AmpliSens
biotechnologies

PCR-diagnostics of sexually transmitted infections

Sampling, storage and transportation of clinical material

Results of laboratory tests, in particular PCR and NASBA, depend on type of clinical material, sampling instruments, storage and transportation conditions.

The most comprehensive information about presence of infectious agent could be obtained by analyzing clinical material from different localizations. To make a topical diagnosis material from all localizations needs to be analyzed separately. To decrease laboriousness and cost of analysis the pooling of different types of clinical material is acceptable.

Male clinical material

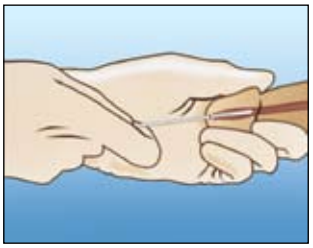
Type of clinical material	Diagnostic task	Detected microorganisms
Urethras epithelial scraping, urethral discharge	Screening of STI*, etiological diagnostics of urethritis, monitoring of antibacterial therapy of urethritis	STI*: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium* OM**: *Mycoplasma hominis, Ureaplasma spp, Streptococcus spp, Staphylococcus spp, Candida spp*, etc.
Foreskin discharge scraping	Diagnostics of balanoposthitis	
Urine	Screening of STI*, etiological diagnostics of urethritis	
Ulcerative-erosive elements discharge scraping	Differential diagnostics of infections which cause ulcerative-erosive lesions	*Treponema pallidum, HSV I/II*
Scraping of epithelium from neoplasms of balanus and perianal area	Differential diagnostics of infections which cause condylomas	Low-carcinogenic risk HPV
Prostate secretions, ejaculate	Etiological diagnostics of bacterial prostatitis	STI *: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium*. OM**: *E.coli, Serratia, Klebsiella, Enterobacter spp, Acinetobacter spp., Pseudomonas aeruginosa, Ureaplasma spp, Streptococcus spp, Staphylococcus spp*, etc

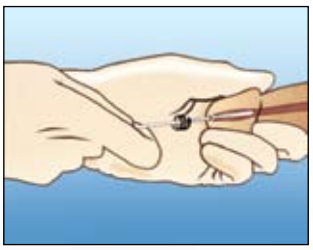
STI * - sexually transmitted infections
OM** - opportunistic microorganisms

To diagnose sexually transmitted infections of men urethral discharge scraping, the first urine portion, prostate secretions and ejaculate are used.

- In most cases of acute urethritis diagnostics or relapse of chronic urethritis anterior urethra discharge scraping is analyzed.
- In chronic, oligosymptomatic inflammatory processes and prostatitis prostate secretions or the first urine portion after prostate massage are taken additionally.
- To diagnose male infertility ejaculate is analyzed additionally.
- In screening tests for sexually transmitted infections it is reasonable to use the first urine portion since it could be taken non-invasively.

Urethral discharge scraping





Sampling of clinical material from urethra:

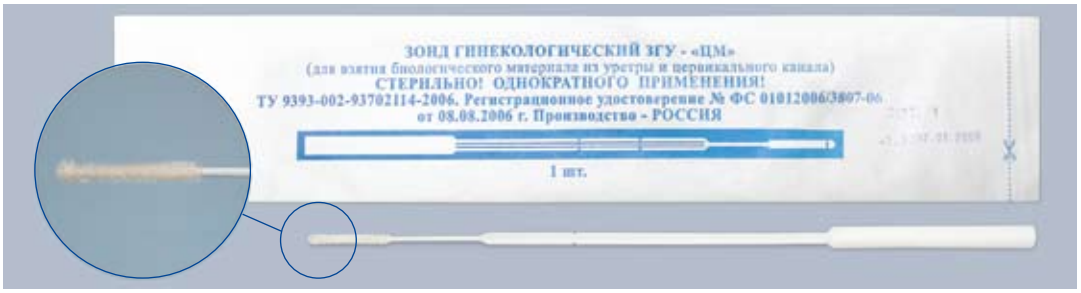
In most cases of sexually transmitted infections diagnostics material for analysis is discharge scraping of anterior urethra.

Before scraping balanus is treated near external urethral opening with sterile physiological solution before sampling, then urethra is massaged.

Universal probe is inserted in urethra to a depth of 1-2 cm. Scraping of epithelial cells is performed by rotatory movements of universal probe.

Recommended instrument for sampling of clinical material

Universal probe for sampling of clinical material from urethra and cervical canal



Urine (first portion)

Sampling of clinical material:

The first portion of morning urine is used for analysis. 20-25 ml of urine is collected in dry sterile container.

The first urine portion is adequate clinical material for sexually transmitted infections diagnostics and a good alternative to scrape of urethral discharge since it is non-invasive procedure.

The analysis of the first urine portion collected after 2 and more hours after last urination is also acceptable.

Sterile plastic container, 60 ml, individually packed

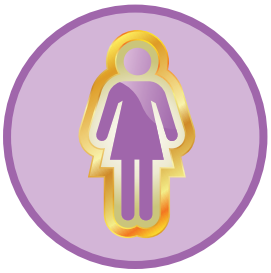
Prostate secretions and/or ejaculate

For diagnostics of upper reproductive organs infections prostate secretions and/or ejaculate are used. Before sampling of prostate secretions balanus is treated with sterile cotton swab.

Prostate secretions are taken after massage of prostate through rectum. Massage is performed by pressing from base to the tip;

After massage prostate secretions are collected in dry sterile container (50-60 ml) or in single-use dry sterile plastic tube (2 ml). Then tube is carefully closed and marked.

Microcentrifuge graded tubes, 2 ml (Axygen, USA)



Female clinical material

Type of clinical material	Diagnostic task	Detected microorganisms
Cervical canal's mucosa epithelial scraping	Cervical screening using HPV test	High-carcinogenic risk HPV
	Etiological diagnostics of cervicitis, endometritis. Monitoring of antibacterial therapy of cervicitis	STI *: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, Treponema pallidum, HSV I/II* OM**: *Mycoplasma hominis, Ureaplasma spp, Streptococcus spp, Staphylococcus spp.*, etc.
Scrape discharge of ulcerative-erosive elements	Differential diagnostics of infections which cause ulcerative-erosive lesions	*Treponema pallidum, HSV I/II*
Scrape of epithelium from condylomas	Differential diagnostics of infections which cause condylomas	Low carcinogenic risk HPV
Vaginal smear or vaginal discharge	High carcinogenic risk HPV screening (for women at the age of 25-30)	High carcinogenic risk HPV
	Screening for sexually transmitted infections	STI*: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium* *OM**:* *Gardnerella vaginalis, Atopobium vaginae, Candida spp, Mycoplasma hominis, Ureaplasma spp, Streptococcus spp, Staphylococcus spp., E. coli*, etc.
	Differential diagnostics of vagina's pathological discharge syndrome	
Urine	Differential diagnostics of urethritis, cystitis	STI*: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium.*

STI* - sexually transmitted infections
OM** - opportunistic microorganisms

For sexually transmitted infections diagnostics of women clinical material is cervical canal epithelial scraping and/or urethra and vagina smear.

For complex examination analysis of clinical material from all localizations is reasonable.

The pooling of clinical material is acceptable unless there is a need for topical analysis.

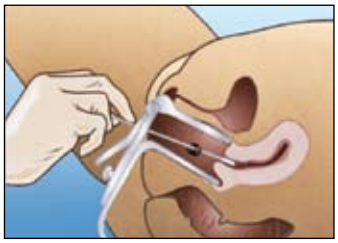
Cervical canal epithelial scraping

It is performed for diagnostics of all forms of infections caused by Chlamydia trachomatis, Neisseria gonorrhoeae, Human papilloma virus, Mycoplasma genitalium, HSV 1,2, CMV.

Analysis is obligatory for assessment of treatment effectiveness of above mentioned infections. Clinical material taken from endocervical canal should contain enough number of simple columnar epithelium cells.

Recommended sample collection instrument

Cytobrush with breakable shaft. It allows to collect the maximum number of epithelial cells.



Before sample collection it is recommended to remove the cervical mucus with a sterile swab

The mucus is removed from the surface of the cervix with a sterile swab, after that, cytobrush or gynecological probe is inserted into the cervical canal and two full clockwise and anticlockwise rotations are performed. Cytobrush (probe) is pulled out from the cervical canal and inserted into the tube with transport media.

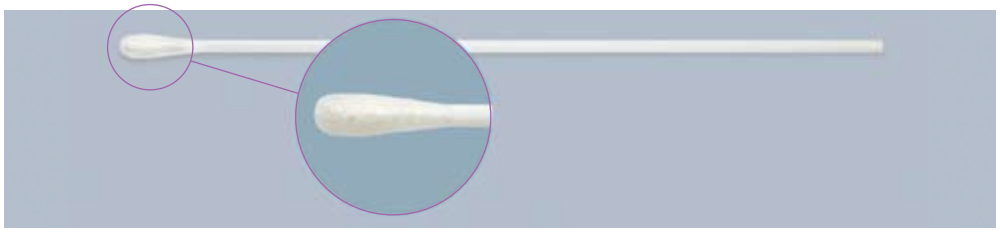
Vaginal discharge (smear)

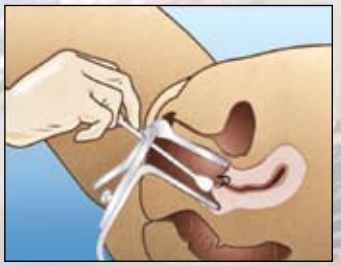
This type of material needs to be analyzed for diagnostics of *Trichomonas vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma (parvum & urealyticum), Candida spp.*, and for diagnostics of bacterial vaginosis.

With AmpliSens kits it is possible to analyze vaginal smears for revealing cervical pathogens – *C. trachomatis and N. gonorrhoeae*.

Recommended sample collection instrument

Swab with polystyrene breakable shaft and viscose tip.

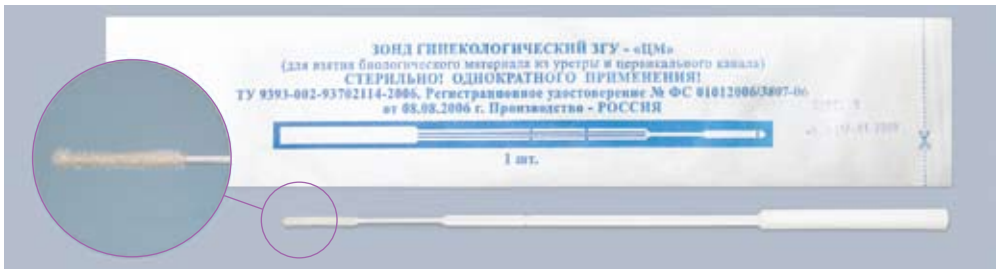




The tip of the probe is dipped into vaginal discharge in the posterior vaginal fornix and is moved with rotations on the surface of mucus membrane trying to collect as much material as possible. The probe is inserted into the tube with transport media.

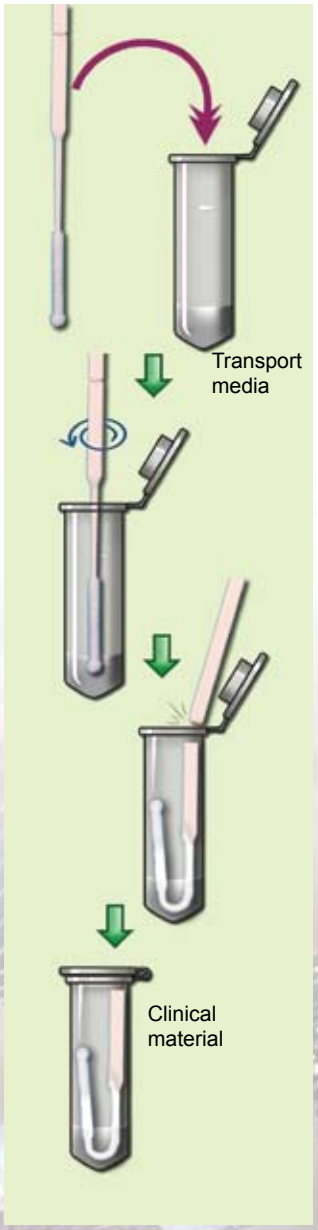
Universal cervical canal and vaginal samples collection instrument

Gynecological probe for collection of biological material from urethra and endocervical canal



Transfer of clinical material

for storage and following transportation to the laboratory



After collection of clinical material, collection instrument is inserted into the tubes with transport media. The tip of the probe (with cytobrush or swab) which contains collected material, is detached from the shaft at the breakpoint and is left in the tube with transport media. If the probe has no breakpoint, the tip of the probe is dipped into the transport media, pressed to the wall of the tube and rotated for 5-10 seconds. After that, the probe is removed from the tube and the tube is tightly closed. Scissors should never be used for detachment of probe's tip!

Advantages of leaving detachable probe's tips in the transport media:

- Adequate and effective washing of viscous material from the probe's surface which allows even few microorganisms to get into PCR tube
- An aliquot of the material is taken for PCR testing, the rest of the material may be used for further or repeated testing

«AmpliSens» transport media

«AmpliSens» transport media are water-salt solutions, which have been adapted for storage and transportation of clinical material. An aliquot of the material is taken for nucleic acids extraction and PCR testing, the rest of the initial clinical material may be stored for the following additional testing.

Transport medium with mucolytic agent

Transport medium contains several components which increase efficiency of DNA extraction from complex types of clinical material:

- **Mucolytic agent** – clinical material, mucosal discharge may contain mucus of different consistency and viscosity. In order to increase the efficiency of following sample preparation, the mucolytic agent is added. It makes mucus to dissolve and release microorganisms and viruses more easily. So it provides standardization of extraction procedure for quantitative PCR tests.
- **Preservative agent** prevents bacterial growth.
- **Stabilizer agent** prevents cell degradation and provides possibility of long-term storage of clinical material at room temperature.

Production form and packaging arrangement

Transport media with mucolytic agent (catalog # 952-CE) supplied in bulk volume of 50 ml.
DNA-sorb-AM" (catalog # K1-11-50-CE and K1-11-100-CE) is recommended for DNA extraction

AmpliSens transport media – the first step to standardization of PCR testing

- Optimal conditions for storage of different types of clinical material for diagnostics of sexually transmitted infections
- Highest possible release of microorganisms from clinical material for effective nucleic acids extraction
- Compatibility with all AmpliSens nucleic acids extraction kits
- Possibility to store initial clinical material for repetitive and additional testing.

InterLabService

Exclusive distributor of AmpliSens® PCR kits developed
and manufactured by Central Research Institute of Epidemiology of Russia (Moscow, Russia).

8/1 Olsuf'evskiy per., 119021, Moscow, Russia
Phone: +7 (495) 664 28 84
Fax: +7 (495) 664 28 89
www.interlabservice.ru