CYTOLOGY USER MANUAL

Cytology User Manual

Introduction

This handbook is intended to serve as a user guide to the services available from the Cytology Laboratory based at Stephenson Way, London. It is aimed for use by all staff groups involved with requesting Cytological investigations.

About Us

Unilabs Cytology Laboratory is an UKAS accredited medical laboratory (No. 9344); accredited to ISO15189:2022 for the scope described in the UKAS Schedule of Accreditation which can be found on the UKAS website: https://www.ukas.com/browse-ukas-accredited-organisations/

Users of the Cytopathology service should refer to the UKAS schedule of accreditation for a list of currently accredited tests. (No 9344)

We provide a wide spectrum of tests for both gynae cervical cytology and non-gynae with rapid turnaround times.

Gynae tests include: ThinPrep PAP smear and High-Risk HPV panel with 16 & 18 genotyping (Cobas), High Risk HPV with reflex PAP smear, ThinPrep PAP smear, Full HPV Subtyping (Including High and Low risk HPV subtypes), Chlamydia and Gonorrhoea PCR and Sexual Health Screen PCR.

Non-Gynae examination samples include fresh body fluids, FNAs, imprints, urines, respiratory specimens, CSFs, and synovial fluids.

Contact Details

Address: UNILABS
Cytology Department
24-32 Stephenson Way
London
NW1 2HD

Telephone enquiries: +44 (0)020 7299 4490
E-mail enquiries: UKdiagnostics_1@unilabs.com

Opening hours: from 09:00 – 17.30, Monday to Friday (except bank holidays).

Clinical advice and interpretation
Contact Dr Mark Wilsher, Medical Director of Cytology.
Mobile phone: +44 (0) 791736390
e-mail mark.wilsher@unilabs.com

Staff contact details
Medical Director of Cytology
Dr Mark Wilsher *MBChB (Distinction) Otago, FRCPath, FRCPA*
e-mail: mark.wilsher@unilabs.com

Pathology Operations Director
Krista De-Four *MSc, MS, CMi*
e-mail: krista.de-four@unilabs.com

Cytology Lead BMS
Bhavnika Limbada *FIBMS, MSc*
e-mail: Bhavnika.limbada@unilabs.com

Quality Manager
Jayne Holloway *MIBMS, BSc*
e-mail: Jayne.Holloway@unilabs.com

Protection of patient information
All patient information is handled under the terms of the Data Protection Act 2018.
All staff complete Unilabs mandatory GDPR training online and comply with the departmental quality manual.

Quality Assurance
The laboratory operates daily internal quality control procedures and participates in recognised national external quality assurance schemes covering; sample processing/staining (PHE TEQA), cytology screening/reporting (PHE GEQA), HPV testing (NEQAS microbiology/parasitology) UKNEQAS CPT (for non-gynae and Cell Blocks) and Digital diagnostic Cytopathology reporting. The laboratory also take part in the London synovial fluid interlaboratory reporting scheme.

Complaints
Complaints may be made directly to the department, or via customer services: UKdiagnostics_1@unilabs.com

GYNAE CYTOLOGY

The cervical screening section of the laboratory provides a service to private hospitals and clinics using Hologic ThinPrep and Roche COBAS platforms. Our laboratory provides a wide range of tests **suited for private clinic** needs.

Gynae tests include:

- ThinPrep PAP smear and High-Risk HPV panel with 16 & 18 genotyping (Cobas)
- High Risk HPV with reflex PAP smear
- ThinPrep PAP smear
- Chlamydia and Gonorrhoea PCR tests (Cobas) (Not Accredited)
- Full HPV Subtyping (Including High and Low Risk HPV subtypes)
- Sexual Health Screen (Chlamydia Trachomatous. Gonorrhoeae, Mycoplasma Genitalium, Ureaplasma, Trichomonas Vaginalis, Gardnerella Vaginalis and Herpes Simplex Type I / II DNA PCR tests)
- HPV mRNA

Any or all of the above tests can be performed on the same specimen vial. Full HPV Subtyping, Sexual Health Screen and HPV mRNA tests are performed at a referral laboratory.

Sample Types

Only Hologic ThinPrep samples will be accepted for the above tests.
Vaginal and vault smears as well as cervical smears are processed.
Unilabs request form can be downloaded from our website, but we also accept clinics/ hospitals own request forms.
Please ensure all request forms have at least three patient identifiers on both specimen and the referring form. Clinical details and any relevant patient history should be given. Sending clinician's name and the location should always be provided. The specimen collection date should be specified. If the insurers are to be billed all details should be written on the request form.

Specimen acceptance criteria

All Gynae cytology samples must be accompanied with a completed request form and include at least three patient identifiers on both specimen and form.
Request form Three patient identifiers are required as below:

- Patients' forename and surname
- Hospital number (HRN)
- Date of birth (DOB)

Sample rejection criteria

- The vial is unlabelled.
- The request form does not contain all the essential information.
- The ThinPrep vial has passed its expiry date.
- The vial is received more than 30 days after collection date.
- For ThinPrep© specimens, the sampling broom head should have been removed from the vial.
- The sample has leaked in transit resulting in a significant loss of fluid.
- The sample is received in formalin.

Advice for smear takers

Gynae samples should only be taken by trained staff.
Samples must be collected using a Cervex-broom. Samples are only viable for 30 days from the date taken therefore should be sent to the laboratory soon after collection.
In follow up for an abnormality in endocervical cells endocervical brush as well as Cervex-broom may be necessary depending on nature of cervix.
Use of lubricants should be avoided. If necessary, only a tiny amount of K-Y jelly can be used on the body of the speculum.
Cervix should be seen and noted. If the sample taker has stated that the cervix is not visualised at the time of sample collection, if no abnormality is detected, an inadequate may be given.
Cervex-broom should be rotated 360' at least 5 times.
Smears should be taken mid-cycle whenever possible.
Follow up smears should be taken at least 3 months after the initial smear.
Samples should be kept at room temperature until transported to the laboratory.
Links below can be used by smear takers for further information:
https://www.gov.uk/government/publications/cervical-screening-primary-hpv-screening-implementation

NHSCSP Sample acceptance policy https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories/guidance-for-acceptance-of-cervical-screening-samples-in-laboratories-and-pathways-roles-and-responsibilities

Results

Gynae results are available on the Unilabs Portal once authorised.

NON-GYNAE CYTOLOGY

Please note all fresh cytology specimens should be sent to the laboratory promptly. For slight delays keep refrigerated and **for overnight transportation add equal volume of cytology fixative such as Hologic CytoLyt / PreservCyt solution to** preserve the cells.

Type of samples

- Serous fluids, cyst fluids and peritoneal washings
- Urine, ureteric washings, urethral washings,
- Brushings (bronchial, gastric, oesophageal, duodenal, biliary)
- Fine Needle Aspiration
- Imprints
- Synovial fluids for microscopy and crystals
- Cerebrospinal fluid (CSF)
- Broncho alveolar lavage (BAL)
- Bronchial washing
- Sputum

Specimen Container: All fluids should preferably be sent unfixed to the laboratory in a standard universal container.

Turnaround Time

Routine turnaround time for non-gynae reporting is 48 hours. URGENT specimens can be reported within the same day.

Specimen acceptance criteria

All Cytology specimens must be accompanied with a completed request form and include at least three patient identifiers on both specimen and form.
Request form Three patient identifiers are required as below:

- Patients' forename and surname
- Hospital number (HRN)
- Date of birth (DOB)

Additional information is required as below:

- Ward/location
- Clinician
- Sample type
- Sample requesters contact details

Clinical details and any relevant patient history should be given. Sending clinician's name, location and specimen collection date should always be provided.
If special stains or additional tests are requested by the clinician, it should be clearly stated on the request form.
If the insurers are to be billed all details should be written on the request form.

Specimen Rejection Criteria

Sometimes tests cannot be performed due to sample acceptance criteria not been met. The potential risk to the patient is delay to the result/diagnosis, patient management pathway and breach in turnaround times.

Summary list for sample rejection

- Insufficient sample received.
- No sample received.
- Labelling or form issues (mislabelled / unlabelled / no forms / no clinical information).
- Sample contamination (e.g., being in the same bag as a leaking sample)
- Samples that are received in expired thinprep vials
- Improper sample containers (e.g., Urine sample received in Boric Acid)

To reduce the risk of sample rejection or delay to provision of results, please ensure all sample acceptance criteria are met.

HIV Positive/High Risk Patients

Doctors responsible for the care of patients have a duty of care towards other members of staff. High risk cytology samples must be clearly labelled with "Risk of Infection" hazard stickers if the patient is a known or suspected carrier of HIV, Hepatitis B/C, TB or SARS-CoV-2. The request form must also state the reason for the risk of infection.

Package and transportation of samples

Cytology samples must be transported to: Unilabs Specimen Reception at:
UNILABS, 24-32 Stephenson Way, London, NW1 2HD
The sample and the request form must be placed in a plastic 'biohazard' Kangaroo bag ensuring that the form and sample are in separate sections of the bag. This will prevent contamination of the request form if the sample container leaks. Parafilm should be used around the lid to lower risk of spillage.

Results

Non-gynae results are available on the Unilabs Portal once authorised.

Specimen types

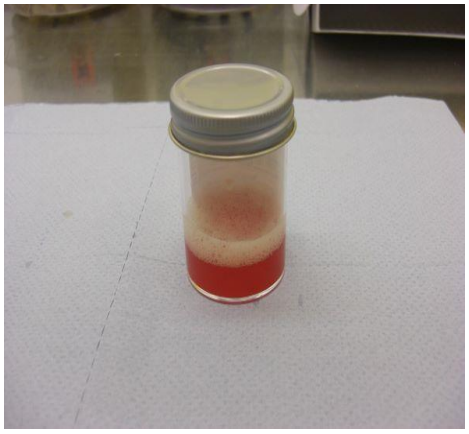
Serous fluid samples (pleural/ascitic/peritoneal/pericardial fluids & peritoneal washing) and all other drained fluids

50 -100 ml of fresh fluid should be sent in a clean dry sterile container with screw top required for reliable assessment of malignancy. The sample should be delivered as soon as possible to minimize cell deterioration. If there is a delay in delivering the sample to the laboratory, the sample should be kept refrigerated at 4°C.

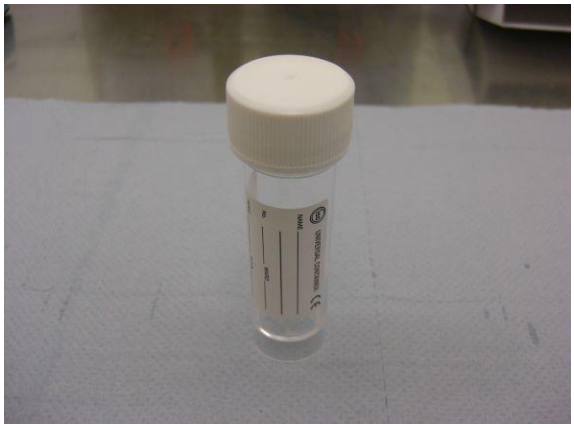
****DO NOT send more than 100ml of as the laboratory is not equipped to deal with this volume of sample****

(Note: no formalin or alcohol should be added to the sample as both can cause interference with adherence to slide and quality of staining)

Serous fluid



Cyst fluid



Cyst fluid samples

Cyst fluid samples should be put into a clean dry sterile container with screw top.

The fluid should be submitted as soon as possible to minimise cell deterioration, so that cell preservation is not compromised.

If there is a delay in delivering the sample to the laboratory, the sample should be kept refrigerated at 4°C.

(Note: No formalin or alcohol should be added to the sample as both can cause interference with adherence to slide and quality of staining)

Cerebrospinal fluid

CSF samples should be collected in clean dry sterile containers with screw top.
About 5ml of a sample is usually adequate for cytological examination. It is **VERY IMPORTANT** to transport the sample to the laboratory immediately as an **URGENT** sample, as the cells degenerate rapidly and therefore must be prepared immediately.

If out of hours sampling is unavoidable, storing the sample in refrigerator at 4°C may help preserve cells for up to 24 hours. Specimens collected at the weekend are unsuitable for malignant cell analysis.

(Please note: If other investigations are required, such as microbiology (MC&S), clinical chemistry (100A, Clinical pathology) and flow cytometry (Cytology dept) , separate samples should be collected and sent DIRECTLY to those relevant departments to avoid unnecessary delays in sample processing.

Brushings

Oesophageal and biliary tract brushings or any material obtained by brushing can be spread on a slide and fixed promptly or sent to the laboratory in a cytology fixative such as PreservCyt. The brush should be included. **Please make sure that the brush tip end is in the fixative**. The necessary patient identifying details must be clearly labelled in pencil on the frosted end of the slide.

DO NOT USE FORMALIN FIXATIVE

Respiratory Tract samples to include: (Sputum, bronchoalveolar lavage, bronchial washings, and bronchial brushings).

Sputum samples: Sputum sample should only be submitted if the patient has suspected lung cancer and is unfit for bronchoscopy. Multiple specimens (usually x 3) may be necessary, but these should be sent on 3 separate days, not all taken at the same time.

Best results are achieved with freshly obtained sputa with an early morning sputum before the patient has eaten and brushing teeth. Contamination with large amounts of saliva or food leads to inadequate specimens.

Sputum samples should be collected into sterile containers with screw top and submitted to the laboratory as soon as possible after collection. The accompanying request form should give precise details of the patient clinical background.

If microbiological examination is also required a separate sample should be sent to the Microbiology department.

Bronchial washings/Bronchial Alveolar Lavages

These specimens are collected during bronchoscopy to investigate focal or diffuse lung abnormalities. The nature of the abnormality being investigated should be clear from the clinical information included with the specimen so that the laboratory can perform the appropriate preparations. Please send a maximum of 25 ml of washings in a clean sterile universal container. If transport is delayed, then refrigerate sample at 4°C.

If microbiological examination is also required a separate sample should be sent to the Microbiology department.

Bronchial brushings

Bronchial brushings are taken at bronchoscopy for the investigation of suspected tumours. The highest diagnostic yield is found when a visible abnormality is sampled. Bleeding induced by biopsy of the

lesion may obscure the cellular material and thus the brushing should be performed before a biopsy is taken. The brush should be broken off, unsheathed, and immersed in cytology fixative such as

PreservCyt. If smears are to be made the brush can be spread on a slide, they must be fixed promptly or sent to the laboratory in a cytology fixative such as PreservCyt. The brush should be included. **Please make sure that the brush tip end is in the fixative**
The necessary patient identifying details must be clearly labelled in pencil on the frosted end of the slide.

Urinary Tract Samples

Please note: The first sample voided in the morning is unsuitable for cytological examination.

Second voided urine sample of the day is considered as the adequate sample. Collect urine in a clean dry sterile container with a screw top.

A neat sample of 20ml to 50ml container is suitable. Urine can be collected from catheters as well as washings from the bladder or upper urinary tract. The appearance of urine cytology is significantly altered by instrumentation or catheterisation which should thus be recorded in the clinical information accompanying the specimen. If there is a delay in delivering the sample to the laboratory, the urine sample should be kept in a fridge at 4ºC; or a preservative, such as Hologic CytoLyt / PreservCyt solution may be added to the sample. 20ml max of urine fluid in a plain sterile container and add equal volume of Hologic CytoLyt/ PreservCyt solution. This must be recorded on the request form.
PLEASE NOTE: RED TOPPED Borate universals are NOT SUITABLE FOR CYTOLOGY. The laboratory will not accept these samples.

If microbiological examination is also required a separate sample should be sent to the Microbiology department.

Synovial fluids
Sample is aspirated from joint for the assessment of birefringent crystals (Gout and Pseudogout). A neat sample should be collected into a clean, dry, sterile 30 ml universal container and sent to the Cytology laboratory as soon as possible.

If microbiological examination is also required a separate sample should be sent to the Microbiology department.

Fine Needle Aspiration

Fine needle aspiration is a reliable method and initial choice of determining the nature of lumps and bumps. This involves aspirating a lump using a fine needle and then testing the material obtained. It is very safe and minimally invasive procedure for the diagnosis and further management.

Material aspirated is spread along the length of the slides using another slide. Half of the slides prepared are immediately fixed using an alcohol spray fixative to prevent air drying, while the others are rapidly air dried. We recommend preparing a maximum of 4 direct spread slides.
Label each slide IN PENCIL on the frosted end of the slide (**Do not write in ink which is washed off in the fixative**) with patient's name, DOB, and hospital number – the details must be written on the same side of the slide as the spread sample. Please ensure that the sample is spread onto the correct side of the slide.

The excess FNA material from the needle is then rinsed into a labelled white topped sterile universal containing saline labelled 'needle washings' for immunohistochemistry if needed enabling more detailed reporting.

The needle washings (in a universal sample container) and slides (in a plastic slide mailer) should be sent to the laboratory.

Airdried slides should never be placed near Formalin as its vapour causes artefact resulting in difficulty in interpretation or an inadequate report.

Please note: Separate samples should be collected for Flow cytometry and sent DIRECTLY to Cytology department to avoid unnecessary delays in sample processing. Samples to be couriered ASAP after extraction to arrive MON-FRI, with the cut off 12pm on Friday and Bank holidays.

For CSF and other very low yield sample Transfix preservative should be added. **(Supplier details: Transfix CSF storage tube- Cytomark Limited).**

Measurement of Uncertainty

To comply with UKAS Medical Laboratories it is necessary to determine the uncertainty of results where relevant. Full consideration and awareness of all identifiable components that contribute to the uncertainty of a test will allow valid results to be obtained and may also indicate aspects of a test or procedure which need improvement.

Cytology uses the evidence from the repeatability or reproducibility of a test where possible to meet this standard.

Please note that a negative cytology report does not exclude the presence of disease.

FACTORS AFFECTING THE UNCERTAINTY OF MEASUREMENT

The following factors can all affect the quality of results in Cellular Pathology:

- Specimen collection procedures including sample quality
- Transportation of samples
- Storage facilities for samples prior to testing
- Quality of reagents and consumables
- Performance of equipment
- Distribution of normal/abnormal cells in an aliquot of sample
- Technical competence of staff undertaking the testing
- Reporting protocols
- Referral of samples to other laboratories for testing

In order to minimize the uncertainty of measurement, all of these factors must be evaluated, monitored and where possible actions taken to minimize them.

Measurement of Uncertainty information shall be made available to laboratory users on request.

FACTORS AFFECTING SAMPLE & REPORT QUALITY:

- Correct sample taking – refer to sections above for non-Gynae
- Use of correct sample container
- Refrigeration of fresh samples if there is a delay in sending / collection (i.e., overnight / weekends).
- Samples in CytoLyt/ PreservCyt solution must be stored at room temperature (between 4°C and 30°C).
- Correct slides used for FNA samples – refer to section above
- Sample spread on correct side of the slide – i.e., sample & patient details written in PENCIL (on the frosted end) must be on the SAME side of the slide.
- Slides must be sent in a plastic slide mailer – one slide per section (maximum of 4 slides per box)
- Ensure that slides are correctly & sufficiently labelled on the ground glass end in pencil – full name, HRN & / or DOB
- Use the correct request form & complete in ink in legible writing
- Correct labelling of sample container & completion of request form
- Ensure sample vial is labelled with specimen site / type.
- Please contact the laboratory with any queries or for additional information.

To download a request form please select from below links:

Unilabs Cytology Gynae request form (link to form)
Unilabs Cytology Non-Gynae request form (link to form)

Please note: New clients should contact ukdiagnostics_1@unilabs.com to register with us before sending specimens