



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

FHI 360
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MECHANICAL

Valid To: November 30, 2026

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:

<u>Test Technology</u>	<u>Test Method(s)</u>
Accelerated Aging	PQC541; ISO 4074
Airburst/Air Inflation	PQC545; ASTM D3492, D6324; ISO 4074, 23409
Determining Compatibility of Personal Lubricants with Male Condoms	PQC570; ASTM D7661; ISO 19671
Specific Gravity	PQC1242; USP 841
Dimensional and Thickness Determination	PQC525; ASTM D3492, D6324; ISO 4074, 23409
Intra-Uterine Device (IUD) Testing	PQC550; ISO 7439 (except 8.5 – 8.6), ISO 7439 – 2015 (except 7.5 – 7.7); TCu380A Intrauterine Contraceptive Device WHO/UNFPA Technical Specification and Prequalification Guidance (all methods in 3.6 except 3.6.2 and 3.6.6); 56 th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, annex 10 (all methods in sections 4 – 7, except 7.2 and 7.7)
Disintegration	PQC1206; USP 701

<u>Test Technology</u>	<u>Test Method(s)</u>
Dissolution	USP 711
Levonorgestrel and Ethinyl Estradiol Tablets	PQC1203
Norgestrel and Ethinyl Estradiol Tablets	PQC1209
Female Condom Testing	PQC561; ISO 25841 (except annex H)
Freedom from Holes	PQC530; ASTM D3492, D6324; ISO 4074, 23409
Tablet Friability	PQC1205; USP 1216
Lubricant Quantity Determination	PQC520
Package Seal Integrity	PQC515; ASTM D3078, D6324; ISO 4074, 23409
pH	PQC1243; USP 791
Tensile	PQC506; ISO 4074; ASTM D3492, D412 (Method B), D6324 (except Annex A2)
Viscosity	PQC1248; USP 912 (Method I)
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
Levonorgestrel and Ethinyl Estradiol Tablets	PQC1201, 1203
Norgestrel and Ethinyl Estradiol Tablets	PQC1208, 1209
Contraceptive Implants	PQC1215
Artesunate	PQC1233
Amodiaquine	PQC1234
Determination of Medroxyprogesterone Acetate in Injectable Contraceptive Products by HPLC (USP)	PQC1240

<u>Test Technology</u>	<u>Test Method(s)</u>
<i>Chromatography – HPLC continued</i>	
Determination of Medroxyprogesterone Acetate in Injectable Contraceptive Products by HPLC (IP)	PQC1241
Artemether and Lumefantrine tablet	PQC1260
Determination of Insecticide Content in Long Lasting Insecticide Treated Nets by HPLC	PQC1272
Uniformity of Dosage Units - HPLC	USP 905
Levonorgestrel and Ethinyl Estradiol Tablets	PQC1201
Norgestrel and Ethinyl Estradiol Tablets	PQC1208
Artesunate	PQC1233
Amodiaquine	PQC1234
Injectable Contraceptive Products (USP)	PQC1240
Determination of Medroxyprogesterone Acetate in Injectable Contraceptive Products by HPLC (IP)	PQC 1241
Artemether and Lumefantrine table	PQC1260
Thin Layer Chromatography (TLC)	PQC1215
Rapid Diagnostic Test Evaluations	PQC1360



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 21st day of November 2024.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 0367.01
Valid to November 30, 2026

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