Covid-19 Test- Tube Firm With U.S. Contract Is Accused of Unsanitary Workplace

A contractor has been assembling Covid-19 testing materials in unsterile conditions in a Texas warehouse where workers only intermittently wear protective gear, according to several former employees.

By Mark Maremont, Susan Pulliam and James V. Grimaldi

A contractor making Covid-19 testing materials for the federal government has been assembling the items in unsterile conditions in a Texas warehouse where workers only intermittently wear protective gear, according to several former employees.

Fillakit LLC was established in Florida in May, six days before winning a $10.2 million contract from the Federal Emergency Management Agency to produce liquid-filled tubes for Covid-19 tests, federal and state databases show.
Several former employees said dozens of workers sit side-by-side filling test tubes by hand, with cooling fans blowing dust around. Teresa Bosworth-Green, a retired science educator who worked at Fillakit for about two weeks in May, said she witnessed vials containing debris and bugs being packaged for shipment. “The environment is not clean at all and certainly not sterile,” asserted Ms. Bosworth-Green.

One worker sent an anonymous complaint this week to Rep. Jackie Speier (D., Calif.), alleging that “Fillakit is delivering inferior and unusable product to the government without oversight or accountability to the taxpayer.” An aide to Rep. Speier confirmed receiving the complaint.

Food and Drug Administration guidelines call for the liquid-filled tubes to be sterile, to avoid contaminating the test results. After patients are tested for Covid-19 with a nasal swab, the swabs are put into tubes to keep them clean for transport to a lab.

Dust, hair or exhalations from unmasked workers could contaminate the test tubes and produce false results, said Catherine Klapperich, a Boston University biomedical engineering professor who is in charge of a new Covid-19 testing lab at the university. She said such kits should be assembled in a completely sterile environment.

FEMA inspects the products to ensure the packaging is intact to maintain sterility and that it isn’t leaking, a FEMA spokeswoman said. “FEMA experienced no issues with sterility or product quality on our side,” she said. Testing for the new coronavirus is critical as the nation reopens, health experts said, and states and businesses have been rushing to procure testing kits as the federal government has stepped away from overseeing Covid-19 testing.

FEMA so far has received more than 3.1 million units from Fillakit, and has sent them out across the country, according to a government official. “All states and territories should have received an allocation,” the official said.

The former employees said Fillakit is managed by Paul A. Wexler, 51 years old, who in 2013 settled an accusation by federal regulators that one of his companies defrauded cash-strapped consumers during the 2008 financial crisis.

In an interview, Mr. Wexler called the Federal Trade Commission allegations unfair and unrelated to Fillakit. He said he was only assisting at Fillakit, and isn’t an owner or employee. He said Fillakit is helping out the country by producing test materials during the pandemic and providing good jobs.
Mr. Wexler said all employees wear masks and gloves and “everything is done the way it’s supposed to be done.” He blamed allegations of unsanitary conditions on a disgruntled former employee fired for making racial slurs, whom he declined to name.

Fillakit’s website says the company has an “amazing workforce” and is “committed to maintaining the highest standard of quality in our production.”

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Mr. Wexler declined to say who Fillakit’s owners are. Records in Florida, where the company was formed, show Kira Doyle as its manager. Former employees say Mr. Wexler introduced Ms. Doyle as his wife. Mr. Wexler declined to discuss that and Ms. Doyle didn’t respond to requests for comment.

The FEMA spokeswoman said Fillakit was a registered contractor at the time it received the award, and on reviewing its quote “nothing was found that would render this company ineligible” for a government contract. The former employees said Fillakit set up shop a few days after winning the FEMA contract in an empty warehouse space in Conroe, Tex., near Houston, and quickly hired dozens of workers.

“Temporary Position assembling Covid-19 Test Kits,” said an online Fillakit ad, offering $15 an hour. Having a valid ID and being able to speak English were the only requirements listed.

Mr. Wexler on the first day introduced himself as the company’s owner, and introduced his wife and another top manager, several former employees said.

“Find a table, put 2 milliliters of solution into these tubes, then cap ‘em and put ‘em in a bucket. That was the training—five minutes,” Ms. Green recalled.

Employees bring in large containers filled with plastic tubes, then use shovels to unload them into smaller bins, former employees said. Mr. Wexler confirmed the use of shovels, said they were plastic and were wiped down every half-hour with alcohol.

Employees filling the vials sat on folding chairs at temporary tables, using a pipette to add a tiny amount of a phosphate buffered saline solution to each tube, which was then
capped, the former employees said.

The solution arrived at the warehouse in what appeared to be sterile bottles, they said, but was poured out into small trays open to the environment.

Air-conditioning in the warehouse couldn’t keep up with the Texas heat, so supervisors brought in large fans, they said. “The fans blew up every piece of dust and debris in the warehouse,” said Ms. Green, 62, who said she quit after the work aggravated a repetitive-strain hand condition.

Phil Jeffers said he occasionally saw “a dark piece of debris,” in tubes. “If I saw that, I’d throw it away,” said Mr. Jeffers, who said he worked at Fillakit inspecting the tubes after they were filled.

Mr. Jeffers, 72, said his main task was to be sure the tubes had the right amount of solution. Workers would dump more than 200 tubes on his table, and he and about six other workers would look at them one by one, examining whether the solution rose to a proper point in the tube. “It was a guess,” Mr. Jeffers said.

Mr. Jeffers said he was let go from Fillakit after he entered the warehouse one day 10 minutes before 8 a.m., when employees reported for duty.

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Another former worker, Candice Rains, 40, said she put caps on tubes eight hours a day at Fillakit. Employees didn’t wear hair nets, she said, and only some wore masks. She said some employees dripped sweat on their work surfaces. Indoor toilets sometimes didn’t work so employees used a portable toilet outside, she said.

When Ms. Rains noticed a co-worker’s hands were bleeding at one point, she said the pair hunted down the tubes the co-worker had handled, wiped the blood off them, and returned them to the bags where they found them.
Ms. Rains said she was fired by Fillakit around the beginning of June because she couldn’t provide her original Social Security card rather than a photocopy.

Vials, swabs and tubes for clinical use are considered by the FDA to be regulated medical devices and manufacturers must register with the FDA. A search of the FDA device-maker database doesn’t turn up Fillakit.

FEMA’s commissions last month also included a $26 million contract with Longhorn Vaccines and Diagnostics LLC to make fluid-filled Covid-19 test tubes. Longhorn President Jeff Fischer said his company ensures sterile conditions so workers don’t accidentally contaminate the tubes. All staff associated with tube-filling must wear masks, gloves, shoe coverings and hair nets, with no skin or hair exposed, he said.

Mr. Wexler has a law degree and held a real-estate sales license in Texas. He was involved in several small health-related firms before Fillakit. He also registered a company in Florida to sell cannabis-infused dog treats. That business never went anywhere, he said.

Corrections & AmplificationsFillakit LLC won a $10.2 million contract in early May from the Federal Emergency Management Agency to produce liquid-filled tubes for Covid-19 tests. An earlier version of this article incorrectly said the contract was valued at $10.6 million. (Corrected on June 18.)

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