

Supplemental Information Supplied by the Developer

Xenobiotic Detection Systems Comments on EPA Site Program Data

Xenobiotic Detection Systems is pleased to have been invited and to have participated in this study. The EPA and Battelle have run a rigorous cross validation study comparing our XDS CALUX screening estimates of dioxin-like chemicals to high resolution gas chromatography/mass spectrometry analysis of chlorinated dioxins/furans and polychlorinated PCBs. This was a highly complex project demanding analytical precision over 7 logs of concentration for these toxic chemicals, and was an exceedingly difficult accomplishment for any analytical procedure.

XDS is proud of the characterization of the XDS CALUX technology provided in this report. It clearly illustrates the value of our technology in examining toxicity issues in soil and sediment samples. The study also demonstrates the technology is applicable to other matrices and situations.

“These data suggest that the XDS technology could be an effective tool to screen samples as being above or below 1 pg/g TEQ or TEQ_{D/F} and total TEQ, and that it could be effective for all three types of TEQ values to determine results above or below 50 pg/g.”

“The total cost for the CALUX by XDS to analyze all 209 samples was \$89,564. The cost for the reference laboratory to analyze all 209 samples by Method 1613B and Method 1668A was \$398,029. The total cost for the CALUX by XDS was \$308,465 less than the reference method.

“During the field demonstration, 43 samples were processed by XDS...in about 5 full working days. XDS completed the remaining 166 samples in their laboratory within 6 weeks of the demonstration. For comparison, the reference laboratory took 8 months to report all 209 samples.”

XDS CALUX was designed to be a screening tool to evaluate contamination by these chemicals. The bioassay was able to provide estimates of contamination particularly at the action levels of regulatory agencies for soil samples and at significant cost savings. The method detection limit was determined to be between 0.53 pg to 0.63 pg TEQ/g sample and provides sufficient sensitivity for screening samples at 1 pg/g TEQ and 50 pg/g TEQ for dioxins/furans yielding approximately 6 % false positives and 0% false negatives.

The screening mode of the XDS CALUX analysis used in this study entails extraction of the sample once, processing with a single determination at a variety of dilutions of the extract to provide a crude estimate of the concentration of dioxin-like activity. This screening mode for the XDS-CALUX assay is not appropriate for defining precision and accuracy with any confidence. However, our quantitative mode of analysis is more appropriate to provide this level of sample detail in an environment of high confidence and at detection levels below one part per trillion.

Due to fiscal, time constraints, and the need to demonstrate the technology in the field in this study, our participation was limited to providing the screening analyses of these EPA-Battelle samples. A more appropriate XDS CALUX analysis for defining precision and accuracy is provided by our quantitative mode of the assay using triplicate analysis (preparing three individual extracts from a single sample and analyzing these independently). This comprehensive triplicate analysis allows for the determination of the relative standard deviation (RSD) of the analyses and this figure is generally less than 20%.

Below is a chart (Figure 1) demonstrating the relationship between results on chlorinated dioxins/furan TEQ provided by XDS CALUX analyses for the EPA-Battelle samples versus the reference GC/MS laboratory results using a log-log plot.

The data correlate well ($R^2 = 0.8448$).

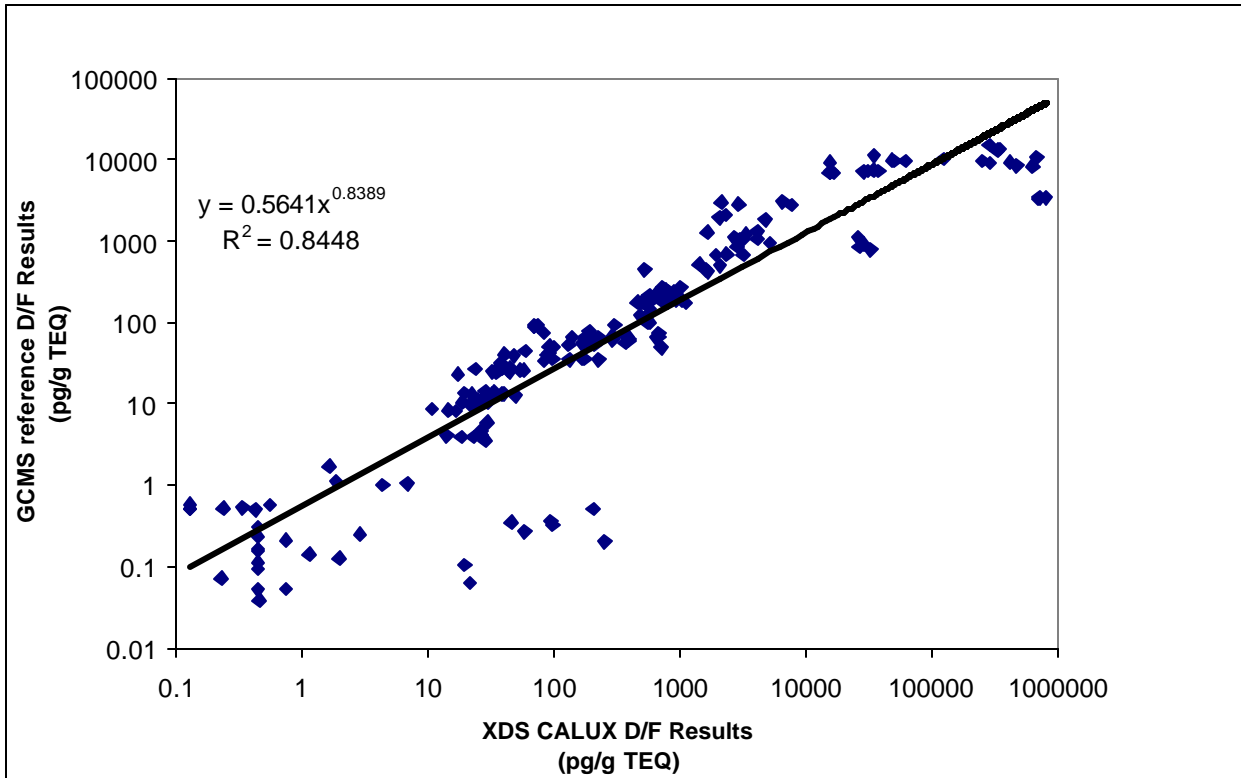


Figure 1

These screening data points do not demonstrate a strict one to one correspondence. This is expected since the TEQ estimates by XDS CALUX receptor based technology provides an estimate of activation of the receptor by the chemical extract. Many biological responses are logarithmically related to concentration. The plotting of this relationship generates one model that describes the relationship.

The deviation from a direct relationship occurs for a number of reasons including such factors as presence of other halogenated dioxins and furans, differences in the REP values of XDS cells versus the TEF values used to scale the GC/MS estimates of TEQ, and the kinetics of binding and activation of the receptor. Modeling the data we can derive a formula to transform the CALUX data to provide a better estimate of the GC/MS data.

The formula for Figure 2 is $y = 0.8389x - 0.2467$, where $y = \log \text{GC/MS}$ and $x = \log \text{CALUX}$.

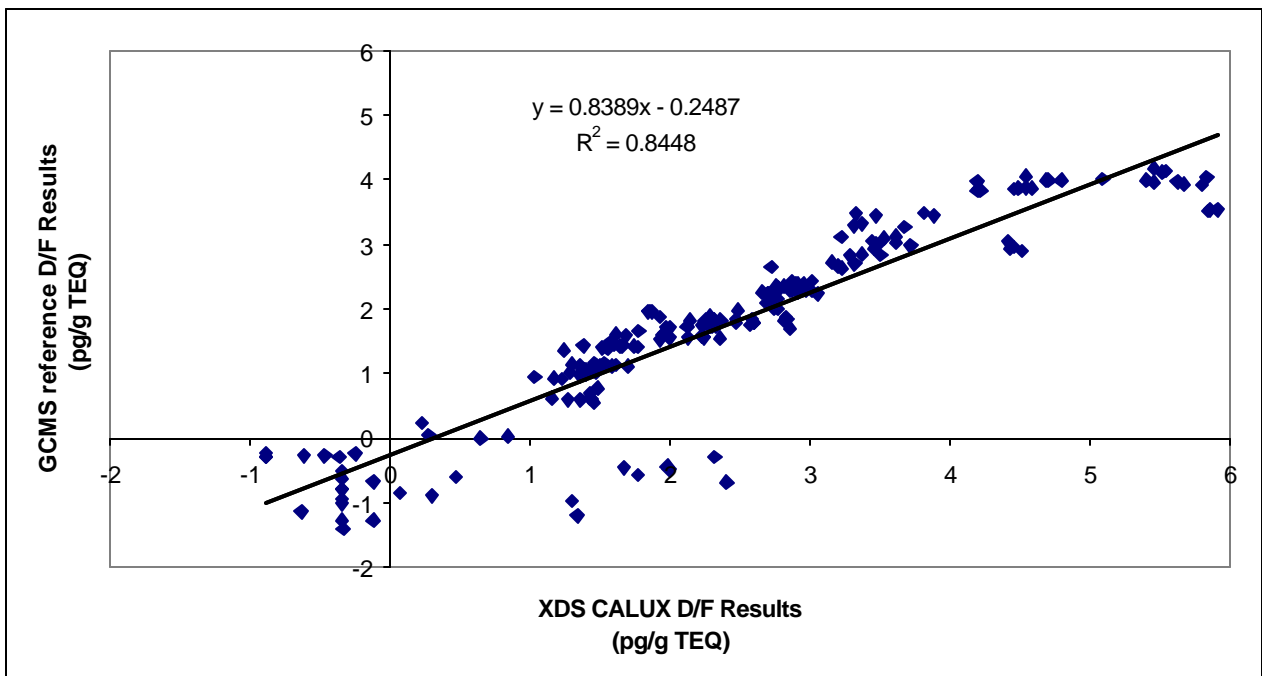


Figure 2

Determining the appropriate model would improve the comparability of the GC/MS and XDS-CALUX estimates of dioxin/furan and Total TEQ concentrations. The XDS CALUX method does underestimate the concentration of PCBs. This is due to the differences in the relative response factors for these chemicals and the WHO TEF values used to scale the GC/MS data.

A point to be noted in the execution of this study is that many of the developers requested or required information about the contaminant levels of the provided samples. Xenobiotic Detection Systems chose not to accept any prior information on any of the sample materials and preferred to keep the study conditions completely double blind and much closer to a real-world analysis scenario.

Savings

This report cited the large difference in the cost of the XDS CALUX analyses and the reference laboratory analyses. Our clients are already aware of this and many use the XDS technology to screen their samples and reduce their need for the more expensive GC/MS congener-specific analyses. The table (Figure 3) below illustrates the savings of using XDS CALUX in conjunction with a GC/MS follow-up confirmation analysis. This table uses the XDS CALUX costs (\$89,564) for the analyses of the 209 SITE samples and the actual cost of the SITE reference laboratory analyses (\$398,029).

209 Samples	CALUX by XDS Screening Analysis	GC/MS Analysis	Screening plus GC/MS	Savings vs. 100% GC/MS
No follow-up required	\$89,564	\$0	\$89,564	\$308,372
1% GC/MS Follow-up	\$89,564	\$5,712	\$95,276	\$302,660
2% GC/MS Follow-up	\$89,564	\$9,520	\$99,084	\$298,852
5% GC/MS Follow-up	\$89,564	\$20,944	\$110,508	\$287,428
10 % GC/MS Follow-up	\$89,564	\$39,984	\$129,548	\$268,388
20 % GC/MS Follow-up	\$89,564	\$79,968	\$169,532	\$228,404
30 % GC/MS Follow-up	\$89,564	\$119,952	\$209,516	\$188,420
40 % GC/MS Follow-up	\$89,564	\$159,936	\$249,500	\$148,436
50 % GC/MS Follow-up	\$89,564	\$199,920	\$289,484	\$108,452
60 % GC/MS Follow-up	\$89,565	\$239,904	\$329,469	\$68,467
70 % GC/MS Follow-up	\$89,566	\$279,888	\$369,454	\$28,482
100% GC/MS	No CALUX Analyses	\$398,029		

Figure 3

XDS Clients

Xenobiotic Detection Systems holds and regards the names of clients as highly confidential information. We do not release client names or provide any client information, without the client's consent. We observe this same confidentiality policy in regard to our CALUX by XDS licensees.

XDS has clients in the animal feed industry, environmental consulting and engineering companies, food producers, leading colleges and universities, municipalities, incineration plants, manufacturing industries and other categories. Additional information, including research abstracts, is available on the XDS web site, www.dioxins.com.

If you are interested in contacting current XDS CALUX clients or licensees, please contact Xenobiotic Detection Systems.

We welcome opportunities to further explain and answer questions on our CALUX by XDS technology. Please contact us at info@dioxins.com or 1-888-DIOXINS (346-9467).

Summary:

Advantages of using CALUX by XDS:

209 SITE samples	CALUX by XDS	Reference Laboratory
Cost	\$ 89,564	\$398,029
Time	6 weeks*	8 months

*If necessary, the SITE samples could have been analyzed within a three to four week period. Our normal (non-expedited) turn around time for analyses is 21 to 30 days.

Faster than GC/MS

Results available in hours and days verses weeks

Less expensive than GC/MS

Costs are in hundreds of dollars verses one thousand dollars or more

Flexible — as screening detection levels and threshold action levels can be client specific

Sensitive — detecting Dioxin/Furans below 1 ppt

Accurate — results are reproducible

Multiple samples can be processed during the same analysis procedure.

Already accepted in the European Union as a screening tool for foodstuffs

Can be rapidly set up in remote mobile facilities with minimal construction

Requires standard laboratory equipment, not excessive expensive instrumentation

Minimal laboratory staff required