The test was created by IMMY, a Norman-based laboratory that manufactures diagnostic tests and reagents for infectious diseases. Full information on their test is available on their website, as well. While the FDA hasn't fully reviewed or authorized this test or most on the market, they did issue a policy allowing companies to use their tests without that full authorization if the test was validated to be accurate and reliable, when the FDA was properly notified, and when the tests are labelled with some mandatory "non-review" language. The full explanation is here, if you're interested in reviewing in its entirety. IMMY has met all the needed criteria and is listed on the FDA website as having a pending request for FDA authorization. (Click "What laboratories are offering serology tests under the policy outlined in Section IV.D of the Policy for Coronavirus Disease-2901 Tests?" in the Q/A portion to see the listing)

So, while we're technically required to say that the test isn't reviewed by the FDA – it's still a high-quality test that has met a high level of scrutiny to be accurate and reliable. In fact, this test is the one being used by the state to conduct antibody testing, so we feel confident that the product meets our high standards.