

Over-the-Counter Diagnostic Tests for the Detection of Pathogens Causing Infectious Diseases

Alberto Gutierrez, Ph.D.

Director, Office of In Vitro
Diagnostics and Radiological health

Microbiology Devices Panel Meeting
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Welcome!

Today's Meeting:

- What will be discussed today are the potential benefits and risks of Over-the-Counter testing for three common diseases/clinical syndromes:
 - Testing for sexually transmitted pathogens, specifically *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/NG)
 - Testing for detection of Group A streptococcus (GAS)
 - Testing for the cause of common respiratory infections, e.g., influenza

FDA's Mission:

- Protect Public Health
- Promote Public Health

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

Why Now...

- This is a panel meeting for CDRH and is occurring at an particularly propitious time:
 - The unnecessary use of antibiotics has emerged as a national and international priority
 - New forms of communication and media are transforming medicine and empowering consumers
 - We are entering an era where new technologies are leading to a golden age of diagnostics

Meeting Goals:

- Open discussion of the risks and benefits of OTC infectious disease diagnostics
- Obtain recommendations regarding approaches that should be considered when evaluating the performance of these diagnostics.
- To discuss should be the acceptable performance criteria for OTC diagnostics