo | Check Off (Yes/No) |
| 1. Have a detailed Standard Operating Procedure (SOP) available. (Guidance provided in Spectroquant® method) | |
| 2. Performing and document an initial demonstration of capability. (Required in Spectroquant® method) | |
| 3. Verify the modified method by analyzing and documenting 3-7 representative effluents (QC in the Spectroquant® method meets this requirement as per 40 CFR part 136.6(b)(2)(i)(A)). | |
| 4. The facility/lab is to show they can get the modified method to work and that it gets comparable results for their effluent. (QC in the Spectroquant® method meets this requirement as per 40 CFR part 136.6(b)(2)(i)(A)) | |
| 5. A demonstration of calibration linearity or use of a calibration curve. (required in Spectroquant® method) | |
| 6. Periodic calibration verification (Required in Spectroquant® method) | |
| 7. An ongoing demonstration of performance (ongoing precision and recovery (OPR) and a blank with each sample batch (Required in Spectroquant® method) | |
| 8. A demonstration of the method detection limit (MDL) (Required in Spectroquant® method) | |
| 9. Matrix spike and matrix spike duplicate for each discharge the first time that the sample of the discharge is analyzed and at a frequency of 5% thereafter (Required in Spectroquant® method) | |
| 10. Meeting the quality control (QC) specifications of the method. (See Spectroquant® method) | |
| 11. Keep on hand the modified method manufacturer's supporting data available for review when the manufacturer has developed the method modification. | |