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Proficiency Testing in Autoimmune Disease Diagnoses: Ensuring Accuracy and Reliability

Henriette Zeuch
in.vent Diagnostica GmbH, Hennigsdorf, Germany
h.zeuch@inventdiagnostica.de

Introduction

Autoimmune diseases, encompassing over 80 distinct conditions, are notoriously challenging to diagnose due to their complex and varied nature. Among these, collagenoses such as Systemic Lupus Erythematosus (SLE) and Sjögren's Syndrome are particularly difficult to identify. Diverse clinical manifestations, which can vary significantly in individual patients, are often mimicking different diseases and leading to potential misdiagnosis.

The detection of autoantibodies, crucial for the diagnosis of these diseases, presents a complex and challenging task. It requires highly specialized laboratory tests, as different autoimmune diseases are associated with unique patterns of autoantibodies.

Figure 1. Overview of sequential steps in proficiency testing for exctractable nuclear antigens (ENA) autoantibodies.

Given the increasing incidence of autoimmune diseases, proficiency testing becomes a vital tool. It is a key aspect of laboratory quality assurance, ensuring that the methods used for autoantibody detection are both accurate and consistent across different laboratories. This process is essential in maintaining high standards in autoimmune disease diagnostics, ultimately aiding clinicians in making informed and accurate diagnoses. Proficiency testing not only evaluates the performance of individual laboratories but also helps in identifying systemic issues and areas for improvement in the diagnostic process as a whole.

Methods

The participating laboratories were provided with native human samples, obtained under ethically impeccable conditions at our dedicated study site. The samples were tested for a panel of extractable nuclear antigen (ENA) autoantibodies that can be detected in cases of collagenoses like Sjögren's syndrome, systemic lupus erythematosus (SLE) or polymyositis. The focus was on evaluating the accuracy and precision of laboratories in detecting these specific autoantibodies, which are essential for the correct diagnosis of these conditions. Figure 1 provides an overview of the process.

Results

Results revealed a high overall accuracy rate in autoantibody detection, with variations observed between laboratories depending on the specific autoantibodies tested. Laboratories exhibited an exceptionally high accuracy in semiquantitative detection of anti-SS-A / Ro autoantibodies, a hallmark of SLE and Sjögren's syndrome. These inter-laboratory variations highlight the ongoing need for quality improvement in diagnostic assays. Herein, proficiency testing feedback reports served as valuable tools to highlight optimization potentials.

Conclusion

Proficiency testing is pivotal in addressing the diagnostic challenges posed by collagenoses, as well as a spectrum of other autoimmune disorders. It provides a systematic approach to enhance uniformity and proficiency in laboratory testing methodologies, a critical factor for precise diagnostic outcomes. Our comprehensive portfolio, encompassing a wide range of prevalent autoimmune diseases, plays a significant role in upholding elevated standards in autoimmune diagnostics. Additionally, it aids laboratories in furnishing accurate and prompt diagnostic results, thereby facilitating enhanced patient care and outcomes.