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Exagen Diagnostics announces collaboration with GSK to drive greater awareness about challenges facing lupus diagnosis and management

Current average time for lupus diagnosis of nearly six years must be improved upon

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Exagen Diagnostics, Inc. today announced a first-of-its kind collaboration with GSK to raise awareness of its laboratory tests, which facilitate early diagnosis and management of systemic lupus erythematosus (SLE), the most common form of lupus, a complex, incurable autoimmune disease.

The collaboration is intended to raise awareness of the importance of a timely diagnosis of SLE, as well as options for monitoring disease activity in patients already diagnosed with active SLE. Both Exagen and GSK share a common goal to help SLE patients shorten the time to their diagnosis, which is nearly six years on average, and to facilitate improved patient health outcomes. GSK will raise awareness of Exagen's AVISE diagnostic and monitoring tests, which have been shown to help diagnose and monitor SLE, to a select group of healthcare professionals.

Ron Rocca, CEO at Exagen Diagnostics explained the collaboration this way, "Every day, hundreds of very concerned patients are looking for answers about the cause of their symptoms. Exagen is dedicated to helping those patients get accurate and timely information and providing their physicians with insights that can put those patients on the path to improved health."

Diagnosing autoimmune diseases, especially SLE, is difficult because signs and symptoms vary considerably from patient to patient. Misdiagnosis is also high because symptoms can mimic many other illnesses. Currently, there is no single test to diagnose SLE and rheumatologists and other healthcare professionals rely on a variety of indicators, including the patient's presentation, medical history and results of laboratory tests to make an accurate SLE diagnosis.

Dr. Arthur Weinstein, Chief Medical Officer at Exagen Diagnostics said, "The technology being used in the laboratory at Exagen is cutting edge and speaking from experience this enhances the ability of physicians to provide a timely diagnosis, as well as ongoing monitoring for SLE patients. This partnership with GSK to raise awareness about these new approaches could lead to an accelerated diagnosis."

According to Sheri Mullen, Vice President, US Immunology at GSK, "As partners to the lupus community, reducing the burden of SLE on patients is a key goal that we share. Through the collaboration, we have a real opportunity to raise awareness of testing and tools to help physicians and their patients better manage the disease."

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 CTD 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 CTD test offers 48% greater sensitivity than traditional anti-dsDNA alone
- Utilization of AVISE CTD has the potential to increase the timeliness and accuracy of SLE diagnosis

AVISE SLE Monitor is a combination of five advanced tests that provides important data to assist physicians anytime they assess the condition 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. Approximately 170,000-200,000 Americans live with SLE. 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 is associated with increased risk of 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

About GSK

GSK – GSK – a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

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