ANTI-ACINETOBACTER BAUMANNII POLYCLONAL ANTIBODY (AB-PAB)

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PATENT STATUS

Patent Pending

BRIEF DESCRIPTION

The inventors have constructed a polyclonal antibody (pAb) for the specific detection of the multi-drug resistant (MDR) bacterial pathogen, Acinetobacter baumannii (A. baumannii), producing the antibody entitled, 'AB-pAb'. The AB-pAb was raised against a recombinant (His-tagged) 22 kDa outer membrane protein (OMP22), an antigenic protein which is conserved across the species. The gene encoding OMP22 was amplified from the clinical A. baumannii isolate, AR_0056, which belongs to the international clonal lineage II, a lineage associated with outbreaks worldwide. The AB-pAb is capable of recognizing purified, denatured, OMP22 by Western blot, in addition to the native protein in whole cells of A. baumannii in vitro.

The pAb was optimized for diagnostic use by, firstly, removing antibodies within the heterogeneous pAb pool which were cross-reactive to other, clinically-relevant Gram-negative bacteria (GNB). This eliminates the issue of cross-reactivity often associated with polyclonal antibodies, which can limit their use as diagnostic tools. Moreover, testing was performed under conditions which mimic those of the blood and urine, further enhancing the novel AB-pAb's ability to recognize target bacteria in patient samples.

When tested against a panel of clinical isolates by indirect-ELISA, for the recognition of A. baumannii from other clinically relevant GNB, the optimized AB-pAb had a sensitivity of 85.5% (95 % confidence interval: 76.11% to 92.3%) and a specificity of 99.5% (95 % confidence interval: 99.53% to 99.99%) at a cutoff, signal-to-noise ratio (SNR) of 0.1275. To our knowledge, no commercial anti-A. baumannii pAbs are currently available which target OMP22, specifically optimized for diagnostic purposes.

SUGGESTED USES

This new test can diagnose Acinetobacter baumanii, a major multidrug-resistant Gram negative bacterial pathogen causing healthcare infections worldwide. The World Health Organization (WHO) has designated Acinetobacter baumannii as a priority 1, critical pathogen in need of new diagnostic tests, drugs, and research.

AB-pAb is a pathogen-specific polyclonal antibody, with commercial applications in both research and diagnostics. Antibodies are integral components of a wide variety of techniques, including immunoassays (enzyme, radio or fluorescence-linked), immunohistochemistry and flow cytometry.

Arguably the most important commercial application of the AB-pAb would be for diagnostic purposes, with particular utility in rapid, point of care (POC) testing devices. Antibodies can be integrated into low cost diagnostic platforms, such as microfluidic or paper based devices, which enable the rapid identification of bacterial pathogens with a high degree of accuracy, sensitivity, and specificity.

The use of this type of test for healthcare infections, such as those caused by A. baumannii, can greatly reduce health care costs. It can also be used by commercial clinical microbiology laboratories for rapid diagnosis as well as by public health reference laboratories for infectious disease surveillance, again with greatly reduced costs.

ADVANTAGES

This antibody-based diagnostic test offers major advantages over the traditional biochemical-based tests or modern nucleic-acid amplification-based tests in terms of simplicity, speed, and cost.

The invention eliminates the issue of cross-reactivity often associated with polyclonal antibodies, which can limit their use as diagnostic tools.

To our knowledge, this would be the first commercially-available anti-A. baumannii pAbs targeting an outer membrane protein (OMP22), specifically optimized for diagnostic purposes.