



For Immediate Release May 2, 2018

**Exagen Points the Way for Patients with
Difficult-to-Diagnose Disease
May is Lupus Awareness Month**

Contact: Vince Heald, Beck Ellman Heald (vheald@behmedia.com) – 858-453-9600

SAN DIEGO, CA and Albuquerque, NM– May is “Lupus Awareness Month” and according to the Lupus Foundation of America, polls show that some two thirds of Americans are unfamiliar with the complex disease that affects approximately 5 million people around the world. “There is a need for greater awareness among patients and physicians,” says Ron Rocca, President and CEO of Exagen, an organization that provides key information to aid in the diagnosis, prognosis, and management of autoimmune rheumatic conditions. “The earlier the diagnosis, the earlier the patient can begin proper treatment,” said Rocca.

In 2012, Exagen released the first and only test incorporating cell-bound complement activation products or CB-CAPs technology. The test is called AVISE CTD and facilitates early diagnosis and management of systemic lupus erythematosus (SLE), the most common form of lupus, a complex, incurable autoimmune disease. Exagen marks May’s Lupus Awareness Month by delivering over 225,000 tests to more than 1,500 healthcare practitioners since launch. This advanced diagnostic tool has been proven in multiple studies to be a significant improvement over traditional lab tests alone and year over year growth of the testing has been over 33% with no slowdown in sight.

“More and more physicians are utilizing AVISE CTD due to its proven track record of aiding in the diagnostic process,” said Dr. Arthur Weinstein, Chief Medical Officer at Exagen. “Patients need to know they have a choice and that using a specialized test like AVISE CTD may help their health care providers gain confidence in their diagnosis and ultimately disease management.”

Lupus is an autoimmune disease in which the body attacks its own healthy tissues and organs. Patients with lupus suffer joint and muscle pain, unexplained fevers, hair loss and fatigue, among a number of other puzzling symptoms. A facial rash can appear across the nose and cheeks, though nearly every case will vary. Women are more likely to get it than men, and there's no definitive cause nor cure, though there are therapy options that focus on reducing the symptoms and minimizing damage to organs.

Because the symptoms of lupus often mimic other rheumatic diseases, or even infectious diseases, it has historically been difficult to arrive at a correct diagnosis. A 2004 study in Archives of Internal Medicine, published by the American Medical Association, showed that as many as 51% of patients with suspected autoimmune or immune disorders are initially misdiagnosed, in part because of ambiguous laboratory test results. The authors of the study warned that "misdiagnosis of systemic autoimmune diseases can have serious consequences."

Doreen Young, a patient who suffered from undiagnosed lupus for 12 years, noted, "I had more than a decade of on-going fatigue, unexplained fevers, and eventual debilitating joint pain. Traditional lab tests for lupus were inconclusive. I felt misunderstood and isolated. After seeking a new rheumatologist, who ordered the AVISE CTD test, [my doctor had more information that led to a diagnosis of lupus](#). Once diagnosed and treated, I began to feel more in control of my life again. This was the first step in what has become a successful disease management process."

Earlier this year, Exagen announced a first-of-its kind collaboration with GSK, a science-driven global healthcare company, to raise awareness of the importance of a timely diagnosis of SLE. "Increased attention through collaborations and events like lupus awareness month can ultimately make a difference in people's lives," said Dr. Weinstein. "Our goal is to help SLE patients shorten the time to their diagnosis, which is nearly six years on average, and to facilitate improved patient health outcomes."

About Exagen's AVISE laboratory tests

AVISE Connective Tissue Disease (CTD) is a diagnostic test which supports care providers with an accurate assessment of critical biomarkers in patients suspected of SLE or rheumatic conditions with similar symptoms. AVISE Lupus uniquely incorporates biologically-relevant CB-CAPs (Cell-Bound Complement Activation Products) into a proprietary algorithm that yields an index value which is associated with the likelihood for the presence of SLE. This amounts to a convenient test for the differential diagnosis of SLE with demonstrated performance of 80% sensitivity and 86% specificity.

- CB-CAPs provide 22% higher sensitivity for SLE than standard complement measures C3 or C4 alone
- The AVISE Lupus test offers 48% greater sensitivity than traditional anti-dsDNA alone

AVISE SLE Monitor is a combination of five advanced tests that provides important data to assist physicians anytime they assess the status of a patient with SLE. This test employs erythrocyte bound C4d (EC4d) along with other key markers which have demonstrated significant correlation to SLE disease activity. AVISE SLE Monitor gives the treating care provider an accurate glimpse into the serologic measures of disease activity allowing for a more complete picture of how well a patient's condition is being managed.

About systemic lupus erythematosus (SLE)

Systemic lupus erythematosus (SLE) is the most common form of lupus, affecting approximately 70 percent of an estimated 5 million people with lupus worldwide. It is a chronic, incurable autoimmune disease producing autoantibodies that can attack almost any system in the body.

Patients with SLE are at risk of irreversible organ damage, which can accrue over time and which can lead to kidney transplants and even death. This prognosis makes the timely and accurate diagnosis of SLE and appropriate management thereafter extremely critical. Improved time to diagnosis and management of the disease can also help reduce healthcare utilization costs for patients with SLE.

About Cell-Bound Complement Activation Products (CB-CAPs)

CB-CAPs (EC4d & BC4d) are stable biomarkers of complement activation. Exagen measures deposits resulting from activation of the complement system using flow cytometry to quantify C4d which is covalently bound to circulating cells including erythrocytes and B cells.

About Exagen

Exagen Diagnostics, Inc. is a College of American Pathologists (CAP) accredited and CLIA certified rheumatology specialty laboratory that focuses on the significant unmet need for accurate and timely diagnosis, prognosis and monitoring of autoimmune connective tissue diseases (CTD). Its groundbreaking solutions address the full continuum of care with tools designed and clinically shown to help physicians deliver accurate, early diagnosis and optimized therapy. For more information, visit www.exagen.com or follow us on [Facebook](#), [Twitter](#), [YouTube](#), [LinkedIn](#), or [Instagram](#).

US Media Inquiries:

Brian McEvelly

Exagen Diagnostics, Inc.
bmcevilly@exagen.com
858-736-5517