Lea König, J Microb Biochem Technol 2018, Volume 10
DOI: 10.4172/1948-5948-C1-038

A novel rapid molecular test for the detection of Mycoplasma contaminants in biopharmaceuticals

Lea König
Certus Molecular Diagnostics AG, Zollikofen, Switzerland

Bacteria of the class Mollicutes, including Mycoplasma and Acholeplasma species, are frequent contaminants of cell cultures in research laboratories, and a major concern in the biopharmaceutical industry. Contamination with these microorganisms may affect virtually every aspect of host cell metabolism and phenotype, and impact the quality and safety of biopharmaceuticals. Failure to meet release specifications due to Mycoplasma contamination has great economical and reputational consequences for the company. Initially, only two approved methods were acceptable for testing of cell-derived biological medicines: the culture method and the indicator cell culture method. Both are very sensitive, with a detection limit of 10 and 100 CFU/ml, respectively. However, they are laborious and time-consuming, requiring up to 28 days. Oftentimes, such long assay times are not feasible, e.g. in the case of advanced therapy medicinal products (ATMPs) with a short shelf-life. Therefore, there is an increasing need for faster detection methods, and since 2007, nucleic acid amplification tests (NATs) are officially allowed for Mycoplasma testing according to Ph. Eur. 2.6.7. Certus Diagnostics has developed a rapid molecular test based on isothermal amplification and real-time detection of Mycoplasma specific nucleic acids. The assay can be performed in less than 40 minutes on any real-time PCR cycler and requires only minimal hands-on time. This rapid test can detect 10 CFU/ml or lower using quantified Mycoplasma reference strains (from EDQM, France and Minerva Biolabs, Germany). Test specificity has been evaluated using closely related bacterial species. We will show the validation data supporting this rapid and sensitive assay.

Biography

Lea König has completed her Master's degree in Biology from the University of Bern in September 2017. In May of the same year, she started working for Certus Molecular Diagnostics Ag, Zollikofen, Switzerland an innovative company founded in March 2017 which develops, produces and sells rapid molecular tests for the detection of microorganisms. The company's first product is a test for the detection of Mycoplasma contaminants in cell cultures.

lea.koenig@certusdiagnostics.com

Notes: