

# Exhibit 14

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF FLORIDA**

JANE DOE #1, <i>et al.</i> ,	)	
	)	
	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	No. 3:21-CV-01221-AW-HTC
	)	
LLOYD AUSTIN, in his official capacity as Secretary of Defense, <i>et. al.</i> ,	)	
	)	
Defendants.	)	

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**DECLARATION OF COLONEL TONYA RANS**

I, Colonel Tonya Rans, hereby state and declare as follows:

1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board certified Pediatrician from 2001-2015.

2. In my current role, my responsibilities include directing a responsive, evidence-based, patient-centered organization promoting optimal immunization healthcare for all DoD beneficiaries and those authorized to receive immunization from DoD by assisting in policy development, providing implementation guidance and education, and engaging in clinical studies and research through clinical collaboration. The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) routinely engages with the medical representatives from the military

departments, U.S. Coast Guard, Joint Staff, Combatant Commands, and others to develop standardized immunization implementation guidance IAW published policy for consistency across DoD where possible.

3. I am aware of the allegations set forth in the pleadings filed in this matter. This declaration is based on my personal knowledge, as well as knowledge made available to me during the routine execution of my official duties. Attached to this declaration are authentic copies of relevant military regulations, instructions, and directives, referenced throughout.

#### **Coronavirus Disease 2019 (COVID-19)**

4. As part of my official duties, I served as a member of the COVID-19 Vaccine Distribution Operational Planning Team (OPT), which was directed to develop and implement the DoD's COVID-19 Vaccine Distribution plan. The Coronavirus Task Force (CVTF) provided overarching guidance to the OPT. The OPT provided routine and ad hoc updates on COVID-19 vaccine deliveries, administration, and adverse events to the CVTF.

5. The virus that causes COVID-19 disease is SARS-CoV-2, a ribonucleic acid (RNA) virus from the Coronavirus family. Like any RNA virus, the SARS-CoV-2 virus mutates and evolves constantly and regularly as it infects and replicates in host cells. Mutations that are beneficial to the virus (i.e., make the virus more easily spread between hosts, evade the immune system) are integrated into the viral genome, thereby increasing "survival" and replication opportunity. This has been seen with the SARS-CoV-2 "Delta" variant, which is twice as contagious as previous variants.<sup>1</sup> However, not all mutations are beneficial to the virus – some can result in virus death and therefore do not infect the host. This is part of the normal biology cycle of all viruses.

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<sup>1</sup> <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>, last accessed 17 Oct 2021.

6. The latest reports from the U.S. Centers for Disease Control and Prevention (CDC) indicate that the SARS-CoV-2 virus spreads when an infected person breathes out droplets and very small particles that contain the virus.<sup>2</sup> These droplets and particles can be inhaled by other people or land on their eyes, noses, or mouth. In some circumstances, viral particles may contaminate surfaces. People who are closer than 6 feet from the infected person are most likely to get infected, especially in areas where there is poor ventilation. Transmission has also been demonstrated to occur beyond 6 feet, for example, when singing or with intense exercise.

7. COVID-19 disease can cause acute symptoms such as fever/chills, cough, shortness of breath, fatigue, muscle aches, headache, loss of sense of smell or taste and/or sore throat. Symptoms appear 2-14 days (usually within 4-5 days) after viral exposure.<sup>3</sup> The infection can affect people in different ways with a variety of symptoms from asymptomatic, to limited and mild (for 2-3 days) to more severe (such as trouble breathing, chest pain, inability to think straight & inability to stay awake). Despite aggressive medical management and ventilator support in an intensive care setting, some individuals have died. As of October 16, 2021, CDC reports that over 44 million individuals in the U.S. have been diagnosed with COVID-19 disease and over 720,000 have died,<sup>4</sup> or approximately 1 in 500 in the total U.S. population of 330 million. Per the CDC, older people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness.<sup>4</sup>

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<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/faq.html>, last accessed 16 October 2021.

<sup>3</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>, last accessed 16 Oct 2021.

<sup>4</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>, accessed 16 October 2021.

8. Although most people with COVID-19 get better within weeks of illness, some people experience post-COVID-19 conditions (aka long/long-haul COVID, Postacute Sequelae of COVID-19 (PASC), long-term effects of COVID, or chronic COVID). Post-COVID-19 conditions include a wide range of new, returning, or ongoing health problems four or more weeks after infection. Those who were asymptomatic during their COVID-19 infection may still develop post-COVID-19 conditions. In one systematic review, more than 50% of COVID-19 survivors continued to have a broad range of symptoms six months after resolution of the acute COVID-19 infection.<sup>5</sup>

### **COVID-19 Impacts on the Force**

9. Infectious diseases have been the single greatest threat to the health of those involved in military operations. As the standard military unit shrinks and becomes more mobile to rapidly respond to global threats, any decrease in personal or unit readiness can significantly decrease operational efficiency and result in military ineffectiveness. Similar to other viruses, SARS-CoV-2 virus can be easily transmitted to others prior to symptom development and therefore may infect significant numbers before being identified. DoD personnel, including Service members, especially those in an operational setting (such as those working on ships, submarines, or engaged in the operation of aircraft and vehicles; those deployed to austere environments; or those engaged in routine field training and airborne exercises), work in environments where duties may limit the ability to strictly comply with mitigation measures such as wearing a face mask, avoiding crowded areas, maintaining physical distancing of at least 6 feet, increasing indoor ventilation, maintaining good hand hygiene, and quarantining if in close contact with

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<sup>5</sup> Groff, et al, JAMA, Short-term and Long-term Rates of Postacute Sequelae of SARS-CoV-2 Infection, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784918>.

a COVID-19 case. This results in personnel in an operational setting being more vulnerable to rapid transmission of COVID-19. Further, although the elderly population and those with medical conditions are more likely to have severe disease, otherwise healthy Service members have developed “long-haul” COVID-19, potentially impacting their long-term ability to perform their missions, and some have unfortunately succumbed to the disease, as described further below. Service members and federal civilian employees are the military’s most valuable asset; without a medically ready force and ready medical force, the military mission is at high risk of failure. Recommendations from evidence-based medicine must remain the core approach to readiness. These evidence-based recommendations will continue to be updated as our understanding of the disease, complications, and impact from vaccination continues to evolve.

10. Between February 2020 and September 2021, there were 196,623 active duty Service members who were identified as new cases of COVID-19 (see “Table” below). The largest monthly peak in cases occurred in January 2021, with 28,105 new cases identified (see “Figure” below). Other peaks occurred in August 2021 with 21,349 new cases and in July 2020 with 11,614 new cases. The percentage of cases that were hospitalized was highest at the start of the pandemic and trended downward through January 2021. The percentage of hospitalized cases then increased from 0.9% in January 2021 to 2.0% in May 2021, and decreased back down to 0.9% in September 2021. In total, 23 active duty Service members have died from COVID-19 as of the end of September 2021. The number of active duty Service members who died from COVID-19 remained very low throughout the first year of the pandemic, with a slight increase in the numbers of deaths occurring between December 2020 and February 2021, and a greater increase occurring in August and September 2021, coinciding with the increased spread of the Delta

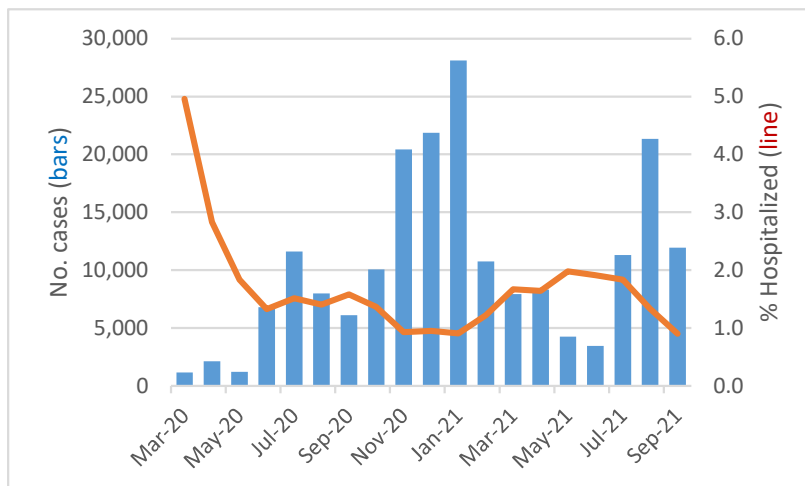
variant. One-half of the 23 deaths in active duty service members occurred between August and September 2021 (n=11).

**Table.** New COVID-19 cases, hospitalizations, and deaths among active duty service members, February 2020 - September 2021

	No. cases	No. cases hospitalized	Percent hospitalized	No. deaths
Feb-20	7	2	28.6	0
Mar-20	1,149	57	5.0	0
Apr-20	2,121	60	2.8	1
May-20	1,201	22	1.8	0
Jun-20	6,798	90	1.3	0
Jul-20	11,614	176	1.5	0
Aug-20	7,975	112	1.4	0
Sep-20	6,087	96	1.6	0
Oct-20	10,046	137	1.4	1
Nov-20	20,418	189	0.9	0
Dec-20	21,868	208	1.0	2
Jan-21	28,105	254	0.9	2
Feb-21	10,750	131	1.2	4
Mar-21	7,920	132	1.7	0
Apr-21	8,303	136	1.6	1
May-21	4,242	84	2.0	0
Jun-21	3,452	66	1.9	0
Jul-21	11,287	207	1.8	1

Aug-21	21,349	284	1.3	5
Sep-21	11,931	107	0.9	6

**Figure.** New COVID-19 cases among active duty service members and percentage of cases that were hospitalized, March 2020 – September 2021



Note: February 2020 is not shown due to the very small number of cases

11. The DoD has provided information on its website concerning the number of vaccinations provided by DoD, the vaccination of the force, and health impact of those who developed COVID-19 infections.<sup>6</sup> As depicted below, data from October 16, 2021, demonstrated of the 378,444 COVID-19 cases within the DoD, 5,356 individuals were hospitalized and 553 have died, including 67 military Service members (Service members include Active Duty, Reserves, and National Guard personnel).

<sup>6</sup> <https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/> last accessed 16 October, 2021.



DOD COVID-19 CUMULATIVE TOTALS				
	Cases	Hospitalized	Recovered	Deaths
Military	247,583	2,252	236,586	67
Civilian	68,650	1,962	58,118	343
Dependent	38,443	478	36,017	27
Contractor	23,768	664	21,450	116
Total	378,444	5,356	352,171	553

In both the civilian sector and in the military, the overwhelming majority of individuals hospitalized or who died were not vaccinated or not fully vaccinated.

12. The bed capacity at DoD's military medical treatment facilities (MTFs) has generally followed local civilian hospital utilization, with some MTFs having high admission rates and a need to temporarily curtail medical services. The National Guard has been called on extensively to provide medical support to the civilian population throughout the pandemic and Services have also provided "manning assist" to other DoD MTFs.

### **Vaccine Impacts**

13. Immunization is a global health and development success story, saving millions of lives across the age spectrum annually from illness, chronic conditions, and potentially death. Immunizations provide benefit at both the individual and community level. First, by stimulating an active immune response, vaccinated individuals are largely protected from the disease of concern. Second, when a high proportion of individuals are immune (i.e., herd immunity) human-to-human transmission is disrupted, thereby protecting those who remain susceptible (i.e., those who may not be able to receive a vaccine or do not mount an adequate antibody response). Disease prevention through immunization also mitigates the need for

pharmacologic treatment (antibiotics, etc.), reducing the risk of drug-resistant pathogen development.

14. As a key component of primary health care, the U.S. Food and Drug Administration (FDA), which provides regulatory allowance for immunizations, has licensed vaccines for over 20 different infectious diseases. The Advisory Committee on Immunization Practices (ACIP), an advisory committee of the CDC, develops recommendations on how to use vaccines to control diseases in the United States. The military also maintains awareness, surveillance, and provides guidance to DoD personnel and beneficiaries on vaccine-preventable diseases in the global setting.

15. According to the CDC, over 403 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through October 12, 2021.<sup>7</sup> Evidence continues to show that the incidence of SARS-CoV-2 infection, hospitalization, and death is higher in unvaccinated than vaccinated persons. For all adults aged 18 years and older, the cumulative COVID-19-associated hospitalization rate was about 12-times higher in unvaccinated persons.<sup>8</sup> Also, according to CDC data, deaths by vaccination status in August showed that unvaccinated persons had 6.1 times greater risk of testing positive for COVID-19 and an 11.3 times greater risk of dying from COVID-19.<sup>9</sup>

16. Although COVID-19 vaccine effectiveness against infection has decreased over time, this is seen more significantly in individuals 65 years of age

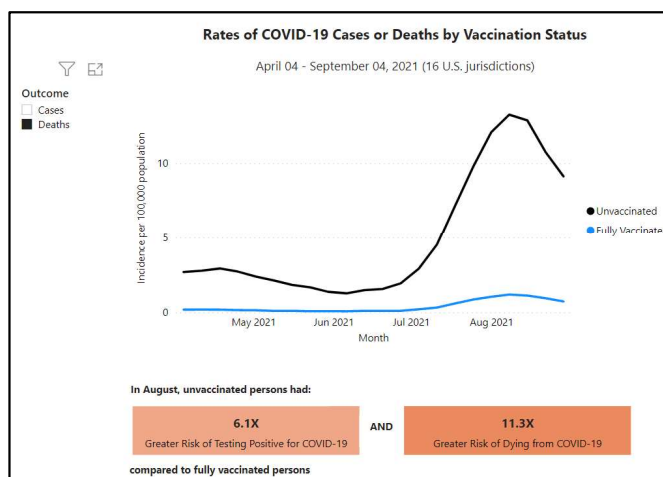
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<sup>7</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>, last accessed October 16, 2021.

<sup>8</sup> <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>, last accessed October 17, 2021.

<sup>9</sup> <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>, last accessed October 17, 2021.

and older. COVID-19 vaccine effectiveness against severe disease (hospitalization and death) remains high.<sup>10</sup>



17. As of October 15, 2021, DoD immunization sites have administered 5.7 million doses of COVID-19 vaccine. As of October 8, 2021, DoD has received a total of 6,470 unique Vaccine Adverse Event Reporting System (VAERS) reports (approximately 11 VAERS reports/10,000 doses administered). Note that the number of VAERS reports/10,000 doses administered for DoD beneficiaries is likely to be lower, as the denominator does not take into account beneficiaries who receive vaccine in the civilian sector.

18. As of October 16, 2021, the DoD has in its possession hundreds of thousands of BLA-compliant vaccine doses that are EUA-labeled, and is using them.

19. Approach to immunizations within DoD are outlined in DoD Instruction 6205.02, “DoD Immunization Program”, June 19, 2019, which states that it is DoD policy that all DoD personnel and other beneficiaries required or eligible

<sup>10</sup> Link-Gelles, Ruth. COVID-19 Vaccine Effectiveness in the United States, presented to the Advisory Committee on Immunization Practices, 22 September 2021 <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html>.

to receive immunizations will be offered immunizations in accordance with recommendations from the CDC and its ACIP. Army Regulation 40-562, Bureau of Medicine and Surgery Instruction 6230.15B, Air Force Instruction 48-110\_IP, Coast Guard Commandants Instruction M6230.4G, “Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases,” October 7, 2013, further states the Military Service policy concerning immunizations follows the recommendations of the CDC, ACIP, and the prescribing information on the manufacturer’s package inserts, unless there is a military-relevant reason to do otherwise.

20. The CDC remains consistent on its recommendations for those who had prior or current SARS-CoV-2 infection, stating “people should be offered vaccination regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection; this includes people with prolonged post-COVID-19 symptoms. Data from clinical trials indicate that the currently approved or authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making.”<sup>11</sup>

21. At present, there is not enough evidence available which demonstrates the durability, duration, or breadth of natural immunity against COVID-19 disease and the variants. Therefore, there is no established serologic correlate of protection. The presence of antibodies is not equivalent to being immune (see lab test section below).

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<sup>11</sup> [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination), last accessed October 16, 2021.

22. Although natural infection for some diseases, in some cases, can result in long-standing immunity (e.g., measles), there is risk of untoward outcomes from the disease itself, which can be chronic or even fatal (i.e., “the price paid for immunity”). Examples of harmful outcomes, outside of COVID-19, include Pneumonia or invasive group B Strep from chickenpox, meningitis or epiglottitis from *Haemophilis influenza* type B, birth defects from rubella, liver cancer from Hepatitis B, and death from measles.

23. Other examples of natural infections that do not mount long-standing immunity, include Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus – where re-infection is possible. Multiple serotypes of some pathogen like influenza, pneumococcus, and possibly with the SARS-CoV-2 variants also makes determination of a protective serologic level more difficult, especially to say there is ‘lifelong adequate immunity’.

24. Although emerging research suggests that prior infection may confer adequate immunity for 6 months or longer, there is also evidence that re-infection risk may increase with time due to waning of this natural immunity, as has been observed in other infectious diseases. Additionally, duration of immunity appears correlated with severity of COVID-19 disease – those who have mild disease are less likely to produce a robust antibody response compared to someone who had more severe disease. Additional studies and validation of post-COVID-19 immunity are required and, for this reason, there is not yet a recommended minimum interval between infection and vaccination.

25. Two doses of an mRNA vaccine or a single dose of the Johnson & Johnson/Janssen vaccine does produce robust immunity, as evidenced by the

significant drop in hospitalization and death once immunization began.<sup>12</sup> We also are learning that a single dose of mRNA COVID-19 vaccine after having had natural infection produces the same or higher levels of antibodies as two doses of vaccine (1 month apart).<sup>13</sup> In addition to CDC's recommendation that serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making,<sup>14</sup> the FDA published a safety communication on May 19, 2021, stating that "the U.S. Food and Drug Administration (FDA) is reminding the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination."<sup>15</sup>

### **Risks from COVID-19 Vaccination**

26. Risks from immunization, including COVID-19 vaccine are rare. CDC provides routine updates on specific adverse events temporally associated with COVID-19 vaccines.<sup>16</sup> CDC updates as of October 13, 2021, include the following:

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<sup>12</sup> Fowlkes A., et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021 <https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7034e4-H.pdf>.

<sup>13</sup> Gazit S., Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections, posted 25 August 2021 <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1>

<sup>14</sup> [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#CoV-19-vaccination), last accessed October 16, 2021.

<sup>15</sup> <https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety>

<sup>16</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>, last accessed October 16, 2021

- A. **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 2 to 5 people per million vaccinated in the United States.
- B. **Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare.** As of October 6, 2021, more than 15 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. CDC and FDA identified 47 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event.
- C. **Myocarditis and pericarditis after COVID-19 vaccination are rare.** As of October 6, 2021, VAERS has received 1,640 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have confirmed 926 reports of myocarditis or pericarditis. CDC and its partners are investigating these reports to assess whether there is a relationship to COVID-19 vaccination.
- D. **Reports of death after COVID-19 vaccination are rare.** More than 403 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through October 6, 2021. During this time, VAERS received 8,638 reports of death (0.0021%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily**

**mean that a vaccine caused a health problem.** A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines. However, recent reports indicate a plausible causal relationship between the J&J/Janssen COVID-19 vaccine and TTS, a rare and serious adverse event—blood clots with low platelets—which have caused deaths.

### **COVID-19 Antibody Tests**

27. As described above, testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making. As of September 26, 2021, the FDA’s EUA Authorized Serology Test Performances<sup>17</sup> lists 87 products, of which all of them had one of the following three statements about immunity interpretation:

- A. “You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.”<sup>18</sup>
- B. “It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.”<sup>19</sup>
- C. “It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. A

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<sup>17</sup> <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance>, last accessed September 26, 2021.

<sup>18</sup> <https://www.fda.gov/media/146369/download>, accessed October 16, 2021.

<sup>19</sup> <https://www.fda.gov/media/138627/download>, accessed October 16, 2021.



positive result for XXX test may not mean that an individual's current or past symptoms were due to COVID-19 infection.”<sup>20</sup>

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Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on October 20, 2021, in Falls Church, Virginia

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Tonya S. Rans  
Colonel, Medical Corps, U.S. Air Force  
Director, Immunization Healthcare Division  
Public Health Directorate  
Falls Church, Virginia

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<sup>20</sup> <https://www.fda.gov/media/137542/download>, accessed October 16, 2021.