



 cliniswab

Microbiology Swabs

**MADE IN ITALY**

# Company Profile



APTACA, since 40 years, manufactures disposable and reusable Devices for Laboratories of Analysis, Hospitals, Research Institutes and for the Pharmaceutical and Chemical Industries. The always growing efforts in research and the development of new products, an excellent service, a very well understandable deep technical documentation, skilled employees with great passion, are only some of the characteristics that allowed us to become a Leader in this field. With this flyer we want to offer a range more complete and of high quality, always more attentive to the needs of Customers and End-Users, who offer us always a great help with their valuable and precious suggestions. Its efficient manufacturing process and high quality attention allowed APTACA to obtain, since 1998, ISO 9001, and from 2007, ISO 13485 Standard Quality System certifications. Certificates released by Certification Body of undoubted prestige and recognized Accredia.

APTACA has a modern and efficient production department with more than 80 press machines for injection moulding and plastic blowing, with more than 700 moulds. The most modern production technologies, together with an highly qualified staff and a thirty years experience in the industry, allow APTACA a great flexibility and ability to meet the demands of its Customers by providing them an excellent service and high quality product with a competitive price.

All APTACA Devices are designed, tested and manufactured internally with high quality materials, conform to the most straight and severe applicable Standards. All APTACA Devices are subject to great quality care controls, carried out in accordance with the European and International Standards and by advanced instruments. Where applicable, APTACA Devices have CE mark in order to grant the maximum safety for the Users.

APTACA during these years obtained a great importance on the National market and, in particular, on International markets thanks to its products quality and competitiveness, by exporting in the World the Made in Italy. Thanks also to a constant presence in the greatest International Fairs, APTACA can depend on a large number of great distributors all over the World , granting in this way the prompt availability of its products and the correct support to local Users.

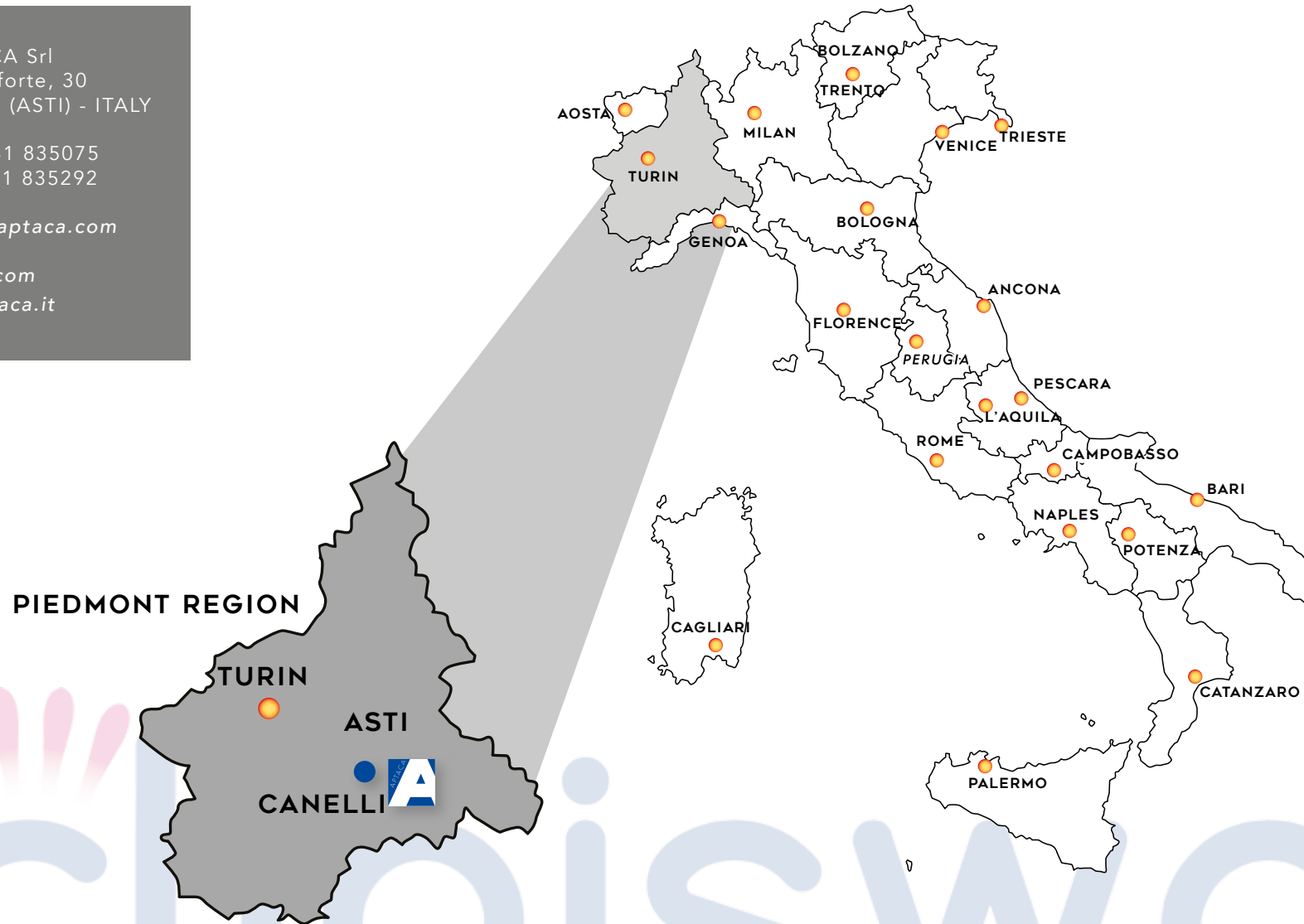
# Aptaca's Headquarter

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# Aptaca's Mission

- The fundamental objective to be pursued to maintain and increase the level of competitiveness against the best competition it is to maintain the full legal compliance and the highest level of customer satisfaction, combined with high quality products working in accordance and respect to the professional ethics, environment and the health and safety for the workers.
- This means offering, in full respect of the duty of law and legally binding regulations, products and services with technical and qualitative characteristics of excellence to meet with the utmost professionalism to customer needs.
- Nuova Aptaca has chosen to pursue these goals with the support of methodologies and tools and supported with an integrated Quality Management System certificate, prevention-oriented, continuous improvement and obtaining the effectiveness of business processes.

“OUR MISSION IS CUSTOMER’S SATISFACTIONS  
AND PRODUCT SAFETY”

# Aptaca's Devices

Nuova Aptaca produces in Vitro Medical Devices (European Directive 98/79/EC as amended), Medical Devices (European Directive 93/42/EC, 2007/47/EC) - Class I and Class IIa sterile certification of compliance issued by Notified Body and devices for general laboratory use.

The products are designed, tested and manufactured internally with high quality materials which meet the most strict standard applicable and subject to the most scrupulous quality checks performed according to European and International standards with cutting-edge equipment. Where applicable, the New Aptaca devices have CE marking in order to ensure maximum safety for users.

Here below the main categories of devices manufactured and marketed:

- Test tubes, with or without additives for clinical chemistry and hematology;

- Microtubes and articles for cryogenics for the biotechnology sector;

- Devices for Microbiology (swabs, petri dishes, inoculating loops, etc ...);

- Device for liquid handling (micropipette tips, pipettes, etc. ..);

- Devices for automatic instrumentation;

- Containers for the collection and transportation of biological samples intended not only to hospitals and laboratory analysis, but also to the large-scale distribution and pharmacies;

- Devices for microscopy and pathological anatomy

# Microbiology Swabs

A complete range of microbiology sterile swabs for Bacteriological applications, available in dry version (Plain swab) or with transport medium to ensure the survival of microorganisms during the transport:

 **TS**  
*Sterile Transport Swabs*

**Agar Gel Transport Swabs:** A sterile, soft rayon swab on a plastic or aluminium shaft with a round bottom plastic pre-labeled tube containing Agar semi-solid gel transport medium, available with or without charcoal. For aerobes and anaerobes microorganisms.

 **LTS**  
*Liquid Medium Transport Swabs*

**Liquid Medium Transport Swabs:** A complete range of Devices ready to use, composed by a Flocked, Foam, Polyester or Rayon swab (plastic shaft) and a test tube with screw cap containing a transport liquid medium, suitable for the transportation and preservation of the clinical microbiological samples.

 **VIRUS**  
*Liquid Transport Medium  
For Virus, Chlamydia,  
Mycoplasma and Ureaplasma*

**Transport System for VIRUS, Chlamydia, Mycoplasma & Ureaplasma:** Devices ready to use, composed by a Flocked, Foam or Polyester swab plastic stick and a test tube with screw cap containing a room temperature stable viral transport medium, suitable for the transportation and preservation of Viruses, such as Influenza H1N1, Chlamydia, Mycoplasma and Ureaplasma specimens.

 **DS**  
*Dry Swabs*

**Dry Swabs:** including cotton swabs and rayon swabs. Swab shaft which can be wood, plastic or aluminum. Swabs are in a round bottom plastic pre-labelled tube without media. Has a tamper-evident seal to assure first time use.

# Microbiology Swabs

— **CliniSwab® is a registered trade mark of Nuova Aptaca Srl. All rights reserved.**

— The study, design, development and marketing is done entirely by Aptaca at its plant in Canelli (AT) - Italy.

— All Devices are **MADE IN ITALY**



— All Devices are manufactured according to GMP standards (Good Manufacturing Practice) and verified by inspections carried out according to specific methodologies according to UNI EN ISO 9001 and UNI EN CEI ISO 13485 and comply to the essential safety requirements and compliance required by regulations and directives in force.



# Microbiology Swabs

Nuova Aptaca Quality System is certified according to:

**UNI EN ISO 9001** - Quality management systems

**UNI CEI EN ISO 13485** - Medical devices – Quality management systems - Requirements for regulatory purposes

Certificates released by Certification Body Italcert S.r.l. of undoubted prestige and recognized by Accredia (Italian Accreditation Body)





# Microbiology Swabs

**Sterile Swabs are CE 0426 marked**, classified as “Medical Devices” in accordance with 93/42/EC Directive, with 2007/47/EC Directive and subsequent amendments. Swabs are sterile and ready-for-use systems intended for clinical samples drawing, transport and maintenance for cultural test. The swab is suitable for short contact with the human body including surgical wounds. Test Tubes are classified as IVD and are intended only for the preservation of samples.

**Swabs are Medical Device Class IIa sterile (Surgically Invasive Transient Use), this means that you can also use them in surgical application.** Swabs from other manufacturers, not in Class IIa, can only be used for natural orifices and not in surgical application.



# CE 0426

For Class IIa Medical Devices is required the involvement of a Notified Body that performs specific tasks in order to ensure compliance and safety of the device. **CE Compliance of our swabs is certified by Notified Body Italcert S.r.l. n° 0426** (authorized by the Italian Ministry of Health and approved by the European Community) [http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe\\_cd=EPOS\\_43748](http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe_cd=EPOS_43748)

# Microbiology Swabs

**Our swabs are also in accordance with the following international standards:**

Farmacopea Ufficiale Della repubblica Italiana Ed. Corrente

**UNI EN 556-1 & UNI EN 556-2:** Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Requirements for terminally sterilized medical devices

**UNI EN ISO 11607:** Packaging for terminally sterilized medical devices

**UNI EN ISO 11737:** Sterilization of medical devices - Microbiological methods

**UNI EN ISO 11137:** Sterilization of health care products - Radiation

**UNI EN 868:** Packaging for terminally sterilized medical devices

**UNI EN ISO 17665:** Sterilization of health care products - Moist heat

**UNI EN ISO 15223 & UNI EN 980:** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

**UNI CEI EN ISO 14971:** Medical devices - Application of risk management to medical devices

**UNI CEI EN 1041:** Information supplied by the manufacturer of the medical devices

**UNI EN ISO 14155:** Clinical investigation of medical devices for human subjects - Good clinical practice



# Microbiology Swabs

## Our Swabs are **STERILE R**:

**STERILE R**

**Sterile R:** Swabs are sterilized by ionizing radiations (Beta Rays - Applied dose: 22,5 kGy – Bundle energy: 10 MeV). Sterilization process is validated and periodically verified by external audit. A **SAL (Sterility Assurance Level) of  $1 \times 10^{-6}$**  is granted. A Device is defined as “sterile” when it’s possible to assure or certify, on statistic basis, that the probability that it results non sterile is equal or lower than a chance of 1 in 1.000.000 i.e. SAL (Sterility Assurance Level) of  **$10^{-6}$** , that is the one we guarantee for our “sterile” products. All our sterilization processes, carried out by irradiations of ionizing radiations (Beta rays), are validated and constantly monitored in accordance with **ISO 11137, ISO 11737, EN 552, UNI EN 556, F.UI:XI and F.EU:IV Norms**. The packaging of sterile Devices is validated and constantly monitored in order to guarantee the microbiological status for the indicated validity period of the integral packaging (**UNI EN 868, UNI EN ISO 11607**).

**Swabs are Apyrogenic or non-Pyrogenic:** Devices where absence, or presence within detection limits, of endotoxins by Gram-negative bacteria is granted. For Devices declared as Apyrogenic a bacterial endotoxin limit 20EU/piece (EU=Endotoxin Unit) on integral packaging is granted. Endotoxins presence is determined by LAL tests (sensitivity 0.03 EU/ml).

All Devices are **LATEX FREE** (During Devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used).



# Microbiology Swabs

**Sterile in medical, easy to open peel-pouch (printed medical paper/plastic or plastic/plastic)**

The easy-peel open pouch enables fast and sure access to the product especially when gloves are used. Packaging ensures the microbiological status of the device for all the period of validity (packaging validated according to UNI EN 868, UNI EN ISO 11607).



**Lot number and expiry date printed on each peel-pouch package and on every tube. Every unit of production can be identified.**

# Microbiological Swabs

In each sales unit, in order to ensure maximum safety for Users, there are operating instructions / warnings for the use of the device, drawn up in accordance with Standard EN 1041 (Information supplied by the manufacturer of Medical Devices in all European languages, Russian and Arabic).



Latinski (LV) LIETOŠANAS NORĀDĀJUMI (Izstrādātājs CEI EN 1041)	Maķi (M) ISTRUKCIJONIJEI GĀLĀL-ŪZŪ (konformāri maķ CEI EN 1041)	Romaņu (RO) INSTRUCȚIUNI DE UTILIZARE (în conformitate cu CEI EN 1041)	Svenska (SVE) BRUKSANVISNING (i överensstämmelse med CEI EN 1041)
<p>Iš klasas sterila medija šķīduma (0342ZE) un 2007/47/EG – Parādības izņemšana profesionālā nolikuma –</p> <p>Ierīci jāizmanto piemērotā temperatūrā (skatīt 1. lappusi), jānodrošina pareiza pārnēsāšana zonā (skatīt tehnisko datu lapas un pielikuma 1. daļu).</p> <p>Izmantojiet ierīci, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā.</p>	<p>Tāpat ir klasē sterila medija šķīduma (0342ZE) un 2007/47/EG – Parādības izņemšana profesionālā nolikuma –</p> <p>Izmantojiet ierīci, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā, ieviešot prasības, kas paredzētas šīs ierīces tehniskajā specifikācijā.</p>	<p>Dispozitiv medical de clasa A la sterili (0342CE + 2007/47/EG) – Destinat exclusiv utilizării profesionale –</p> <p>Utilizați dispozitivul numai pentru scopul de probă convenționalului modului de transport alate (dacă este cazul) și locului de prelucrare a probei (A se vedea fișa tehnică și eticheta).</p> <p>Utilizați dispozitivul numai conform cerințelor și instrucțiunilor produsului biologic unicat pentru diagnosticul patogenilor ageni patogeni, precum bacterii aerobice, anaerobe, anaerobe facultative în conformitate cu scopul dispozitivului unicat.</p>	<p>Steril medicinsk produkt, klass A (0342ZE) och 2007/47/EG – Endast avsedd för yrkesmässig användning –</p> <p>Använd den medicinska produkten endast för typen av provmaterial som är lämpligt för den vätska transportmedel (om detta finns) och det fastslagna provningsområdet (Se läsnäs datu lappas och etichetter).</p> <p>Använd den medicinska produkten endast för typen av provmaterial som är lämpligt för vätska transportmedel (om detta finns) och det fastslagna provningsområdet (Se läsnäs datu lappas och etichetter).</p>
<p><b>GERUKSAANWIJZING (in overeenstemming met CEI EN 1041)</b></p> <p>Sterile medicinale hulpmiddel klasse A (0342ZE) + 2007/47/EG – Utlukkende bestemt for profesjonell bruk –</p> <p>Her hulpmiddel alleen gebruiken voor het type monster dat geschikt is voor het gekozen transportmedium (indien aanwezig) en de vastgestelde plaats(en) (zie technische fiche en label).</p>	<p><b>INSTRUKCIJA OSUJEĆU (zgodnie z CEI EN 1041)</b></p> <p>Wytyć medycynę klasy A sterylnej (0342ZE) + 2007/47/EG – Wyłącznie do użytku profesjonalnego –</p> <p>Używać wyrobku wyłącznie do pobierania próbek odpowiednio do wybranego rodzaju transportu (jeśli jest konieczny) określonego miejsca pobrania (patrz arkusz danych technicznych) (etykieta).</p>	<p><b>NAVOD NA POUPRAČE (v skladu s normo CEI EN 1041)</b></p> <p>Zabavljiva pomočilo trdnosti Ila, sterilno (0342ZE + 2007/47/EG) – Uključeno za strokovno uporabo –</p> <p>Pomočilo uporabljajte le za določene vzorce, vrnjene pri zbiranju vzorca (če je potrebno) in pre uravnoteženo obdelavo vzorca.</p>	<p><b>NAVODILA ZA UPORABO</b> (v skladu s standardom CEI EN 1041)</p> <p>Sterilni medicinski pripomočki razreda Ila (0342ZE + 2007/47/EG) – namenjeni za strokovno uporabo –</p> <p>Pripomoček uporabljajte samo za vrste vzorcev, ki ustrezajo izbranim transportnim posodam (če je na voljo) in določeno mesto vzorčenja (glej tehnični list in nalepko).</p>
<p><b>Русский (RUS)</b></p> <p><b>ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ (в соответствии со стандартом ИСО EN 1041)</b></p> <p>Медицинское устройство класса стерильности А (0342ZE + 2007/47/EG) – Предназначено исключительно для профессионального использования</p>	<p><b>CEI EN 1041 (in conformitate cu)</b></p> <p>Medicinsko ustrojstvo klase sterilnosti A (0342ZE + 2007/47/EG) – Prednačeno izključno za profesionalno uporabo</p>	<p><b>cliniswab LTS</b> Liquid Medium Transport Swabs</p> <p>CE 0426</p> <p>NOUVA APTACA S.R.L. Regione Monforte, 30 - 14053 Canelli (AT) ITALY www.apta.com - info@apta.com Tel. (+39) 0141/83.50.75 / Fax (+39) 0141/83.52.92</p>	<p><b>STERILE R</b></p> <p>IS: LTS Rev. 1 del 30.06.2017</p>

TAMPONI CON TERRENO DI TRASPORTO LIQUIDO Modalità d'uso / TAMPONS AVEC MILIEU DE TRANSPORT LIQUIDE Mode d'emploi / ZARAGOTOS CON MEDIO DE TRANSPORTE LIQUIDO Modo de empleo / TUPFER MIT FLÜSSIGEM TRANSPORTMEDIUM Anwendung / ТАМПОНИ С ЖИДКОМ ТРАНСПОРТНЫМ СРЕДСТВОМ Способ применения	1	2	3	4	5
<p>Open the blister pack from the "peel here" indication and aseptically remove the swab from the blister pack.</p> <p>1. Ouvrir le blister d'où se trouve l'indication "Peel here" et extraire le tampon du blister en utilisant une technique aseptique.</p> <p>2. Abrei el blister en el lugar de indicación "Peel here" e retire a zaragota do blister, usando técnica asséptica.</p> <p>3. Den Blister bei der Angabe "Peel here" abziehen und den Tupfer mit aseptischer Technik aus dem Blister nehmen.</p> <p>4. Вскрыть блистерный упаковку в том месте, которое обозначено надписью "Peel here", и извлечь тампон из блистера с соблюдением асептических процедур.</p>	<p>Unscrew the cap and insert the swab into the test tube, being careful not to spill the liquid.</p> <p>5. Insérer le tampon dans le tube, après avoir vissé le bouchon, en veillant à ne pas renverser le milieu de transport qu'il contient.</p> <p>6. Introduzir o tampão no tubo, após estar desvité o bouchon, em evitando a não perder o meio líquido nele contido.</p> <p>7. Dopo de aver avvitato il tappo, introdurre a zaragota no tubo, tenendo o cuidado de não deixar sair o meio liquido nele contenuto.</p> <p>8. Den Tupfer in das Röhrenden einführen, nachdem der Deckel abgeschraubt worden ist; dabei dürfen Äußen, das enthaltene Flüssigmedium nicht zu verschütten.</p> <p>9. Открутить крышку и поместить тампон в пробирку, следя за тем, чтобы не пролить содержимое в новую пробирку.</p>	<p>Break the swab in the test tube by placing the "breakpoint" indicated on the shaft of the swab against the edge of the test tube. It is 180°.</p> <p>3. Spaccare il tampon nella provetta ponendo il "breakpoint" presente sull'asta del tampon contro il bordo della provetta e inclinare di 180° esercitando una pressione moderata (non applicabile per i tamponi asséptici).</p> <p>4. Romper el hisopo dentro de la probeta. Para ello, colocar el punto de rotura presente en la varilla del hisopo contra el borde de la probeta e inclinar 180° ejerciendo una presión moderada (no aplicable para los hisopos de aluminio).</p> <p>5. Break the swab in the test tube by placing the "breakpoint" present on the tip of the tampon contre le bord du tube et l'incliner de 180° en exerçant une pression modérée (non applicable pour les écouvillons à bâtonnet en aluminium et pour les écouvillons sans point de rupture).</p> <p>6. Entfernen Sie die Probe aus dem Reagenzglas, indem Sie die Röhrenden gegen den Rand des Reagenzglases drücken und mit realisiertem Druck um 180° geneigt wird (nicht anwendbar für Tupfer mit Aluminiumstäben und Tupfer ohne Sollbruchstelle).</p> <p>7. Den Tupfer im Röhrenden brechen, indem die Röhrenden des Reagenzglases gegen den Rand des Reagenzglases drücken und mit realisiertem Druck um 180° geneigt wird (nicht anwendbar für Tupfer mit Aluminiumstäben und Tupfer ohne Sollbruchstelle).</p> <p>8. Открутить крышку и поместить тампон в пробирку, следя за тем, чтобы не пролить содержимое в новую пробирку.</p>	<p>Remove the cap and insert the swab into the test tube with the patient's data and keep it at room temperature. Deliver it to the laboratory within 48 hours.</p> <p>5. Retirar a zaragota do tubo e inserir o swab no tubo com os dados do paciente e entregar ao laboratório no prazo de 48 horas, a temperatura ambiente.</p> <p>6. Abrei el blister, sacar el tubo con los datos del paciente y enviar al laboratorio antes de 48 horas a temperatura ambiente.</p> <p>7. Abrei el blister, sacar el tubo con los datos del paciente y enviar al laboratorio antes de 48 horas a temperatura ambiente.</p> <p>8. Retirar a zaragota do tubo e inserir o swab no tubo com os dados do paciente e entregar ao laboratório no prazo de 48 horas a temperatura ambiente.</p> <p>9. 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Retirar a zaragota do tubo e inserir o swab no tubo com os dados do paciente e entregar ao laboratório no prazo de 48 horas a temperatura ambiente.</p>



# Microbiology Swabs

Each sale unit of our Swabs is clearly and correctly identified by a detailed and easy to read labeling system, even using symbols conforming to **UNI CEI EN ISO 15223-1** (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied), which allows complete traceability, including through barcode and safe use of the device.

**REF 301/SG**  
Quantity (pcs): 900  
(6 x 150 pcs)

**cliniswab<sup>TS</sup>**  
*Transport Swabs*

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Swabs plastic stick and rayon tip, with AMIES clear medium in test tubes Ø12x150 mm in PP, with label, sterile individually wrapped peel-pack

Tamponi asta plastica e puntale in viscosa, con terreno di trasporto AMIES chiaro in provetta in PP Ø12x150 mm, con etichetta, sterili confezione singola peel-pack

Escobillones estéril en plástico, torunda en viscosa, tubo en PP Ø12x150mm con medio de Amies sin carbon, etiqueta, embalaje individual peel-pack.

Zaragotao (aplicador) de viscoso haste de plástico, tubo Ø12x150 mm em PP com meio de transpote AMIES, eitiqueta, estéril, embalagem individual peel-pack.

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<b>LOT</b> TEST	2017 - 06	2019 - 06	
<b>CE</b> 0426	(MDD Class IIa)	<b>MADE IN ITALY</b>	
<b>1</b>	<b>STERILE R</b>		

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30 °C  
Rev. 2

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01040710TEST#1519063700900

For professional use only-Per uso professionale-Solo para uso profesional-Apenas para uso profissional

**LOT**

Lot number, Batch number



Date of manufacture (yyyy - mm)



Use by, expiry date (yyyy - mm)



Medical Device (93/42/EC Directive)

**STERILE R**

Sterilized using irradiation



Do not reuse, Single use, Use only once.



Consult instructions for use



Keep away from sunlight



Keep dry



Temperature limitation



Do not use if package is damaged



Latex free



Manufacturer

# Microbiology Swabs

## Quality control

On the Devices, throughout the full production process, are carried out the strictest quality controls in order to meet all the required specifications.

Eventually available in accordance with **CLSI M40-A Standard** (Quality Control of Microbiology Specimen Transport Devices) tested.

The quality checks are carried out on the basis of internal and international standards.

Each production lot of Swabs is quality controlled and certified to ensure the conformity of the device:

- Mechanical strength and flexibility of the shaft
- Closing force / pressure of plug / stopper (mechanical test)
- Correct wrap of the fiber to the shaft
- pH of the medium at 25°C
- Medium optical controls and mechanical controls
- Medium solidity by immersion with an applicator (simulated use)
- Transport medium opalescent appearance and absence of granules in suspension
- Survival rate of organisms on medium



**The devices are approved and marketed only when all the controls provided have given positive results**

# cliniswab<sup>TS</sup>

## Transport Swabs

## Transport Swabs - Main Features

A sterile, soft rayon swab on a plastic or aluminium shaft with a cylindrical test tube Ø12x155 mm made in plastic (unbreakable medical Polypropylene) containing Agar semi-solid gel transport medium (Amies, Stuart or Cary Blair type), available with or without charcoal, or liquid transport medium for Virus or Chlamydia (Liquid transport medium is contained into the sponge deposited on the tube bottom). Amies Agar Gel Medium Swabs are also available in XL version with about 6 ml of transport medium which allows a better bacteriological sample inoculation inside the medium, ensuring a safer anaerobic bacteria viability.

- For aerobes, anaerobes microorganisms and fastidious organisms.

- Transport at room temperature or refrigerated temperatures.

- Soft rayon swab tips are inert and non-toxic to micro-organisms and patients. Rayon is a semi-synthetic material. Tips preserve the sample longer (no fatty acids). The texture is close to that of cotton, but it has none of the fatty acids or other substances that can be inhibitory to fastidious bacteria. It has also been shown to be compatible with many molecular based diagnostic tests.

- Sterile (SAL 10<sup>-6</sup>), Pyrogen free & Latex free.

- Color coded caps to facilitate easy recognition and to distinguish different Devices.

- Tamper evident tube seal: Test tube and cap is pre-labeled for patient and sample identification and as a seal indicating that the product has not been previously used

- Individually wrapped in medical peel-pouch.

- Shelf life 2 years



The label for cliniswab TS Transport Swabs includes the following information:

- Product name: **cliniswab<sup>TS</sup> Transport Swabs**
- Regulatory information: **PATENTED CE 0426 ET-INN-APT Rev.0**
- Fields for patient and sample identification:
  - Name/Nome/Apellido
  - Age/Età/Edad
  - Sex/Sexo/Sevo (M/F)
  - Specimen/Campione/Espécimen
  - Date/Dato/Fecha
  - Hospital/Ospedale/Hospital
  - Ward/Reporto/Sala
  - Address/Indirizzo/Dirección
- Manufacturer information: **NUOVA APTACA SRL Regione Monforte, 30 - 14053 Canelle (AT) - Italy www.aptaca.com**
- Origin: **MADE IN ITALY**
- Seal: **Do not use if seal is broken** (with a vertical line and a broken seal icon)
- Additional markings: **STERILE** and a circular icon with a cross.



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## *Transport Swabs*

The applicator shaft of the swab is mounted on the tube plug which serves as an optimal grip for an efficient swab handling.



### There is a choice of shaft:

**Plastic shaft, Rayon tip:** made in anti-shock polystyrene, very flexible but easily breakable as needed, with rayon tip, atoxic. Particularly suitable for mouth, throat, vagina, urogenital apparatus, skin, wounds and surgical wounds.

**Aluminum shaft, rayon tip:** atoxic shaft, with rayon tip, ideal for arduous or delicate sampling. The narrow dimension of the swabs shaft (only 0.9 mm), the high flexibility and strength, the small fiber tip, make it particularly suitable for urogenital, urethral, ocular, nasopharyngeal and paediatric uses.



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## Transport Swabs

### There is a choice of Transport Medium:

Transport Medium is contained in a cylindrical test tube Ø 12 x 155 mm, in transparent, unbreakable medical polypropylene (PP), to preserve sample and user's safety. With pressure cap in polyethylene (HDPE) with specific colour according to medium type. Pre-labelled on test tube to allow a correct sample identification. Item code, lot number and expiry date printed on each label for a full traceability.

**STUART:** Stuart Media, as per by Dr. R.D Stuart creation, was the first media for transporting clinical swab samples. Stuart transport medium allows survival of many microorganisms, such as *Trichomonas vaginalis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Corynebacterium diphtheria* and *Neisseria gonorrhoeae*.



**AMIES:** Amies transport medium allows the survival of many micro-organisms, such as *Shigella flexneri*, *Neisseria*, *Trichomonas vaginalis*, *Enterobacterias*, *Haemophilus*, *Corynebacterium*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Salmonella typhi*, *Brucella abortus*. Amies modified Stuart's original formula by replacing the glycerophosphate in the original formula for an inorganic phosphate buffer. The metabolism of glycerophosphate by coliform organisms and other Gram-negative rods, in Stuart's original formulation, resulted in proliferation of these organisms from throat, wound and fecal specimens. Amies also found that NaCl at 0.3% w/v was optimal for the preservation of *Neisseria gonorrhoeae*. Calcium and magnesium salts were added in the belief that these ions were of importance in checking the permeability of the bacterial cells and contributed to their survival.



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## Transport Swabs

**STUART AND AMIES** are available with or without charcoal: the presence of charcoal in medium neutralizes toxins and inhibitory substances. The Amies formula with charcoal has been shown to improve the recovery of *Neisseria gonorrhoeae* and is often moreover recommended for *Bordetella pertussis*.



**CARY BLAIR:** Particularly suitable for the transport of microorganisms present in faecal and rectal specimens. Sodium glycerophosphate presents in Stuart medium, is replaced by buffer phosphate to avoid, in the medium, the growth of bacteria that has glycerophosphate reductase. The medium is particularly suitable for the transport of *Salmonella*, *Shigella*, *Campylobacter* and *Vibrio*: furthermore its high pH relatively alkaline minimize the bacterial destruction due to formation of acid. Viability of *Vibrio* cultures for up to four weeks.



**VIRUS:** The liquid transport medium is inside a sponge, at the bottom of the squeezable test tube, in order to allow direct inoculation of the sample. The addition of antibiotic substances avoids the proliferation of bacteria or fungi. The foam sponge with transport medium allows the survival of virus such as Papiloma, Pseudorrabia, Influenza aviar (H7N1), Influenza A (H1N1) o H1N1/09 pandemic, Suid herpesvirus



**CHLAMYDIA:** liquid transport medium for *Chlamydia trachomatis*. The liquid medium is inside a sponge, at the bottom of the squeezable test tube, in order to allow direct inoculation of the sample.





## Liquid Medium Transport Swabs Liquid Transport Medium for **VIRUS**, Chlamydia, Mycoplasma & Ureaplasma

### Main features

A complete range of Devices ready to use, composed by a Flocked, Foam, Polyester or Rayon swab, plastic shaft with break point, and a test tube with screw cap containing a liquid medium, suitable for the transportation and preservation of the clinical microbiological samples.

- CliniSwab<sup>LTS</sup> is suitable for aerobes, anaerobes microorganisms and fastidious organisms.
- CliniSwab<sup>VIRUS</sup> is a room temperature stable viral transport medium, suitable for the transportation and preservation of Viruses, such as Influenza H1N1, Chlamydia, Mycoplasma and Ureaplasma specimens.
- Transport at room temperature or refrigerated temperatures.
- The Devices standard dimensions make them suitable both for use with automatic instruments whether for manual use.
- The liquid medium type allows to dilute the samples easily and rapidly obtaining a homogeneous solution ready to be used and appropriate in order to obtain many samples equal rates to carry out different analysis.
- Swabs with break-point and screw cap with "capture" system.
- High level of reliability, reproducibility and repeatability thanks to consistent and standardized absorption and release.
- Rapid automatic elution. Instant and spontaneous release into liquid media.
- Sterile (SAL 10<sup>-6</sup>), Pyrogen free & Latex free.
- Color coded caps to facilitate easy recognition and to distinguish different Devices
- With label on each test tubes with lot number and expiry date printed on it to grant full traceability
- Packed in peel-pack, easy opening, totally in plastic material for the Devices optimal protection.
- Shelf life 24 months for CliniSwab<sup>LTS</sup> and 18 months for CliniSwab<sup>VIRUS</sup>

# cliniswab *LTS*

*Liquid Medium Transport Swabs*

# cliniswab *VIRUS*

*Liquid Transport Medium  
For Virus, Chlamydia,  
Mycoplasma and Ureaplasma*

Swabs with Flocked, Foam, Polyester or Rayon tip and plastic shaft. They allow an excellent specimen collection and subsequent release into liquid transport medium. Plastic shaft with “breakpoint” to allow the swab breaking into the test tube and the successive collection by the screw “capture” cap after the tube closing. It allows to dispose of the swab together with the cap in a safer way.

## Flocked Swabs:

Syntetic fiber flocked swab that allows a excellent clinical sample collection and the following immediate release into the liquid transport medium. It has a plastic shaft with “breakpoint” to allow the swab breaking into the test tube and the successive collection by the screw “capture” cap after the tube closing. It allows to dispose of the swab together with the cap in a safer way. Available in three versions on sampling site base:

■ **Standard tip:** swabs, standard dimensions, for buccal, nasal, vagina, rectal, cutaneous and wound sampling;

■ **Fine tip:** swabs, thin dimensions, for oropharyngeal, urethral and ocular sampling;

■ **Paediatric tip:** swabs, small dimensions.

## Foam Swabs:

Special polyurethane foam, medical grade, swab tip that allows a very good clinical sample collection and the following immediate release into the liquid transport medium. The soft foam bud is more comfortable for patients, and has significant advantages for both conventional and molecular methods. It has a plastic shaft with “breakpoint” to allow the swab breaking into the test tube and the successive collection by the screw “capture” cap after the tube closing. It allows to dispose of the swab together with the cap in a safer way. Available in two versions on sampling site base:

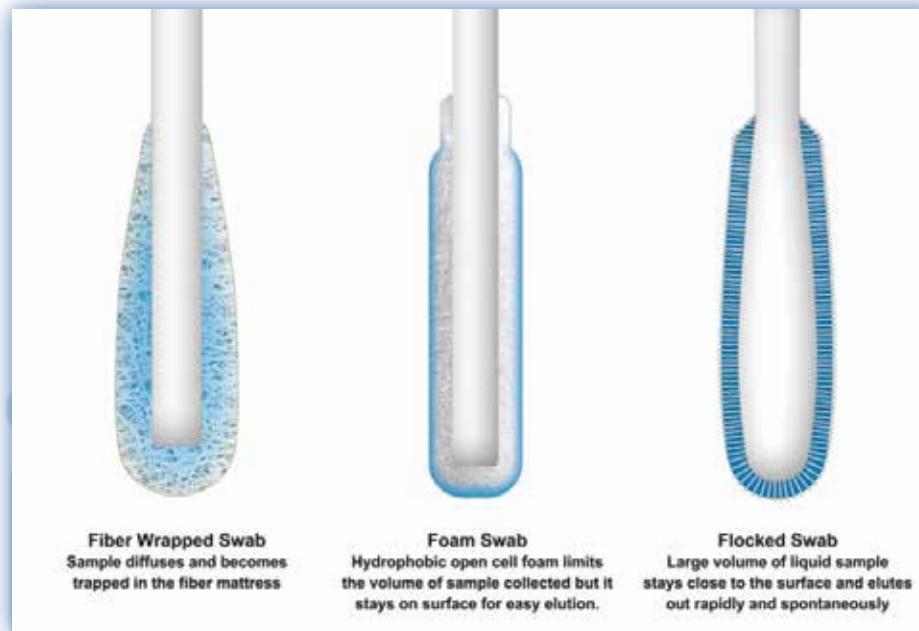
■ **Standard tip:** swabs, standard dimensions, for buccal, nasal, throat, vagina, rectal, cutaneous and wound sampling;

■ **Fine tip:** swabs, small dimensions, for paediatric, urethral, urogenital and nasopharyngeal sampling.

**Polyester and Rayon Swabs:**

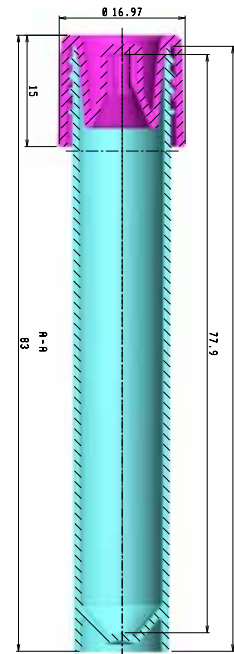
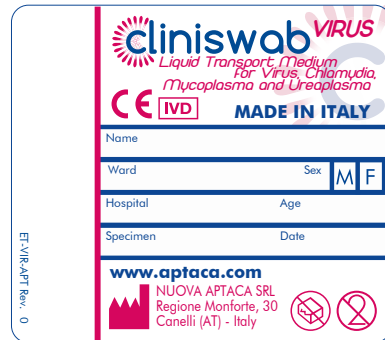
Swabs with Polyester tip and plastic shaft or Rayon tip (plastic shaft or aluminium shaft for urethral use). They allow an adequate specimen collection and subsequent release into liquid transport medium. Plastic shaft with "breakpoint" to allow the swab breaking into the test tube and the successive collection by the screw "capture" cap after the tube closing. It allows to dispose of the swab together with the cap in a safer way. Available in two versions on sampling site base:

- **Standard tip:** swabs with break point, standard dimensions, for buccal, nasal, throat, vagina, rectal, cutaneous and wound sampling;
- **Aluminium shaft, rayon tip:** swabs aluminium shaft (without break point) and rayon tip, very small dimensions, for paediatric, urethral, urogenital and nasopharyngeal sampling



### There is a choice of Transport Medium:

Liquid Transport Medium is contained in a cylindrical test tube  $\varnothing 13 \times 80$  mm, in transparent, unbreakable medical polypropylene (PP), to preserve sample and users safety. With screw cap in polyethylene (HDPE) with "capture cap" technology, The specific color cap identifies instantly and secure the medium content. Pre-labelled on test tube to allow a correct patient and sample identification. Item code, lot number and expiry date printed on each label for a full tracciability.



**AMIES:** Swabs with pink screw cap test tube containing 1 ml of liquid AMIES transport medium for the sampling and preservation of aerobes, anaerobes and other fastidious bacteria such as *Streptococcus pyogenes*, *Neisseria gonorrhoeae*, *Bacteroides fragilis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, etc within 48 hours (24 hours for *Neisseria gonorrhoeae*) at room or refrigerated temperature. They can be used for the collection and preservation of mycobacterium and fungi. Amies is a medium of conservation consisting of inorganic phosphate, calcium and magnesium salts and sodium chloride with a reduced environment due to the presence of sodium tioglicollato.



# cliniswab *LTS*

*Liquid Medium Transport Swabs*

# cliniswab *VIRUS*

*Liquid Transport Medium  
For Virus, Chlamydia,  
Mycoplasma and Ureaplasma*

**STUART:** Swabs with blue screw cap test tube containing 1 ml of liquid STUART transport medium for the sampling and preservation of bacteria *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, *Haemophilus influenzae*, *Bacteroides fragilis*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Corynebacterium diphtheria*, enterobacteria and bacteria of the upper respiratory tract. These microorganisms are kept viable for no more than 24 hours. More resistant bacteria are kept for 72 hours; rule of thumb is, however, to submit to the microbiological analysis, as soon as possible, all samples.



**CARY BLAIR:** Swabs with green screw cap test tube containing 2 ml of liquid CARY BLAIR transport medium, for the fecal or rectal clinical samples and for preservation of enteric pathogens agents as *Salmonella*, *Vibrio*, *Escherichia coli*, *Shigella flexneri*, *S. typhimurium*, *E. faecalis* (VRE), *V. parahaemolyticus*, *Y. enterocolitica*, *C. jejuni*, *C. difficile*, *Campylobacter*. The Cary Blair Transport Liquid Medium is especially suitable in epidemiological investigations for *Vibrio parahaemolyticus*, rectal swabs, especially when they have to be transported to a central diagnostic laboratory.



**SELENITE:** Swabs with white screw cap test tube containing 2 ml of liquid medium SELENITE (Selenite broth) type for the fecal clinical samples or rectal swab, designed for the transportation, survival and isolation of *Salmonella enterica* and *Shigella sonnei*, reducing the growth of the other enteric pathogens like *Escherichia coli* and fecal streptococci. The selenite present in the medium inhibit microorganisms other than *Salmonella*, particularly coliforms and enterococci. *Pseudomonas* and *Proteus* are not inhibited. Dipotassium phosphate maintains constant pH and reduces the toxicity of selenium.





# cliniswab<sup>LTS</sup>

Liquid Medium Transport Swabs

# cliniswab<sup>VIRUS</sup>

Liquid Transport Medium  
For Virus, Chlamydia,  
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**SALINE SOLUTION:** Swabs with light blue screw cap test tube containing 2 ml of sterile buffered saline sodium chloride solution, pH 7.2. Particularly suitable to obtain immediately a ready to use dilute clinical sample solution for inoculation and analysis.



**VIRUS:** Swabs with red screw cap test tube containing 1 ml of liquid VIRAL transport medium for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the CliniSwabVIRUS can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasma culture. Viral transport medium, stable at room temperature, consists of a balanced buffer solution to maintain neutral pH, anti-microbial agents and a preservative. Organisms viability maintained at room temperature and on ice. Suitable also for long term freeze storage. This product is not intended to be used for the collection and transport of general bacterial and fungal specimens.



## SPECIMEN CULTURES IN THE LABORATORY

CliniSwab<sup>LTS</sup> and CliniSwab<sup>VIRUS</sup> are suitable for Manual Processing or Automated Processing. They are compatible for use with most automated microbiology platforms. Consult with microbiology automated platform manufacturer instructions for specific information.

Manual processing with swab applicator



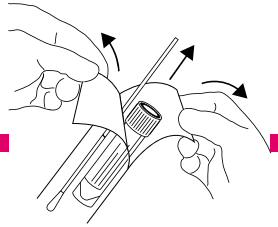
Manual processing without swab applicator



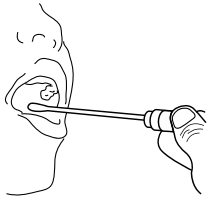
Streak plating example



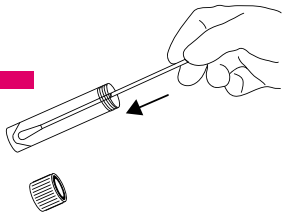
## HOW TO USE



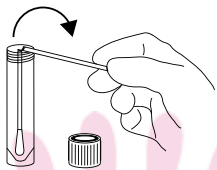
Open the blister pack from the “peel here” indication and aseptically remove the swab from the blister pack;



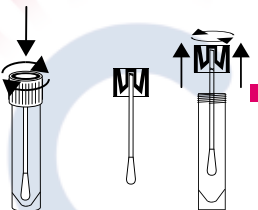
Take the sample from the patient by applying moderate pressure;



Unscrew the cap and insert the swab into the test tube, being careful not to spill the liquid medium contained inside;



Break the swab in the test tube by placing the “breakpoint” indicated on the shaft of the swab against the edge of the test tube. Tilt it 180°, using moderate pressure (not applicable for alluminium shaft swabs). Discard the broken part of the shaft in accordance with current regulations for medical waste;



Firmly tighten the cap onto the test tube and shake gently. Label the test tube with the patient’s data and keep it at room temperature. Deliver it to the laboratory within 48 hours. When the cap is removed, the swab will also automatically be removed. Analyze the sample by performing standard clinical laboratory procedures.

# cliniswab<sup>DS</sup>

## Dry Swabs

### Dry Swabs - Main Features

Sterile Dry Swabs (Plain swabs) including cotton swabs and rayon swabs. Swab shaft which can be wood, plastic or aluminum. Swabs are inside a cylindrical test tube Ø12x155 mm made in plastic (unbreakable medical PP), without media.

- For specimen collection, transport and general laboratory use. Dry swabs are intended for use when a test is to be carried out immediately, or does not require target organisms to remain viable.
- Cotton swab tip is a natural product (100% cotton – conform to European Pharmacopea) that may contains fatty acids such as oleic acid. These can inhibit recovery of some bacteria if not used immediately. Sterilisation by irradiation can make this inhibitive effect worse, especially when used in a transport device.
- Soft rayon swab tips are inert and non-toxic to micro-organisms and patients. Rayon is a semi-synthetic material. Tips preserve the sample longer (no fatty acids). The texture is close to that of cotton, but it has none of the fatty acids or other substances that can be inhibitory to fastidious bacteria. It has also been shown to be compatible with many molecular based diagnostic tests.
- Color coded caps to facilitate easy recognition and to distinguish different Devices.
- Tamper evident tube seal: Test tube and cap is pre-labelled for patient and sample identification and as a seal indicating that the product has not been previously used
- Available sterile individually wrapped in medical peel-pouch or sterile save-space test tube in bulk.
- Shelf life 5 years.



# cliniswab<sup>DS</sup>

## Dry Swabs

The applicator shaft of the swab is mounted on the tube plug which serves as an optimal grip for an efficient swab handling.



### There is a choice of shaft:

- Plastic shaft, Rayon tip:** made in anti-shock polystyrene, very flexible but easily breakable as needed, with rayon tip, atoxic. Particularly suitable for mouth, throat, vagina, urogenital apparatus, skin, wounds and surgical wounds.
- Aluminum shaft, Rayon tip:** atoxic shaft, with rayon tip, ideal for arduous or delicate sampling. The narrow dimension of the swabs shaft (only 0.9 mm), the high flexibility and strength, the small fiber tip, make it particularly suitable for urogenital, urethral, ocular, nasopharyngeal and paediatric uses.
- Wooden shaft, Cotton tip:** made in 100% cotton tip (European Pharmacopea) and atoxic wooden stick. Swabs for general clinical use, everyday performance, suitable for throat, vagine, skin and wounds drawings, Gram-positive, Gram-negative. Not recommended for *N. gonorrhoeae* or *C. trachomatis*.



"Thank you for  
your attention"

To see our complete swabs range

click here

To see our complete product range visit [www.aptaca.com](http://www.aptaca.com)



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