

Brian O'Shea looks at the lower end of the biological detection market and asks whether we are getting closer to a product that combines low cost with moderate fidelity

The search for the Holy Fail(safe)

IF EVER there is a sizzle in CBRN it has to be in bio. For years the emphasis was on chemical and R/N and then, with the anthrax letters, everything changed – and not for the better. Suddenly there has arisen a massive industry in generating the threat; we are still being told in 2008 that deadly viruses can be manufactured in a garage and could kill hundreds of thousands. Even were that true, and the author has to sign up to a degree of scepticism, terrorists lack the means to distribute it effectively. Much of the emphasis seems to be on how easy it is to make Y Pestis, rather than how easy is it to disseminate?

Garage biologists?

Equally, biological detectors seem to be set at the worst-case scenario – smallpox etc – rather than those agents that might actually survive the ramshackle delivery system in

significant quantity. The first indication of biological terrorist research is likely to arrive the same way that it does for experimentation with explosives – hospital visits after an “accident”. The UK could have seen something similar last year, when a gentlemen turned up at a hospital asking for the antidote to mustard gas, as his friend had had an “accident”. In much the same way that people who play with explosives often miss fingers, people who make BWA outside of a BSL3/4 lab may well find that they (neighbours, wives, family, friends, etc, etc) get more than they bargained for. Yes, it can be done, but if it were safe why would governments have stringent safety for labs?

There is also the realisation that just because you can produce it, doesn't mean that it can be produced in significant quantities. If you insist on trying to make pathogens outside of government labs then eventually –

depending on the level of the technician – something will go wrong; this law of averages militates against trying to produce huge volumes of agent. Small amounts are also unlikely to be explosively released, ensuring red force will use some form of (what Nato used to call) Release Other Than Attack (Rota), and not all agents are happy to be released in such a fashion.

All of this leads to a robust threat spectrum, yet this is inevitably where the problems start – no one wants to release a threat spectrum of BWA. Usually people suggest it is very close to the Centre for Disease Control (CDC) list – presumably this means they replace hemorrhagic fevers with ricin – yet quite why any civil agency should have major concerns over smallpox – unless specific intel has suggested it – is unclear. So, without robust threat spectrums, the biological detector market is free to proliferate, both in terms of agents and



Portable and efficient? (L-R) Smith's BioSeeq Plus, NBC Sys Incubus, Idaho's Razor, Research International's BioHawk
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variety and number of detectors. The variety of agents means the detector cannot be specific, and with that lack of specificity come false alarms. Yet there is still the demand out there for a tactical biological detector, something you take to the sample and which provides you with a basic assessment of what you are seeing.

A quick overview of the handheld market reveals: General Dynamics' 4Warn Version 3 and Version 4, Smiths Detection's Bioseq Plus, QTL's Biosensor Z200R, Environics' Envi Assay, NBC Sys' Detinbio (also called Incubus), Scott Health and Safety's Prime Alert, Response Bio's RAMP, Northrop Grumman's HISSS, Selex S&AS's Nexsense B, Research International's BioHawk, Idaho Technology's Razor EX, Alexeter's Defender, TetraCore's BioThreat Alert and Redline Alert, New Horizon Diagnostics' Smart and Advnt's Prostrips and Badd (this is not meant to be definitive, just indicative).

The devices are pretty much split between quick and easy, and specific and not so easy. In the former category there are the assay strips – Advnt, Response Bio, ENVI Assay, TetraCore and New Horizon Diagnostics. These require minimal to no training, will provide a result in anything from three to 30 minutes and as New Diagnostics so eloquently put it, "No known rapid screening assay is 100 per cent specific, therefore results should be confirmed by an alternative method." In terms of choosing between the various strips, the defining factor is the quality of the assays themselves, and the systems are starting to become more specific. TetraCore are offering a new anthrax test that has higher reliability than gamma phage lysis, while Advnt offer anthrax, ricin, SEB, Bot Tox and plague, for example.

It is fair to say that the lower end of the market is driven by the assays and their association readers; they are cheap – Advnt's single assays, BADD, cost \$27 each – require no training and will give you that "bronze"-level detection of the "this might well be something" variety. The "gold" standard of the assays is probably the BioHawk system which combines air sampling, similar to those used on high-spec detectors, with assay technology. So, as opposed to the other systems which are one use and

dispose, BioHawk reuses the reagents in a strip up to 30 times before it needs to be discarded and is able to hand the information out to the network via RS232 or wireless. Considering that approximately 90 per cent of alerts are likely to be benign, with eight per cent likely to be of chemical toxicity, then this quick and dirty solution is often warranted.

Shake and bake

Those requiring higher specificity usually plump for a PCR detector – Smith's Bioseq, Selex's Nexsense B or Idaho Technology's Razor EX. PCR is a great deal more specific than assays, and will provide accurate results – if treated in the right way. The last point is an important caveat – PCR, like any other sensitive scientific equipment (though the three above are all ruggedised for field use) works on the principal of garbage in, garbage out. PCR works from having a sample introduced to it; that sample can either be taken from the ground, via a swab, or from the air using an air sampler. Once the need for samples is brought into the equation you are left with the need to produce a clean sample – if the sample is not clean then you cannot use PCR effectively – and sample preparation is a fine art. Smith's Bioseq would seem to have the right plan, with a simple cartridge into which the sample can be put cleaned by shaking it. There has to be an element of scepticism here, however, as most other sample preparation devices for PCR have the same size and weight envelope as patio heaters; this is either a technological step-change of enormous proportions, or... well something else. Some PCR detectors, such as Nexsense B, come with their own sample collection and preparation, but this adds both weight and cost. There also needs to be an intake of sufficient power – if it takes in less air per minute than the average human then who is the detector?

This brings us up to the crux of biological detection, which is: what are you looking for? Any positive detection is going to see a sample sent to a 'gold' standard lab, since any confirmed attack will be of worldwide importance – and might result in a Nato Article 5 situation. The handheld silver standard

that PCR offers needs support to be wholly accurate; once you plan that sample collection and preparation in, does it remain handheld?

At the same time, assays still don't offer the confidence that people would like: the Gold standard lab tests are costly and time intensive and there are still enough false alarms to make people chary of the cost. In many respects there is a need for the mature approach to bio detection that currently exists in many civilian fields. The military is often split into basic, advanced and specialist, while civilian forces utilise the first two and rely on reachback for the third. While the technology needs to improve, so do things like Sampling and Identification of Biological Agents (Siba), as PCR and other detectors work best when they are given what they like. Currently the threat is at the level where something needs to be done, but nothing too seriously – because that costs money that could be used on other things.

Currently the two nations that provide the bulk of bio detection to Nato are the US and UK, but many light role teams are going to start offering a capability, and the challenge for the military will be to ensure the level of training is high enough so the operatives will be able to evaluate the information the detector is providing. Civilian forces are, it is fair to say, even further behind the curve and are still looking for the detector that will work the same way that chemical ones do – where the operator's level of training can be minimal. Technology in handheld bio detectors is improving to the stage where the operator can have greater faith in them than ever before, but it still needs a level of training and understanding that is far higher than that expected of chemical and radiological detection. Improvements in reagent and assay technology will see the false alarms minimised, but not eradicated, yet it is the silver standard that many people are aiming at, and an error free, low maintenance and support, easy to operate system is still a decade off. An investment in a robust understanding of the threat and an improvement in training will provide the capability that is required in the meantime.