



## TITLE: Noninvasive Quantitation of Full Versus Empty Capsids Using Water Proton NMR

### Key Investigator

Bruce Yu  
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### Field

Pharmaceutical

### Technology

NMR  
Quality Control  
Vaccine  
Drug Manufacturing  
Freeze-Thaw

### Advantages

Contact-free, non-destructive  
Fast and Reliable  
In Situ testing

### Status

Available for licensing

### Patent Status

Eur. Patent Appl. 20 903  
982.5  
U.S. Patent Appl. 17,842,990

### UMB Docket Reference

BY-2020-059

### External Reference

Marc B. Taraban, Michael T. Jones, and Yihua Bruce Yu  
Analytical Chemistry 2021 93 (48), 15816-15820  
DOI:10.1021/acs.analchem.1c04088 **Rapid and Noninvasive Quantification of Capsid Gene Filling Level Using Water Proton Nuclear Magnetic Resonance**

### Summary

This invention proposes a method for using NMR relaxation rates to determine whether capsid preparations contain empty or full viral capsids and to quantify the capsid content of the preparation.

### Market

The method developed by UMB researchers utilizes nuclear magnetic resonance (NMR) relaxation rates to evaluate the quality of capsid preparations. The market for capsid evaluation is driven by the increasing demand for safe and effective vaccines, gene therapies, and drug delivery systems.

The current methods for capsid evaluation, such as electron microscopy and gel electrophoresis, require sample destruction or labeling, making them time-consuming and costly. In contrast, this patented method provides a non-destructive, real-time, and quantitative evaluation of capsid preparations. This method offers increased efficiency and reduced costs in vaccine development, gene therapy, and drug delivery.

The global market for vaccines is projected to reach \$93.2 billion by 2026, growing at a compound annual growth rate of 6.5% from 2020 to 2026. The increasing prevalence of infectious diseases, coupled with the growing focus on immunization programs, is driving the growth of the vaccine market.

In addition to the vaccine market, the gene therapy market is expected to grow significantly in the coming years. The global gene therapy market size is projected to reach \$35.67 billion by 2028, growing at a compound annual growth rate of 30.6% from 2021 to 2028.

### Technology

The method developed by UMB researchers utilizing nuclear magnetic resonance (NMR) relaxation rates presents a promising approach for the evaluation of the quality of capsid preparations. Capsids are protein shells that encapsulate and protect genetic material and are essential components in the delivery of vaccines and gene therapies.

The patented method utilizes NMR relaxation rates, R1 and R2, with a preference for R2(1H2O) of water, to distinguish between empty and full viral capsids and quantify the capsid content in each preparation. Specifically, the method involves measuring the transverse relaxation rate of solvent R2,m in the capsid preparation and comparing it to reference transverse relaxation rates of solvent R2,r for full and empty viral capsids. The comparison of the R2,m value to the reference R2,r values allow for the identification of empty and full viral capsids and the quantification of the capsid content in the preparation. This approach provides a rapid, non-invasive, and quantitative way of evaluating the quality of capsid preparations.

In addition to its applications in quantifying capsid content and identifying empty and full viral capsids, the NMR relaxation rate method can determine if a capsid preparation has undergone stress such as temperature excursions, freeze/thaw cycles, light exposure, or agitation. The comparison of the measured R2,m to the reference R2,r values representing an acceptable range for the capsid preparation can indicate whether the preparation has experienced substantial stress and acceptable for use.

This method offers a significant advantage over other analytical methods for the evaluation of capsid preparations, such as electron microscopy and gel electrophoresis, as it does not



require sample destruction or labeling, enabling real-time monitoring of sample quality.

### **Technology Status**

Type the status here.