

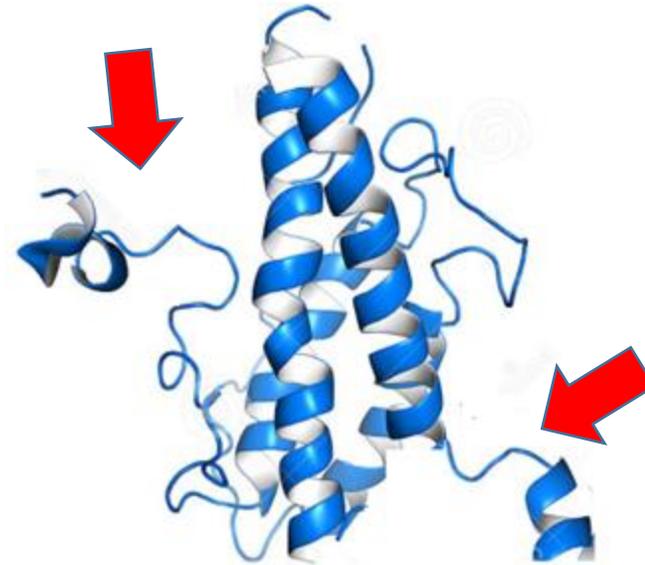
How to Produce the World's Best Human Growth Hormone

Hormone Purity is not the Only Important Parameter



99% purity, hormone was correctly folded in the tertiary structure

Biological effect: **YES**



99% purity, hormone is INCORRECTLY folded in the tertiary structure

Biological effect: **NO**

How to Check the Biological Effect?

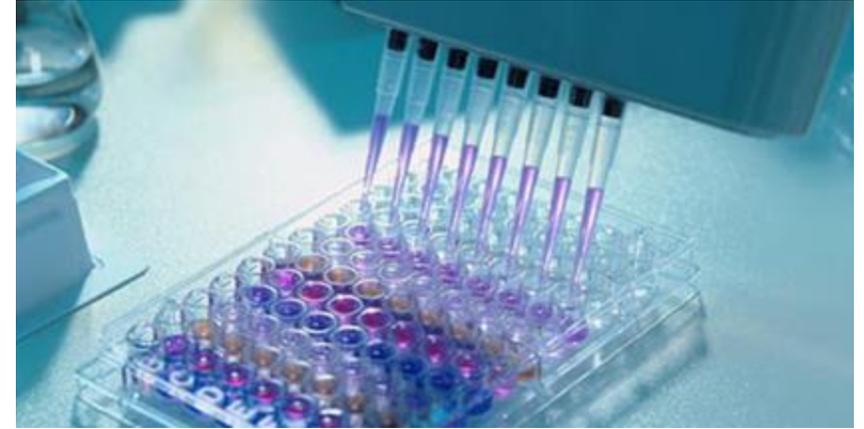
HPLC? – **NO**. It is absolutely the same in the correctly and incorrectly folded growth hormone.

Checking the level of growth hormone after injection? (LabCorp, Quest etc.) – **NO**. The measurement of growth hormone in the blood after injection is simple pharmacodynamics, diffusion of the hormone from the injection site to the blood, which is influenced by numerous factors (injection site, temperature, solvent composition). How quickly the hormone gets from the injection site to the blood is not an indicator of HOW this hormone AFFECTS the organism.

To evaluate how the growth hormone affects the process of mitosis? To check if it accelerates it? **YES**

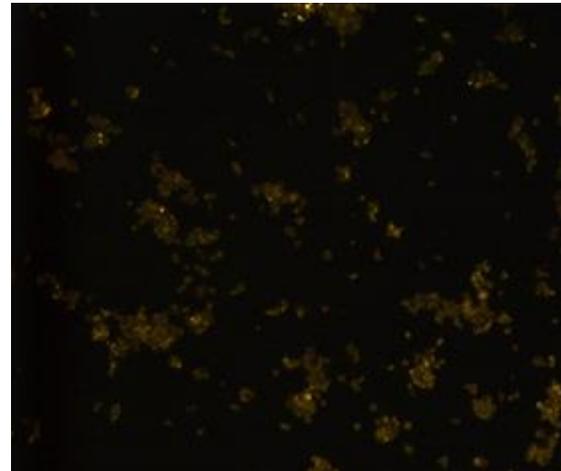
The Evaluation of the Biological Effect of Growth Hormone is the Measurement of the Effect on Mitosis

The samples of the growth hormone are added to the culture of special cells. These are mammal cells that can “sit” in the test tube in a special nutrient medium and react to the presence of growth factors.

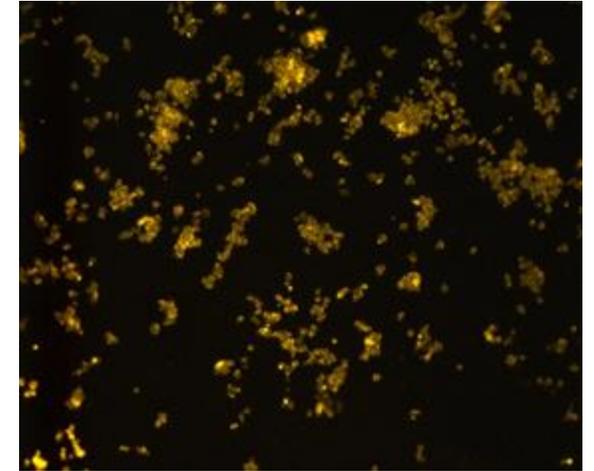


If the hormone has a correct three-dimensional structure, the cells are activated, their metabolism enhances, they grow, and include a special fluorescent stain. Thus, the dividing cells start to fluoresce:

BEFORE



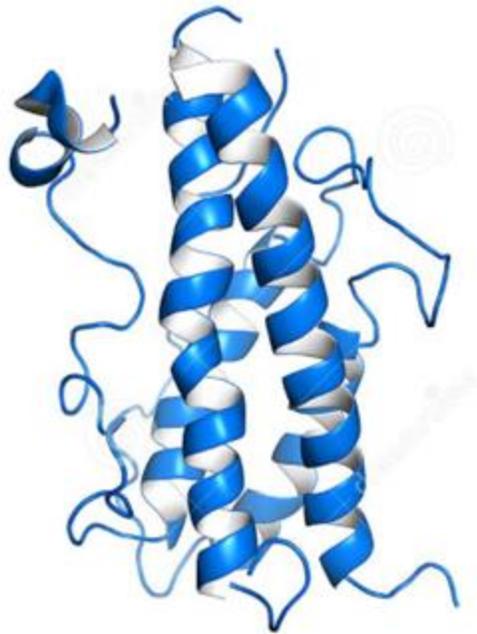
AFTER



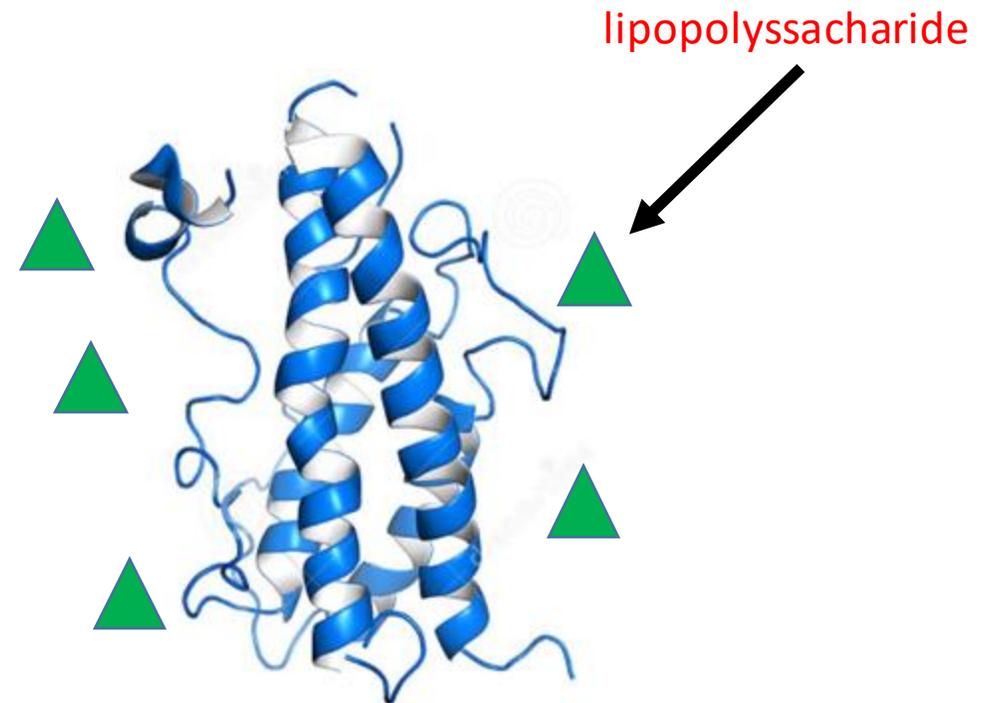
The measurement of the intensity of this fluorescence is the parameter of **BIOLOGICAL ACTIVITY**. The measurement in comparison with the standard (European Pharmacopeia) allows the researchers to calculate the biological activity in Units.

The Qore Pharm is the only company in the world that can analyze the biological activity of the growth hormone at different stages of production to obtain the highest quality of the molecule, which provides a perfected product that is of an extremely high-quality.

Special Significance for the Quality of the Product have NON-protein Impurities that are not all Seen During HPLC (chromatogram)



99% purity shown by HPLC, hormone is correctly folded in a three-dimension structure



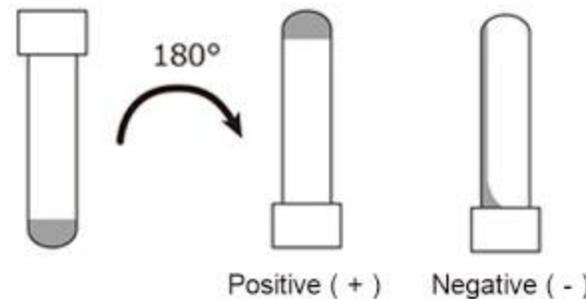
99% purity shown by HPLC, hormone is correctly folded in a three-dimension structure, **BUT** has impurities of **lipopolysaccharide (parts of cell membranes)**

The Evaluation of the Content of Bacterial Lipopolysaccharide Performed Using the Lysate of Amebocytes Obtained from Horseshoe Crabs



The term **LPS** was introduced to scientific semantics by R. Pfeiffer in 1892. The thermostable component of gram-negative bacteria was called **lipopolysaccharide (LPS)**. **LPS** can interact with different human cells and, depending on the dose, cause damage to them. Severe consequences of **LPS** in a human organism are allergies and anaphylactic shock.

In the presence of **lipopolysaccharide**, amebocytes obtained from horseshoe crabs, gravitate to the bottom of the test-tube and “agglomerate”. A gel clot is formed. It is used for the evaluation of the purity of the growth hormone-containing drug.



We thoroughly control the content of lipopolysaccharide, which makes our product completely safe and contributes to its quality.