# Chilling Ingredient Used in the COVID-19 Vaccine

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The horseshoe crab is thought to be 300 million years old; that's 200 million years older than dinosaurs. They don't sting, don't bite and don't harm us in any way. The annual spring congregation of egg-laden horseshoe crabs on the east coast provides a vital food source for annual migrations of millions of shorebirds.

But even this harmless sea creature may be annihilated by pharma's insatiable drive to make a universal coronavirus vaccine. In 1990, biologists estimated 1.24 million crabs spawned in Delaware Bay, a main egg-laying nursery grounds and prime collection point for the companies. By 2019, that number had dropped to 335,211. Conservation groups feel that the planned harvest by vaccine manufacturers may lead to the species' extinction.

Horseshoe crabs are known for their unique blue blood. But it's not the blood's color that is the attraction. A unique chemical found in its blood, called coagulogen, is used by the drug companies to detect as little as a few parts per billion of dangerous endotoxin bacterial contamination in any medication, medical devise or vaccine. According to <u>Associates of Cape Cod, Inc,</u> one of a handful of horseshoe crab blood processors, that's like "finding a grain of sand in an Olympic swimming pool."

First licensed in the 1970's, coagulogen has become the gold

standard of pharmaceutical purity testing. This simple test, referred to as a limulus amebocyte lysate test, or LAL for short, is named after the white blood cells (amebocytes) from which the chemical is harvested. The extract is so powerful that if even a trace of endotoxin is present, coagulogen will neutralize it into a gel. If no gel is formed, the product is considered to be free of bacteria. The FDA mandates that all injectable or indwelling materials to be certified as endotoxin-free using the LAL test before a product can be manufactured and sold into the market.

### Harvesting the Crab: Big Business

The American LAL industry has been around a long time. The first commercial LAL production facility was established in Chincoteague, VA in 1971. Currently, several production facilities are located from Massachusetts to South Carolina. After the FDA granted approval for the commercial use of the LAL test in 1987, demand for testing reagents soared through the 1990s. Currently, drug companies require at least 80 million test units each year for drug and device testing. With the specter of using the LAL test to certify more than 15 billion COVID vaccines – two shots for every human on planet – the demand for horseshoe crab blood and LAL testing reagents may soom be stratospheric.

The crabs are harvested by local fisherman and taken to collection facilities which then return them to water within 24 to 72 hours of harvesting their blood. The crabs are returned to the ocean a great distance from where they were initially picked up to avoid recurrent rebleeding from the same crab. The process is rather straight forward: the animals are strapped into collection devices and a catheter is inserted into the sinuses where their blood is removed. Pharma claims it is a harmless procedure, similar to a human giving blood.

But how harmless is exsanguinating 30 percent of the animals'

### blood?

Nearly 500,000 sea creatures are caught and then bled each year. This number is about to explode. The value of the commercial harvest of horseshoe crabs grew from about \$400,000 in 2004 to more than <u>\$1.8 million in 2014</u>. In 2018, a teaspoon of LAL was worth about \$75 and the market value had ballooned <u>to \$112 million</u>.

"The problem is that the companies need a large supply of the blood from live crabs," a <u>2014 article in The Atlantic noted</u>. "Horseshoe crabs live on the seafloor, near the shore. When they want to mate, they swim into very shallow water, and horseshoe crab collectors wade along, snatching the crabs out of their habitat.

## Synthetic Alternatives

Because the demand for the LAL agent is about to explode as global vaccine demand is ramped up, alternatives for coagulogen are being explored. It appears a replacement for the blood harvesting may have been found.

Numerous articles have been published about the development of a recombinant Factor C (rFC) test, a recombinate, synthetic alternative to the LAL test. Comparative testing of samples tested with both the LAL and recombinant rFC suggests that the new test may even be superior for identifying bacterial endotoxins.

The results of a six-year study was published in the journal, *Microorganisms*, in March 2020. The study, which compared endotoxin sensitivity of LAL assay and two different rFC-based assays, demonstrated that both rFC-based assays were comparable to LAL. In fact, the rFC-based methods generated even better endotoxin recovery rates than traditional LAL testing. <u>The researchers concluded</u>:

"The rFC-based tests were found to represent reliable methods,

as equivalent or even superior to LAL assays and suitable for routine bacterial endotoxin testing."

A similar study, released in July 2020, <u>concluded:</u>

"rFC assays offer a number of benefits, including compliance with the principles of the 3Rs, i.e., replacement, reduction, and refinement of animal testing by safeguarding animal welfare and promoting more ethical and sustainable use of animals for testing... In summary, we demonstrated that both LAL and rFC assays are adequate for testing and releasing four vaccine products."

#### https://youtu.be/c5SzE93kynU

Conservationists fear that the demand for horseshoe crab blood for COVID-19 vaccines may exterminate the crabs and greatly impact the shorebird population that depends on them. A synthetic substitution would be good news for the horseshoe crab population and for the entire environmental and marine ecosystem. And better for humans too.

If it becomes impossible for people to refuse the <u>hydrogel-</u> <u>contaminated</u> COVID19 vaccine, at least the vaccine will not decimate the horseshoe crab population for its manufacturing process.

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