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Evaluation of Aptiva CTD Essential for the detection of antibodies linked to ANA-associated rheumatic diseases (AARD) in a large U.S. reference laboratory.

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Abstract

Background

The detection of autoantibodies represents a hallmark in the diagnosis of antinuclear antibody (ANA)-associated rheumatic disease (AARD). Therefore, thorough validation is recommended before implementing novel methods into diagnostic use. Recently, a novel particle-based multi-analyte system (Aptiva®) was developed and commercialized for diagnostic laboratories. The objective of the study was to compare Aptiva with the routine automated multiplex immunoassay technology used at a large US-based reference laboratory.

Methods

Positive and negative samples spanning the entire analytical measuring range for a total of ten autoantibodies (dsDNA, RNP, RNP/Sm, Sm, Ro, La, Ribo-P, Centromere, Scl-70 and Jo-1) were collected at Labcorp. All samples (n=677) were tested using the routine multiplex technology and in parallel using Aptiva® CTD Essential (Inova Diagnostics, San Diego, USA) which measures antibodies to dsDNA, RNP, Sm, Ro60, Ro52, La (SSB), Ribo-P, Scl-70, Centromere and Jo-1. Receiver operating characteristics (ROC) curve analysis was performed to assess the agreement between methods. Since the routine method used at Labcorp reports Ro combined, Aptiva Ro52+Ro60 were compared to Ro from routine testing.

Results

Moderate to high level agreements were observed between the two methods depending on the analyte. When results from the routine methods were used as binary classifier for

ROC curve analysis, the area under the curve (AUC) ranged from 0.732 (Scl-70) to 0.986 (Ro52+Ro60 vs. Ro) [Figure 1].

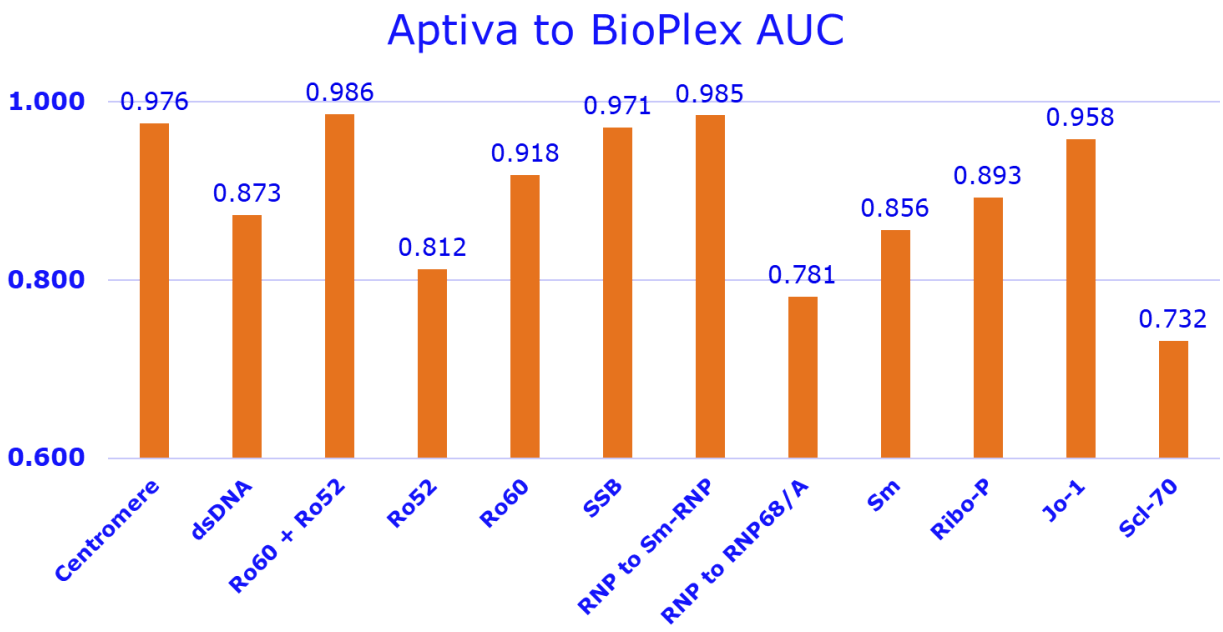

Figure 1. Summary of areas under the curve (AUC) derived from receiver operating characteristic curve (ROC) analysis per analyte / combination of analytes when comparing Aptiva against routine automated multiplex immunoassay technology results as binary classifier.

Conclusion

The data support the use of Aptiva CTD Essential in diagnostic use. Further investigations are needed to further elucidate the observed differences particularly with dsDNA, Sm, Sm/RNP and Scl-70 antibodies.