



Tti Testing Laboratories

OVER 30 YEARS OF EXCELLENCE IN QUALITY ASSURANCE



DIVISION 15 • SURGICAL DEVICES

Surgical & medical devices **testing**

Every instrument, every barrier, tested.

Tti Labs tests surgical instruments and surgical PPE in an ISO Class 5 & 7, BSL-2+ stainless-steel facility. It was Pakistan's first IAC-certified antimicrobial testing lab.



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www.ttilabs.net



FIRST IN PAKISTAN

In 2021 Tti Labs became Pakistan's first lab certified by IAC for specialized microbiology and antimicrobial testing.

The U.S. IAC certified microbiology lab works in ISO Class 5 and Class 7 environments.

MEDICAL TESTING SINCE 2020

One lab for surgical instruments and surgical PPE.

Tti Labs set up an accredited Medical Testing and Biocompatibility Laboratory in 2020, during the COVID-19 pandemic. It tests face masks, surgical gowns, medical textiles and other healthcare products critical to public safety. It also tests antimicrobial performance and runs microbiological analysis.

Founded in 1995, Tti Labs has its 25,000 sq ft headquarters in Lahore. It runs 544 accredited methods and processes 600+ samples a day. 1,500+ global brands trust Tti Labs.

- ISO/IEC 17025 accredited testing laboratory, PNAC LAB 022
- ISO/IEC 17020 accredited inspection body, PNAC IB-006 (Tti Inspections Pvt Ltd)
- PNAC is a signatory to the Global ACI MRA (formerly ILAC MRA)
- U.S. IAC certified microbiology lab
- Approved for ISO Class 5 & 7 standards
- Offices in Lahore, Karachi, Faisalabad and Sialkot



Technical & QA/QC experts



Regulatory & technical support



Reports for national & international requirements



Sample chain-of-custody



DIVISION 15 • SURGICAL INSTRUMENTS

Eight instruments, four test families.

Tti Labs tests medical devices and surgical products for safety, sterility, biocompatibility and functional performance.



01
Curettes



02
Ear cannula



03
Forceps



04
Needle holder



05
**Probes /
directors**



06
Retractors



07
Scalpel



08
Scissors

FOUR TEST FAMILIES • SEE P. 04

Sterility & microbiology
 Material & chemical safety
 Packaging & sterile barrier
 Performance & function

Instrument range: Tti Labs' Division 15 scope (Tti Labs Magazine). Test families: ttilabs.net and Tti Labs Magazine.

FOUR TEST FAMILIES

Four test families, from sterility to strength.

Tti Labs groups its device tests into four families. They cover microbiology, material chemistry, the sterile pack and mechanical performance.



Sterility testing

Sterility & microbiological testing



Bacterial endotoxin (LAL) testing

Sterility & microbiological testing



Bioburden testing

Sterility & microbiological testing



Extractables & leachables, residual analysis, elemental impurities

Material & chemical safety



Sterile packing test, container closure integrity

Packaging & sterile barrier testing



Mechanical strength, dimensional verification

Performance & functional testing



The test families apply to the instrument range as a whole. Ask Tti Labs which tests suit your device.



PAKISTAN'S SURGICAL INSTRUMENT CLUSTER

Next door to Sialkot's instrument makers.

TDAP calls Sialkot the world's largest producer of surgical, dental and veterinary instruments. Tti Labs acquired Sialkot's Cleaner Production Centre (CPC) Laboratory in 2012, with the Pakistan Gloves Manufacturers & Exporters Association (PGMEA).

2,500⁺

Companies in Sialkot make dental, veterinary and beauty instruments

95%

Of Sialkot's products are sold internationally

~10,000

Instrument types produced and exported

446.6^m

US\$ exports in 2022, medical, surgical and related HS lines

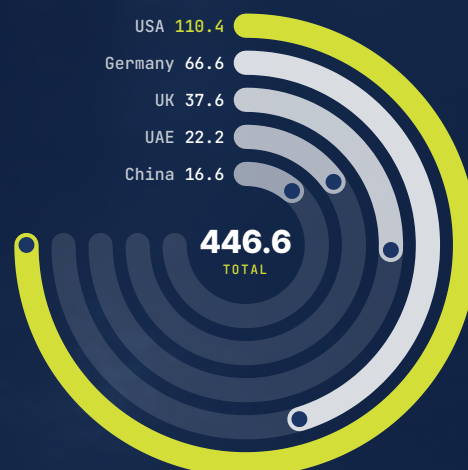
1994

The US restricted surgical instrument imports from Pakistan and required FDA compliance

Sialkot office

Opposite Mag Town Masjid, Kashmir Road, Sialkot-51310 · (052) 3573367

EXPORTS BY MARKET, 2022 (US\$ M)



Source: TDAP, Surgical Instruments sector brochure (2023), pp. 3, 6, 9-10. Export tables cite ITC Trade Map (US\$ 446,633 thousand in 2022).

DIVISION 15 • SURGICAL PPE

Surgical PPE, tested before it reaches the hospital.

Surgical PPE must deliver consistent performance, verified safety and full regulatory acceptance before it reaches hospitals, clinics and frontline professionals. Tti Labs supports makers with accredited testing, inspection and compliance services.

ISO • FDA • WHO

EN 455 Surgical gloves

EN 13795 Gowns & drapes

EN 14683 / ASTM F2100 Medical masks



Masks

Sterile and non-sterile medical face masks



Gowns

Sterile barriers against microbial and fluid exposure



Gloves

Barriers against microbes, chemicals and cross-infection



Drapes

Sterile barriers during medical procedures



Hazmat suits

Healthcare hazmat suits, registered under Division 15



Scrubs & coveralls

Coveralls share the accredited barrier methods of masks, gowns and drapes



Tti Labs tests and registers surgical PPE under Division 15, not the general PPE division (Division 03). Division 03 covers industrial and occupational protection.

EN 14683 · ASTM F2100 · STERILE & NON-STERILE

Six tests at the mask wall.

Tti Labs tests sterile and non-sterile medical face masks to EN 14683:2019 and ASTM F2100:2019. Tests cover filtration, breathability, synthetic blood penetration, microbial cleanliness and flammability.

EN 14683:2019

Medical face masks: requirements and test methods

ASTM F2100:2019

Standard specification for performance of materials used in medical face masks

SR.	TEST	WHAT IT SHOWS	METHOD
01	Bacterial filtration efficiency (BFE)	How well the material stops a bacterial aerosol	ASTM F2101-25 / EN 14683:2025
02	Particle filtration efficiency (PFE)	How well the material stops sub-micron particles	ASTM F2299 / F2299M-24
03	Synthetic blood penetration	Whether a jet of synthetic blood passes the outer face	ASTM F1862 / F1862M-24 / ISO 22609:2004
04	Differential pressure (breathability)	Air resistance across the material	EN 14683:2025
05	Microbial cleanliness (bioburden)	Microorganisms carried on the finished mask	ISO 11737-1:2018/Amd 1:2021 / BS EN 14683:2025
06	Flammability	How the material behaves near a flame	Listed on ttilabs.net; no accredited method



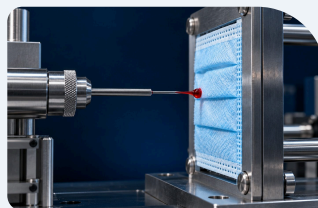
Bacterial filtration

ASTM F2101-25



Particle filtration

ASTM F2299 / F2299M-24



Synthetic blood

ISO 22609:2004



Breathability

EN 14683:2025

Methods: PNAC LAB 022 Rev. 09 (3 Aug 2026), pp. 5-6, matrix "Textile Materials / PPE & Medical Devices". The scope lists EN 14683:2025; ttilabs.net names the 2019 edition.

STERILE BARRIERS • EN 13795 • AAMI PB 70

Keep the sterile barrier intact.

Surgical gowns and drapes keep sterile barriers in place during medical procedures. They protect wearers from microbial and fluid exposure.

Tti Labs tests microbial, viral and blood penetration resistance, hydrostatic pressure and lint generation. It also tests tensile and tear strength, seam integrity and liquid barrier performance.

EU

EN 13795-1:2019

EN 13795-2:2019

EN 13034:2005+A1:2009

US

ASTM F2407:2019

ASTM F3352:2019

AAMI PB 70

TEST

METHOD

Barrier & penetration

Synthetic blood penetration ASTM F1670 / F1670M-25 • ISO 16603:2004

Dry microbial penetration ISO 22612:2005

Wet bacterial penetration ISO 22610:2018

Water penetration (hydrostatic pressure) AATCC 127-2017(2018)e • ISO 811:2018 • EN 20811:1992

Water resistance, impact penetration AATCC 42-2017e

Antibacterial finish AATCC 100-2019 • AATCC 147-2011(2016)e • ASTM E2149-25

Strength & comfort

Tear strength (trapezoid) ASTM D5587-15 (2024)

Seam strength ASTM D751-19 • EN 14325:2018 + A1 (2024)

Bursting strength & distension (pneumatic) ISO 13938-2:2019

Air permeability ASTM D737-18 (2023) • ISO 9237:1995

Methods: PNAC LAB 022 Rev. 09, pp. 5-6. ttilabs.net also names viral penetration, lint generation and tensile strength; the PNAC scope has no method for them.





EN 455 • ASTM D3577 • 21 CFR 800.20

Gloves tested for holes, strength and safety.

Surgical gloves protect healthcare professionals and patients from microbial contamination, chemical exposure and cross-infection. Tti Labs tests physical integrity, tensile strength, elongation, puncture resistance and freedom from holes. It also tests sterility, biocompatibility and chemical residue compliance.

REGION	STANDARD	SCOPE
EU	EN 455 series	Medical gloves for single use
EU	EN ISO 374	Protective gloves against dangerous chemicals and micro-organisms
EU	EN ISO 21420	Protective gloves: general requirements and test methods
US	ASTM D3577	Rubber surgical gloves
US	ASTM D6319	Nitrile examination gloves for medical application
US	ASTM D6978	Resistance of medical gloves to permeation by chemotherapy drugs

EN 455 covers single-use medical gloves in four parts:

01

Freedom from holes

02

Physical properties

03

Biological evaluation

04

Shelf life

US FDA • 21 CFR 800.20

1.5

AQL, SURGEONS' GLOVES

2.5

AQL, PATIENT EXAMINATION GLOVES

FDA checks gloves by visual examination and a water leak test with 1,000 ml of water. It sets sample sizes at general inspection level II. FDA treats a lot as adulterated when defectives reach the rejection number.

COVERALLS • PNAC LAB 022

Coveralls share the accredited matrix with masks, gowns and drapes. Methods cover synthetic blood penetration, bursting strength, dry microbial and wet bacterial penetration, bioburden and antibacterial finish.



Tti Labs' ISO/IEC 17020 inspection body inspects PPE garments, face masks and gloves against the buyer specification.

Standards and evaluations: [ttilabs.net](https://www.ttilabs.net). AQL: eCFR 21 CFR 800.20, current to 29 Sep 2026.

U.S. IAC CERTIFIED • ISO CLASS 5 & 7 • BSL-2+

Microbiology in clean air.

Tti Labs runs medical device testing and surgical instrument evaluation in a stainless-steel BSL-2+ facility. Its U.S. IAC certified microbiology lab works in ISO Class 5 and Class 7 environments.



ISO 5

3,520 particles > 0.5 µm per m³ • Class 100 • active-air action level 1 cfu/m³

ISO 7

352,000 particles > 0.5 µm per m³ • Class 10,000 • active-air action level 10 cfu/m³

Class limits: US FDA aseptic-processing guidance (Sep 2004), Table 1. They are reference limits, not Tti Labs measurements.

TEST	METHOD
Sterility	USP <71>
Endotoxin	USP <85> & USP <161>
Bioburden	ISO 11737-1:2018/Amd 1:2021
Antibacterial finish	AATCC 100-2019 • AATCC 147-2011(2016)e • ASTM E2149-25

HYGIENE & INFECTION CONTROL	SERVICE
Clinical disinfectants	Performance testing
Hand sanitizers	Performance testing
Environmental monitoring	For the facility
Surgical devices	Comprehensive evaluation
BSL-2+ facility	Stainless steel, established 2019-2021



Sterility
USP <71>



Antibacterial finish
AATCC 147



Disinfectants & sanitizers
Performance testing



Environmental monitoring
Hygiene & infection control

Methods: PNAC LAB 022 Rev. 09. Sterility and endotoxin: p. 18, matrix "Pharma & Cosmeceutical Products". Bioburden and antibacterial finish: pp. 5-6. Hygiene services: ttilabs.net.

EU MDR · US FDA

Where devices sit in the rules.

EU · REGULATION (EU) 2017/745, ANNEX VIII RULE 6

I

Reusable surgical instruments

"Transient" means normally intended for continuous use for less than 60 minutes. Rule 6 moves some devices up to class IIb or III. For reusable surgical instruments, Article 52(7)(c) limits notified body involvement to reuse aspects. These include cleaning, disinfection, sterilization, maintenance, functional testing and the instructions for use.

IIa

Default for surgically invasive devices, transient use

US FDA · 21 CFR 878.4800, MANUAL SURGICAL INSTRUMENT FOR GENERAL USE

I

General controls

Listed devices include the cannula, curette, forceps, retractor, scalpel blade, scalpel handle and one-piece scalpel, reusable or disposable.

510(k)

Exempt, subject to 878.9

US FDA · 21 CFR 878.4040, SURGICAL APPAREL

II

Surgical gowns & masks

The classification excludes scrub suits.

I

Other surgical apparel

US FDA · MEDICAL GLOVES

I

Non-powdered surgeon's gloves, 21 CFR 878.4460

eCFR, current to 29 Sep 2026.

I

Non-powdered patient examination gloves, 21 CFR 880.6250

Tti Labs tests samples and reports results under ISO/IEC 17025. Classification and conformity decisions rest with the manufacturer, the notified body and the regulator.

MILESTONES IN MEDICAL TESTING

2012**CPC Laboratory, Sialkot**

Acquired with PGMEA for the glove, sports goods, leather and PPE industries

2019–2021**IAC & medical devices**

ISO Class 5 & 7, BSL-2+ facility

2020**Medical & Biocompatibility Lab**

Face masks, surgical gowns, medical textiles, antimicrobial performance

2021**First IAC certification in Pakistan**

Specialized microbiology and antimicrobial testing

WORK WITH US

01**Quotations.**

Quotations for device and surgical PPE testing, by email.

quotations@ttilabs.net

02**Customer portal.**

Submit requisitions, track samples and retrieve reports online.

etrf.ttilabs.net

03**Accredited testing.**

EN, ISO, ASTM, AATCC and USP methods in Tti Labs' laboratory.

ISO/IEC 17025

04**Report.**

Tti Labs reports results against the standard you name.

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Tti Testing Laboratories

Every instrument, every barrier, tested.

Tti Labs is a trusted quality partner to leading global buyers. It offers end-to-end TIC solutions that bridge manufacturing realities and global compliance expectations.

ISO/IEC 17025 Accredited

ISO/IEC 17020 Inspection

U.S. IAC Certified Microbiology Lab

ISO Class 5 & 7

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Images are illustrative and AI-generated; they do not show Tti Labs premises, clients or samples. Method codes follow PNAC LAB 022 Rev. 09; confirm scope and edition when you order.

