



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

FHI 360  
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MECHANICAL

Valid To: November 30, 2022

Certificate Number: 0367.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on pharmaceutical products, rubber and synthetic contraceptives:

**Test Technology**

**Test Method(s)**

Accelerated Aging	PQC541; ISO 4074
Airburst/Air Inflation	PQC545; ASTM D3492; ISO 4074
Specific Gravity	PQC1242; USP 841
Dimensional and Thickness Determination	PQC525; ASTM D3492; ISO 4074
Intra-Uterine Device (IUD) Testing	PQC550; ISO 7439 ( <i>except 7.5-7.7</i> )
Disintegration	PQC1206; USP 701
Dissolution <i>Levonorgestrel and Ethinyl Estradiol Tablets</i> <i>Norgestrel and Ethinyl Estradiol Tablets</i>	USP 711 PQC1203 PQC1209
Female Condom Testing	PQC561; ISO 25841 ( <i>except annex H</i> )
Freedom from Holes	PQC530; ASTM D3492; ISO 4074
Tablet Friability	PQC1205; USP 1216
Lubricant Quantity Determination	PQC520
Package Seal Integrity	PQC515; ASTM D3078; ISO 4074
pH	PQC1243; USP 791

**Test Technology**

**Test Method(s)**

Tensile	PQC 506; ISO 4074; ASTM D3492, D412 (Method B)
UV-VIS Spectrophotometry	PQC1211
Volume of Injection Injections – Volume In Container	PQC1244; USP 1
Burst Testing for Nets and Fabrics	PQC580; ISO 13938-2
Mass Per Unit Area Determination of Insecticide-Treated Mosquito Nets	PQC581; ISO 3801
Testing of the Washing Effect on the Dimensional Stability of Long Lasting Insecticidal Mosquito Nets Using Electrolux Wascator M223 FOM 71 CL	PQC586; ISO 6330
Netting Mesh Size Determination of Insecticide- Treated Mosquito Nets	PQC582

**Chemical Tests**

Chromatography - HPLC	USP 621
<i>Levonorgestrel and Ethinyl Estradiol Tablets</i>	PQC1201, 1203
<i>Norgestrel and Ethinyl Estradiol Tablets</i>	PQC1208, 1209
<i>Contraceptive Implants</i>	PQC1215
<i>Artesunate</i>	PQC1233
<i>Amodiaquine</i>	PQC1234
<i>Determination of Medroxyprogesterone Acetate in Injectable Contraceptive Products by HPLC</i>	PQC1240
<i>Artemether and Lumefantrine tablet</i>	PQC1260
<i>Determination of Insecticide Content in Long Lasting Insecticide Treated Nets by HPLC</i>	PQC1272
Uniformity of Dosage Units - HPLC	USP 905
<i>Levonorgestrel and Ethinyl Estradiol Tablets</i>	PQC1201
<i>Norgestrel and Ethinyl Estradiol Tablets</i>	PQC1208
<i>Artesunate</i>	PQC1233
<i>Amodiaquine</i>	PQC1234
<i>Injectable Contraceptive Products</i>	PQC1240
<i>Artemether and Lumefantrine table</i>	PQC1260
Thin Layer Chromatography (TLC)	PQC1215





## Accredited Laboratory

A2LA has accredited

**FHI 360**

*Durham, NC*

for technical competence in the field of

**Mechanical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).



Presented this 23<sup>rd</sup> day of October 2020.

A blue ink signature of the Vice President of Accreditation Services.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 0367.01  
Valid to November 30, 2022

*For the tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.*