CAPE Technologies

Technical Note TN-006

Quality Assurance for Screening Method Data

Do I need to follow up my Method 4025/4025m results with analysis by conventional methods?

The US EPA Office of Solid Waste and Emergency Response has accepted the CAPE Technologies DF1 Dioxin/Furan Immunoassay for use in Method 4025 under the SW-846 Compendium of Solid Waste Methods. This means that screening results from Method 4025 are considered valid and acceptable for regulatory purposes when SW-846 methods are required and when adequate quality assurance (QA) is included.

Method 4025/4025m for dioxin/furan TEQ is a screening method rather than a definitive method. Technically you should expect to confirm some percentage of both positive and negative results by the definitive method. However, with proper QA performed within Method 4025, it is possible to generate valid screening results with minimal everyday support from conventional methods like 8290. The final answer depends partly on how you plan to use the results, and partly on the regulations that govern your particular situation.

If you are only interested in relative quantitation, as described in Technical Note TN-004, then your QA requirements, including followup, are much less rigorous. If you are interested in absolute quantitation, per TN-004, then your requirements are subtantially more rigorous. In either case, you should read the discussion below.

US EPA SW-846 methods, including Method 4025, are written as performance based methods, part of a performance based measurement system (PBMS). Under PBMS, method performance is not guaranteed by following the written protocol, though this is obviously an important part of running the method. The validity of results from a method is not assured by the intrinsic validity of the method, but rather through proper use of an ongoing stream of QA samples. These samples are selected specifically to demonstrate method attributes such as sensitivity, specificity, accuracy, and precision.

During routine screening use of Method 4025, nearly all QA requirements can be met within Method 4025, with no need for routine confirmation by Method 8290. Sensitivity and precision are addressed primarily using blanks and samples spiked near the decision level and analyzed only by Method 4025 (method blanks, spiked method blanks, matrix spikes, duplicates, and matrix spike duplicates). Quantitative use of Method 4025 allows for determination of spike recovery values and corrections based on these QA samples. Frequency of blanks, spikes, and replicates are determined by your individual situation.

Accuracy is addressed to a significant degree with these same QA samples, but can be further established based on selected reference samples such as Standard Reference Materials (SRMs). However, beyond these routine QA samples analyzed within Method 4025, any final assessment of quantitative accuracy requires that some number of samples be analyzed by Method 8290 or an equivalent definitive GC-MS method. The specifics of this confirmation process will be determined by your individual situation.

Remember that under PBMS, "It is the responsibility of the analyst to demonstrate that the method is working correctly." Or, as stated in Section N of the DF1 Kit Insert (IN-DF1), "Proper quality assurance is the responsibility of the analyst and is essential to analytical success"