



DEFINITIVE RESOURCE

COMPREHENSIVE TESTING

*Product Quality
Evaluation and Consulting*





ENSURING PRODUCT QUALITY AND COMPLIANCE WITH INTERNATIONAL STANDARDS IS ESSENTIAL TO GLOBAL PUBLIC HEALTH

Global epidemics of HIV/AIDS and other infectious diseases endanger the health of millions of people. The possibility of distributing substandard prevention products puts too many lives at risk for disease transmission or unintended pregnancy. While international regulations mandate consistent high quality devices and pharmaceutical products, the evaluation process is not a job for the inexperienced. Proper compliance testing requires proven experience and specialized proficiencies.

Your definitive resource is Family Health International (FHI). Regulatory agencies, manufacturers and public health agencies around the world rely on FHI for technical expertise. From facility audits and compliance testing to establishing specifications and dispute resolution, we ensure that products meet global performance requirements.

FHI's team of skilled technicians evaluates the integrity of thousands of condom batches annually. This includes pre-shipment quality testing for the U.S. Agency for International Development (USAID), the United Nations Population Fund (UNFPA), Population Services International (PSI) and other sponsors. Regardless of where condoms are manufactured they must be tested according to stringent international standards.

WHY FHI

Product evaluation using international standards and specifications (ISO, ASTM, USP, WHO)

More than 3,000 condom batches evaluated annually

Track record of laboratory consistency, reliability and accuracy since 1990

Affiliation with international standards organizations

Global presence in public health research, education and services



COMMITMENT TO STANDARDS DEVELOPMENT

FHI has a long history of collaborative relationships with international aid agencies and manufacturers to improve product quality and reliability. We fully understand the technical standards required for condoms and contraceptives because FHI actively participates in international standards organizations—most notably, the International Organization for Standardization (ISO).

COMPLETE EVALUATION OF CONDOMS

In evaluating products for acceptance and distribution worldwide, FHI first assesses the manufacturing process. Is production equipment adequate or does it need updating? Are proper quality control procedures in place? Identifying and correcting deficiencies up front can prevent problems later when testing batches. Our rigorous testing covers every specification and performance requirement, in addition to proper labeling and packaging. We also perform compatibility studies to determine the effect of various lubricants and other medical treatments on condom integrity and performance. Virtually all of our new business results from customer referrals, reinforcing FHI's reputation for reliability and consistency.

ADVANCED LABORATORY

FHI's state-of-the-art testing facilities in Research Triangle Park, North Carolina, and Bangkok, Thailand, comply with industry standards. We routinely participate in sanctioned interlaboratory proficiency trials. Our highly trained technicians and on-site chemists adhere to Good Laboratory Practices (GLPs) in their evaluations of medical devices and pharmaceuticals used in family planning and disease prevention services.

EXPERTISE BEYOND TESTING

From purchasing through required reporting, FHI guides organizations, manufacturers and governments through compliance with international standards. We provide test results, interpret those results and make recommendations for improving product performance. FHI's sought-after technical expertise assists decision makers with proper manufacturing procedures, technical staffing and product use, in addition to helping with complaint resolution, quality disputes and other regulatory issues.



RELY ON FHI TO

Assess production capabilities

Set up laboratory operations

*Establish standard operating procedures,
test methods and sampling protocols*

*Provide technical assistance with
testing and product quality*

Assist in handling import detentions

*Consult on 510(k) notifications and
other regulatory submissions*

GLOBAL PUBLIC HEALTH LEADER

Established in 1971, **FHI** ranks among the largest and most established nonprofit international public health organizations. We partner with national governments and local communities in more than 70 countries to meet the public health needs of the world's most vulnerable people. In fact, our Product Quality Compliance (PQC) laboratories have worked jointly with **FHI** researchers for more than 15 years to address the most critical public health issues of the day: HIV/AIDS, sexually transmitted infections and other infectious diseases, unintended pregnancy, and maternal morbidity and mortality.

TRUSTED SOURCE

Why trust critical product evaluations to just anyone when you can leverage the global and scientific expertise of **FHI**? Call us to ensure seamless testing and fully compliant products. *For the Research Triangle Park, North Carolina, laboratory call 800.919.7038 (within USA) or 919.544.7040 extension 661. For the Bangkok, Thailand, laboratory call 66.02.285.5505.*





APPLY FHI'S TECHNICAL EXPERTISE

PRODUCT EVALUATIONS

Medical Devices

Male and Female Condoms

Medical Gloves

Intrauterine Devices

Pharmaceuticals

Oral Contraceptives

Implants

Injectables

Spermicides/Microbicides

Antiretrovirals

Tuberculosis Drugs

Antimalarial Products

ADDITIONAL SERVICES

Product Characterization

Product Stability Shelf-Life Studies

Package Integrity Evaluation

Product Compatibility

Prototype Design and Evaluation



IMPROVING LIVES

KNOWLEDGE

AND UNDERSTANDING

FAMILY HEALTH INTERNATIONAL

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