



**PREMIER BIOTECH COMPANY STATEMENT REGARDING NBC STORY ENTITLED
“Unapproved Chinese coronavirus antibody tests being used in at least 2 states”:**

NBC ISSUES CORRECTION

On April 16, 2020, NBC published an article entitled “Unapproved Chinese coronavirus antibody tests being used in at least 2 states.” This article was false and misleading and put Premier Biotech in a false light suggesting Premier Biotech is distributing unapproved serology test kits illegally on the US market. We know this article has caused confusion and concern among our customers. We have written NBC legal counsel objecting to the story and requesting an immediate retraction or correction. In Premier Biotech’s letter to NBC we stated the following facts:

- 1) The product **is lawfully on the U.S. market** under FDA’s COVID-19 policy (see below);
- 2) The diagnostic **has been validated** by testing as per FDA’s policy; and
- 3) The product **was lawfully exported** from China at the time of purchase.

As a result of our correspondence on April 17, 2020, and additional information obtained after the original article, NBC corrected the article on April 18, 2020, adding the following:

“After publication of this article, a lawyer for Premier Biotech contacted NBC News to stress that the tests were lawfully exported from China and are ‘lawfully on the U.S. market under FDA’s COVID-19 policy.’ The lawyer also said that the “diagnostic has been validated by testing as per FDA’s policy.”

Labich of USC also sent a post-publication statement saying the tests were legally exported and legal for sale in the U.S., and that they had been found to be accurate. Labich said that Premier Biotech reports the accuracy of the tests to the FDA, and that two separate assessments found the tests’ positive readings for coronavirus were correct 99.5 and 100 percent of the time.

‘These data show that the tests have enough accuracy to be used for public health surveillance purposes,’ Labich said.”

As you know, Premier Biotech is the U.S. reseller of a test from a Chinese manufacturer named Hangzhou Biotest Biotech Co. Ltd. Our serology test was tested to demonstrate its effectiveness in both China by the manufacturer and a major U.S. university.

We explained to NBC that before we distributed our serology test, we obtained an opinion from our outside FDA regulatory counsel, DuVal & Associates, interpreting published FDA Policy. In short, FDA’s policy states as follows (the remainder can be found on FDA’s website):

Considering that serology tests are less complex than molecular tests and are solely used to identify antibodies to the virus, FDA does not intend to object to the development and distribution by commercial manufacturers or development and use by laboratories of serology tests to identify antibodies to SARS-CoV-2, where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

See “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff Document, issued on the web on March 16, 2020, at page nine (“D. Commercial Manufacturer Development and Distribution and Laboratory Development and Use of Serology Tests ***Without an EUA***”).

We also explained to NBC that the product was lawfully exported from China at the time of purchase. The fact is that Premier Biotech’s test was lawfully shipped to the U.S. from China. At the time of shipment, the test was not restricted from being shipped from China. NBC’s story later admits to those facts that these tests were shipped into the U.S. market “after the FDA relaxed its guidelines for tests in mid-March,” and “before the Chinese government banned their export just over two weeks later.” But those statements cannot correct the overall misimpression that has been created and carried on throughout the article, i.e. that Premier Biotech is selling an unapproved diagnostic.

We understand this NBC story has caused confusion amongst our customers, so we wanted to set the record straight. Should you have any questions or concerns, please call or write Premier Biotech at 888-686-9909 and/or press@premierbiotech.com.