

Specialists in Diagnostic Histopathology

Laboratory Guide 2025

www.cellularpathologyservices.co.uk

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Out of hours Service 07775 44 66 88

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For all out of hours enquiries relating to results, courier pickups and urgent consumables or if you need to discuss a result with a pathologist.

Address

Unit 12, Orbital 25 Business Park, Dwight Road, Tolpits Lane, Watford, WD18 9DA



Dear Colleague,

We know that your clinical practice depends upon timely results and high quality responsive Pathology Services. We hope our Laboratory Guide provides you with information and guidance covering the services and tests that are available at Cellular Pathology Services Limited. We have also included information on common procedures specific to your patients.

CPS has built its reputation on providing **quality, comprehensive** and **customised** Histopathology and Cytopathology services to its clinical and hospital clients. Our staff and pathologists will take care of all clinical, technical and administrative aspects of the Cellular Pathology Service tailored to the clinical needs of your patients.

Our Pathologist cover is available 24 hours a day, 7 days a week to provide you with support. Our Team aim to assist you with obtaining results, supplying consumables and arranging specimen collection. Please do not hesitate to call our office on 01923 233 299 during opening hours and our Out of Hours mobile on 07775 44 66 88 if you think we can be of assistance or by email info@cellpathservices.co.uk.

If you cannot find information on a test or have a question regarding any aspect of the services please do not hesitate to contact us on <u>info@cellpathservices.co.uk</u> so that we can help you.

I would be very happy to receive your call and hear your views on my mobile 07879 637874) or by e-mail joseph@cellpathservices.co.uk.

We aim to help you provide the best possible patient care.

Finally, we aim to update this Laboratory Guide annually.

Dr Joseph A-Jabbour

Managing Director Cellular Pathology Services Ltd

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O1 About this Laboratory Guide



1.1. GENERAL INFORMATION

This Laboratory Guide contains material to support you in using our services. It includes information on turnaround times and how to obtain your results. It also explains how to order consumables and book courier collections.

The laboratory of Cellular Pathology Services is located on the outskirts of Watford with good transport links to the Motorway network. Our location enables us to service large areas of London and the Home Counties using our own in-house fully UN3373 compliant couriers.

Nationwide and International samples can also be sent to us securely and in compliance with P650 sample packaging requirements

1.2. SPECIALIST INFORMATION

The Laboratory aims to provide a high quality of service to our users and patients.

We participate in all relevant technical External Quality Assurance (EQA) schemes, which are used to ensure the quality of the tissue processing and staining procedures.

Each of the Consultant Cellular Pathologists is experienced in general histopathology but also sub specialises in particular aspects of pathology. For example, these include dermatopathology, uropathology, breast pathology, gynaecological pathology and gastrointestinal pathology. Pathologists participation in External Quality Assurance Schemes (EQA) is a requirement of practicing at CPS.

To ensure accurate diagnosis, the laboratory offers a comprehensive range of special and immunohistochemical stains to aid in diagnosis.

External referrals for second opinion are readily available. We participate regularly in Multi Disciplinary Team meetings (MDT) in various hospitals and as required.

We do not report on renal biopsies, paediatric tumours or brain biopsies. There are no facilities for receiving or handling autopsies or post mortem samples.

1.3. COMPLAINTS PROCEDURE

CPS can receive complaints in a number of ways including email, letter, or by phone on the main contact number or via consultant pathologists.

When making a complaint factual information will need to be passed onto CPS in writing to <u>info@cellpathservices.co.uk</u> in order for a full investigation to be completed.

Complaints will be passed to the Director of Operations who will acknowledge the omplaint within 3 working days, and explain the investigation process.

The investigation process can take up to 30 working days will a full response after 44 working days. If the complaint cannot be resolved within this timeframe then the complainant will be informed.

1.4. PROTECTION OF PERSONAL INFORMATION

Protection of personal information in CPS is governed by our policy on Information Governance. CPS is registered with the Information Commissioner's Office (ICO) as a holder of confidential data.

CPS complies with the Data Protection Act 2018 (DPA 2018) and the General Data Protection Regulation ((EU) 2016/679).

Our Client Data and Privacy Policy can be viewed and downloaded from our website <u>www.cellularpathologyservices.co.uk</u>.

Request for confidential data must be sent in writing to IT@cellpathservices.co.uk.

1.5. UNCERTAINTY MANAGEMENT

In line with UKAS requirements and ISO15189, CPS has established a policy for uncertainty measurement.

1.6. VISITORS

Please email <u>info@cellpathservices.co.uk</u> to make an appointment enquiry.

02 Contact Details

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Contact Details

2.1. PRIMARY CONTACT

Office Number: 01923 233299 Email Address: info@cellpathservices.co.uk Website: www.cellpathservices.co.uk

2.2. OPENING HOURS

09.00 - 18.00 Weekdays

2.3. ADDRESS

Unit 12, Orbital 25 Business Park, Dwight Road, Tolpits Lane, Watford, WD18 9DA

2.4. OUT OF HOURS SERVICE

Contact Number: 07775 44 66 88

For all enquiries relating to results, courier pickups and urgent consumables or if you need to discuss a result with a pathologist.

2.5. CONTACTS

Laboratory Director Director of Laboratory Operations Quality Lead Lab Operations General & Results Enquiries Office & Account Enquiries Sales Enquiries HR Enquiries IT Enquiries

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Information for Patients

3.1. HISTOPATHOLOGY

This discipline involves the examination of tissue removed from patients to determine the presence or absence of abnormalities, to make a tissue diagnosis and assess excision. For example, a patient may notice a pigmented lesion, an ulcer or lump in the skin, or find blood in the urine or experience a change in bowel habit. These symptoms will prompt a number of investigations that may or may not involve sending tissue to the histopathology laboratory for analysis, to rule out or confirm a cancer or other abnormalities.

When received in the Laboratory, these samples will undergo a number of quality controlled processes that include: confirming that the patient's ID and the requesting doctor's ID are on the specimen; to ensure that samples are made ready as soon as possible for overnight or rapid processing; to ensure that cutting and staining of microscope and digital image analysis slides are of a high standard for presentation to the histopathologist.

The histopathologist examines these initial tissue sections and may in some cases request additional further work such as routine or special stains or immunohistochemical stains to determine the nature of the abnormality, if any exist. In breast cancer, hormonal receptors (ER, PR and HER-2) will also be assessed and reported.

The histopathologist may also discuss the results with your Doctor before or after issuing the report, as clinically appropriate. We also participate in a number of multidisciplinary meetings in a number of hospitals to correlate our results with other tests (e.g. x-rays or scans) and to discuss further management of the patient.

CPS monitors turnaround time for histopathology specimens as one of its Key Performance Indicator (KPI). Urgent processing of samples is possible, please consult with your doctor.

Patient Consent

Consent from the patient for the surgical procedure and histological analysis including all associated testing such as special stains, immunohistochemistry, molecular diagnostics and all other genetic studies within the laboratory, so to enable the making of the diagnosis to facilitate treatment of the patient's condition, is obtained by the hospital/clinician who is sending the sample to the laboratory. Histological analysis may also include using material for quality control processes. If the patient does not consent to this, it is the responsibility of the requesting clinician/hospital to ensure that this information is communicated clearly and speedily to the laboratory, and this must be stated clearly on the request form.

3.2. DIAGNOSTIC CYTOLOGY

Cytopathology is the discipline that involves the microscopic examination of cells exfoliated into body fluids such as urine or obtained from body cavities in the chest, abdomen or from cysts. This is different from Gynaecological cytology which is detailed in point 3.3 and section 11.

Cytology samples can also be obtained by aspiration of cells from solid lumps using a fine needle.

Gynaecological cytology refers to the examination of cervical specimens. Cervical samples are examined by a liquid-based cytology technique using a Thin-Prep vial. This is detailed in the next section of this guide – Gynaecological Cytology.

CPS monitors turnaround time for diagnostic cytology specimens as one of its KPI. Urgent processing of samples is possible, please consult with your doctor.

Fine Needle Aspirations

Fine needle aspiration (FNA) is frequently used in cytology to provide a rapid diagnostic procedure performed in an outpatient setting with or without the use of imaging. This involves the use of a needle to extract cells and spreading them onto microscope slides. The slides are submitted to the laboratory for proper handling and staining so that the Consultant Pathologist can examine the slides and issue a report. Often the pathologists will discuss the findings with your surgeon or physician so as to extract the maximum amount of information from your FNA sample.

Urine Cytology

The epithelial cells lining the urinary tract are naturally shed into the urine. Cytological assessment of these cells can be useful in the screening, diagnosis and follow-up of urological malignancy, in particular, transitional cell carcinoma. Samples may be obtained by direct collection of urine, from bladder washouts or from cystoscopy, catheterisation or ureteric brushes.

When patients are asked to submit a urine sample for cytological examination, it is important to collect the 2nd voided urine of the day (an early morning urine will have stagnated overnight in the bladder resulting in degeneration of the cells and render them unassessable).

If you are asked to submit three separate samples, these need to be collected on 3 different days, numbered consecutively starting with 1 and dated, so your Doctor can rely on the result. Submitting 3 different sample pots from the same urine sample or taken on the same day of each other is not recommended.

Minimum acceptable volume useful for cytological assessment is 25mls. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4° Celsius. A delay in sending the sample may have an effect on the quality of the cells in the sample as these can degrade over time.

Sputum Cytology

Examination of sputum samples can be a useful tool in the detection of lung and bronchial cancer. The epithelial cells lining the bronchi are naturally shed into sputum during coughing.

A good deep cough early morning sputum sample, before eating or brushing your teeth, produces the best sample. You may be asked to submit three separate occasions (different days) to increase the yield if a lung carcinoma is suspected; these samples should be labelled consecutively 1, 2 and 3 and dated.

Each specimen should be sent promptly to the laboratory without waiting for the next specimen to be obtained. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4° Celsius. A delay in sending the sample may have an effect on the quality of the cells in the sample as these can degrade over time.

3.3. GYNAECOLOGIC CYTOLOGY

Cervical Samples

The cervical smear test is designed as a primary HPV screening test. The same sample can be used to undertake other related tests such as thin prep and to detect sexually transmitted infections of the cervix.

In taking the cervical sample a speculum is used to open the vagina to allow inspection and collection of cells from the cervix, the entrance to the uterus. The cells are collected and sent to the laboratory for processing for HPV testing.

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O4 Specimen Packaging and Transporting

Cellular Pathology Services

Specimen Reception



OUTWARD

Inadequate packaging of samples may cause leakage of tissue or cellular material, which might result in the loss of the actual pathology sample, therefore jeopardizing the laboratory's ability to undertake the test. Moreover, there is potential harm to the transporting courier. Hence, we advise all personnel handling, packaging and transporting cellular pathology samples to follow these rules and advice. If you require any assistance, do not hesitate to call us on our office phone number.

Specimens known to be infected with high-risk organisms should be appropriately labelled and placed into a biohazard bag. Leaking specimens may neither be collected nor accepted into the laboratory.

Samples or request forms received unlabelled or without the minimum essential identification criteria may be referred back to the requesting practitioner.

4.1. CLOSING SPECIMEN POTS

It is extremely important to close the specimen pots tightly and securely ensuring that the seal is not broken. Improper closure of the specimen pot(s) is the most common cause for leakage.

4.2. REVIEWING SPECIMENS

Prior to packaging the specimen for transport to the laboratory, please check the request form and the specimen pot(s) to make sure that they are labelled correctly and that the form and the sample show the same patient details.

The patients full name and date of birth time of collection and test requested should be identical on all items.

Please ensure any additional relevant paperwork, such as endoscopy reports, are included with the request form.

4.3. SPECIMEN TRANSPORT BAGS

All specimen bags have two pockets - the front pocket is for the completed request form and the back pocket for the specimen pot(s). Once both request form and specimen pot(s) are in the specimen bag, seal the bag properly.

When packing the sample, place the request form in the outer pocket. This is to avoid it being contaminated should the sample leak and also allows us to read the request form without touching the sample container.

4.4. PREPARATION FOR TRANSPORT

Maintain formalin specimen pots, FNA slides, Thin-Prep vials at room temperature and refrigerate fresh diagnostic cytology specimens (such as fluids and cyst aspirates) over the weekend, unless otherwise noted in the specimen requirements. This should be refrigerated up to a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

4.5. HEALTH AND SAFETY NOTE

When decanting formalin into the specimen container, gloves and safety glasses should be worn and the procedure carried out in a well ventilated room. Formalin is a strong irritant and contact with the skin and eyes must be avoided. Inhalation of fumes can cause damage to the respiratory system.

In the event that spillages of this chemical should occur, use copious volumes of water to rinse it away and mop up any residue. Open windows and doors to increase ventilation.

4.6. POSTING YOUR PATHOLOGY SAMPLES

Small histology specimens or ThinPrep[™] vials for posting must be packaged in accordance with UN3373 regulations. CPS are able to advise you on what to use or, provide all the postal packs to achieve compliance.

4.7. UN3373 REGULATIONS

Any sample which is to be posted or couriered by non-medical courier to CPS must adhere to the following instructions for packaging.

1. Primary packaging

The 'specimen pot' should be of relevant size to the specimen and contain the appropriate fixative. Ensure that the lid is securely tightened to avoid leakage during transportation.

2. Secondary packaging

A polythene bag provides the secondary packaging layer into which the specimen container is placed. There should be absorbent tissue paper within this bag to soak up any leakage should this occur. This bag will need to be sealed and the corresponding request form placed into the outer side pocket of the bag.

3. Outer packaging

An appropriate UN3373-compliant transport container must be used for specimens sent by courier overnight or by post. These can be provided free by CPS on request.

4.8. SPECIMEN COLLECTION

All specimens will be collected centrally from the designated collection area at each hospital / clinic site at the time agreed. CPS will arrange for the collection of specimens as agreed with the client.



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5.1. COMPLETION OF REQUEST FORM

If you need assistance with this process, please contact our staff on our office phone number, who are more than happy to assist you.

In the interest of patients, our staff will contact you or your staff if there is any issue with the completion of the request form or the sample labelling.

Where there are discrepancies, such specimens cannot be processed until correct information is supplied.

5.2. TESTING PROFILE

The laboratory undertakes a comprehensive list of Histological & Cytological tests. The detailed list is too long to be included in this guide, however, it can be obtained from our office on 01923 233 299.

We do not report on renal biopsies, paediatric tumours or brain biopsies. There are no facilities for receiving or handling autopsies or post mortem tissue.

5.3. INFORMATION REQUIRED ON REQUEST FORM

All samples must be accompanied by a fully completed Histology/Cytology request form.

The following information are required, and should be written clearly and legibly:

- Patient forename and surname (or anonymous)
- Patient date of birth
- Patient gender
- Patient ID number
- Name and signature of requesting consultant
- Date and time of sample collection
- Clinical details
- Anatomical site of each specimen identified by a letter / number
- Hospital / Clinic Name

It is also desirable to have the following information:

- Patient address
- Patient GP
- Priority status of the case for triaging
- Who to invoice
- NHS number (if known)
- If you wish to be emailed or phoned with results then please state this on the form providing relevant phone number and/or email address

5.4. INFORMATION REQUIRED FOR SAMPLE LABELLING

Specimen containers must have a minimum of the following information written clearly and legibly:

- Patient forename and surname (or anonymous)
- Date of birth
- Patient ID number
- Biopsy type and site plus cross reference on request form
- Date and time of collection

It is also desirable to have the following information:

- NHS number (if known)
- Patient gender

The date and time that the specimen was taken allows us to assess whether the material has been in formalin long enough for it to be processed on receipt.

We regret that in some cases where it is not possible to resolve un-labelling or mislabelling of sample and request forms, it may be necessary to return the whole case to the base hospital/clinic for correct labelling so as to correctly identify the patient.

Such discrepant specimens cannot be processed until correct information is supplied.

5.5. URGENT REQUESTS

Urgent requests should be clearly marked on the top of the request form. Please state clearly on the request form when the result is required and include a contact phone number.

5.6. HIGH RISK SAMPLES

Any samples that are considered to be High Risk (such as HIV +ve, Hep B, Hep C) must be clearly labelled with this information. These cases may take slightly longer to process as we need to allow such samples to fix for a longer period to reduce the risk from High Risk samples.

We cannot handle samples that have a known history of Creutzfeldt Jakob Disease (CJD). Radioactive specimens such as Sentinel nodes should be clearly marked as such and should not be submitted until the radioactivity has decayed to acceptable levels. For advice from our pathologists, please contact us on our office phone number.

5.7. REFERRAL LABORATORIES

CPS uses accredited Laboratories to refer samples that require additional specialist testing, for either processing alone or both processing and reporting.

These main labs include:

- HSL Advanced Diagnostics London
- The Doctors Laboratory London
- St Thomas' Hospital St John's Institute of Dermatology London
- Genomic Health California, USA
- Sarah Cannon Molecular Diagnostics London

Patient consent

Consent from the patient for the surgical procedure and histological analysis including all associated testing such as special stains, immunohistochemistry, molecular diagnostics and all other genetic studies within the laboratory, so to enable the making of the diagnosis to facilitate treatment of the patient's condition, is obtained by the hospital/clinician who is sending the sample to the laboratory. Histological analysis may also include using material for quality control processes. If the patient does not consent to this, it is the responsibility of the requesting clinician/hospital to ensure that this information is communicated clearly and speedily to the laboratory, and this must be stated clearly on the request form.





Results

6.1. TURNAROUND TIMES

Our aim is to speedily issue quality reports, to ensure that our clinical colleagues can continue management of their patients in the shortest possible time frame.

Even more rapid same day processing can be arranged for some very urgent specimens, please contact us to arrange this.

CPS monitors turnaround time from receipt of samples in the laboratory for all specimen types as one of its KPI.

6.2. RESULTS SERVICES

We despatch results as demanded by the requesting doctor for the convenience of their clinical practice.

We can e-mail and post hard copies in any combination and to more than one address or location.

Emails are sent automatically within 120 minutes of reporting.

Our team would be delighted to arrange the most convenient method of delivery of results to your clinic, secretary or your hospital by any combination of these methods.

Telephone results can also be obtained by calling our team on our office phone number.

Clinical results are also available via online result service (Client Poral).

6.3. THE E-RESULT SERVICE

Once reported, the results are made instantly available to you 24 hours a day, 7 days a week.

Clinical users, their secretaries and hospitals can access their reports online via a secure access system, provided they have obtained a username and a password from us. Applications can be obtained by emailing info@cellpathservices.co.uk.

This online service is accessible at all times using a secure private Internet access.

The E-Result userguide is available to view on the website. View the LIMS userguide

07 Requesting Consumables



7.1. GENERAL INFORMATION

All Histology and Cytology specimen collection consumables can be obtained from CPS. Please allow 5-7 days for delivery of consumables.

Request for consumables can only be made online via - Client Portal.

For urgent despatch of consumables you are welcome to call our office on 01923 233 299.

7.2. HISTOPATHOLOGY

We can supply various sizes of pre-filled 10% neutral buffered formalin pots: 20ml, 60ml and 120ml.

Formalin buckets for larger specimens are also available in the following sizes: 500ml, 1000ml, 2500ml, 5000ml, which can be supplied with 10% neutral buffered formalin on request.

7.3. DIAGNOSTIC CYTOLOGY

All supplies such as glass slides, slide boxes, cytofix spray and universal containers of various sizes can be provided.

7.4. GYNAECOLOGIC CYTOLOGY

All the necessary collection supplies can be provided. These include conventional brush, spatula, Thin-Prep vials and plastic broom.

7.5. IMMUNOFLUORESCENE

Michel transport medium for skin lesion immunofluorescence testing.



Handling Histological Samples





Handling Histological Samples

8.1. SPECIMEN HANDLING

Samples for routine Histological examination should be placed into 10% formalin and sent to the laboratory with the next courier.

Samples for Immunofluorescence, frozen sectioning or cytology must **NOT** be placed in formalin, see section 9.4, 9.6 and 9.7 for guidance on these specimen types.

8.2. ROUTINE HISTOLOGY REQUESTS

Immediately place each specimen in a tightly secured, leak-proof container with 10% neutral buffered formalin. Do NOT allow the specimen to dry out.

For optimal sample fixation, the formalin volume to specimen ratio should be 10:1. Best clinical practice is to use a separate container for each specimen.

Do NOT crush or stretch the specimen with forceps or other instruments.

Ensure that you use the correct container size; do not force a large specimen into a small container as this will deform the specimen and reduce the rate of fixation and could affect the results.

Specimen labelling and completion of request forms is covered earlier in this guide in section for "Requesting Specimen Analysis".

8.3. HISTOLOGY REQUESTS FOR SPECIFIC TISSUE TYPES

Breast core biopsies

These must be immediately placed in formalin pots, to preserve both the tissue integrity and ER, PR and HER-2 receptors. These core biopsies must be fixed for at least 6 hours before they can be processed, again to ensure optimal expression of hormonal receptors.

Breast wide local excisions and mastectomies

These must be fixed in formalin immediately to ensure that tumour tissue is fixed properly and its assessment (including hormonal receptors) is not compromised.

If these cannot be sent to the laboratory immediately, it is advisable that formalin is injected around the tumour area as this has been found to improve fixation and reduce tissue autolysis.

When specimens x-rays are taken please send these with the sample for correlation to avoid potential delays in the assessment of these specimens.

Skin excision for malignancies

It is preferred that skin excisions for malignancies are orientated by placing a suture or a double surgical nick on the specimen, stating its location (e.g. 12 o'clock). This makes it possible for the pathologist to measure precise peripheral margins as well as the deep margin. This information should be provided on the request form.

Colectomies and resections of small intestine

These specimens must be fixed in formalin immediately and sent to the Laboratory for proper handling. The specimens may need to be inked and opened partially or completely. This ensures the penetration of formalin into tumour tissue from both the mucosal and serosal surfaces.

Lymph node

Do not handle or palpate the node. Nothing of value will be learnt from such examination and may distort the architecture to an extent that makes subsequent histological interpretation very difficult or impossible.

As formalin penetrates lymphoid tissue slowly, the node should be immediately placed in formalin fixative. Correct fixation is vitally important. If there is any indication of an inflammatory condition, and particularly if tuberculosis is suspected, a portion of the lymph node should be submitted fresh in a sterile container to a Microbiology Laboratory, and a portion of it fixed in formalin and sent to the Histopathology laboratory for histological examination. Attempts at microbiological culture from formalin fixed tissues will be unsuccessful, although increasingly PCR studies can be undertaken on formalin fixed tissue.

Prostatic Core biopsies including mapping biopsies

Place all cores from one site in a separate pot from the other sites. If appropriate, the lab will merge the prostatic cores. For mapping prostate core biopsies, please send the biopsy grid and the MRI scoring of the prostatic zones.

Cone/LLETZ Excisions of the Cervix

Place the specimen in formalin intact. If the specimen is taken in pieces, a drawing explaining the relationships between the various pieces will be very helpful in determining which margins the pathologist should be reporting on.

Unusual Cases

If special investigations such as electron microscopy and muscle or nerve biopsies for degenerative conditions are required, please discuss them with us in advance. These may require non-routine fixation, special transport media and referral to a specialist laboratory.

Specimens requiring consent

We are unable to examine, process or dispose of specimens that contain foetal tissue without a fully completed consent form, which must be submitted to the laboratory with the specimen.

Consent forms are available from our team on 01923 233 299 or info@cellpathservices. co.uk. We **cannot** handle foetal specimens of 24 weeks or greater gestational age.

Specimens that may contain foetal tissue require a consent form include:

- Products of conception (miscarriage)
- Salpingectomy for suspected ectopic pregnancy
- Termination of pregnancy specimens

8.4. FROZEN SECTIONS

Frozen sections will be undertaken after discussion with one of the Consultant Histopathologists. Contact the Histopathologists on our office phone number.

Requests for frozen section should be booked at least a week in advance. However, we may be able to assist you with ultra urgent requests for frozen section such as may occur as a result of an unexpected intraoperative finding.

Handling specimens for Frozen Section

Fresh specimens for frozen section must be sent directly to the frozen section station at either the hospital or CPS without delay in a dry container. Do NOT add any formalin.

The telephone number of the theatre should be noted on the request form so that the pathologist can discuss the frozen section findings with the consultant surgeon.

8.5. MOHS SURGERY

CPS offers a MOHS micrographic surgery frozen section service for skin cancer and conservation of tissue. This can be in the form of on-site support from a Biomedical scientist and/or a Pathologist.

Specialist equipment will be required for an on-site service. Alternatively a courier to the CPS premises for the MOHS frozen section can be arranged. Please contact the organisation to discuss requirements further and before your service is put into place.

8.6. DIRECT IMMUNOFLUORESCENCE

This is a procedure for detecting in-vivo deposition of immunoglobulins, complement components and fibrinogen in a patient's skin or oral mucosal tissue.

Procedure for biopsy

Specimens for direct immunofluorescence studies must be sent in Michel's transport medium, which is available on request from CPS.

Whenever possible, biopsy a single fresh small blister including adjacent clinically uninvolved skin (perilesional). For a large blister, biopsy edge of blister and adjacent uninvolved skin (perilesional). Cut the perilesional end and send for immunofluorescence studies and the remaining blister for histology. For uninvolved skin, a 3mm punch biopsy is sufficient for IMF.

8.7. INDIRECT IMMUNOFLUORESCENCE

10ml clotted blood should be sent to the laboratory within 48 hours or serum separated and sent within one month of collection.

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9 Handling Diagnostic Cytology Samples

Diagnostic cytology is mainly concerned with providing a diagnosis in patients with suspected disease, whereas most gynaecologic cytology is concerned with the detection of pre malignant disease in predominantly well women as part of a screening programme.

The method of cell sampling will depend upon the site to be examined. In many cases, cells will naturally exfoliate; in others assisted exfoliation may be required with the use of brushes. Less accessible lesions can be sampled using fine needle aspiration (FNA) cytology with or without the assistance of imaging devices such as ultrasound, X ray guidance, Computerised Assisted Tomography or Nuclear Magnetic Resonance.

Although the primary aim of diagnostic cytology is to assist in the making of a diagnosis for malignant disease, sometimes it is useful for the detection of infective agents.

Sampling of the respiratory tract can be used to diagnose both primary and secondary (metastatic) lung tumours. Unless the tumours have characteristic features it is not possible to always distinguish between primary and metastatic disease.

Fine needle aspiration cytology, urine cytology, fluid cytology, joint fluid cytology for crystals and other diagnostic cytology samples are processed and examined at the CPS laboratory. All these samples are seen and reported by a Consultant Pathologist.

CPS monitors turnaround time for diagnostic cytology specimens as one of its KPI. Urgent processing of samples is possible, please discuss with the pathologist.

9.1. FINE NEEDLE ASPIRATION

Fine needle aspiration (FNA) is frequently used to provide a rapid diagnostic procedure performed in an outpatient setting with or without the use of imaging.

Prepare direct smears on slides, which should be labelled in pencil with the patient's surname. If you are taking material from more than one site, indicate the individual site on each slide. It is also important to indicate whether or not the slides are fixed, by labelling them as "dry" or "fixed".

9.2. URINE CYTOLOGY

The cytological analysis of urine is useful in the screening, diagnosis and follow-up of urological malignancy, in particular, transitional cell carcinoma. Cytological assessment is based upon the examination of desquamated epithelial cells the urine passes from the excretory tubules in the kidney via the ureter and bladder to the urethra. A combination of urothelial cells and squamous cells (derived from the trigone and/ or urethra) and glandular cells may be present. Additionally, vulvovaginal contaminant squamous cells are also normally seen in samples from women. Samples may be obtained by direct collection of urine, bladder washouts, samples obtained from cystoscopy, catheterisation or ureteric brushes. It is important to know how a sample has been obtained; cystoscopy and instrumented samples are typically very cellular and may lead to an erroneous diagnosis of low-grade transitional cell carcinoma.

Using a sterile container, collect the 2nd voided urine of the day (an early morning urine will have stagnated overnight in the bladder resulting in degeneration of the cells). Submit on three separate occasions (different days) to increase the yield if a urothelial carcinoma is suspected; these samples need to be labelled as urine sample1, 2 or 3. Minimum acceptable volume useful for cytological assessment is 25mls. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4°Celsius. This should be refrigerated up to a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

Please do not send a single sample for both Cytology and Microbiology testing as samples cannot be shared.

9.3. SPUTUM CYTOLOGY

Using a sterile container collect a good deep cough early morning sputum sample, before the patient has ingested food or cleaned their teeth. Submit on three separate occasions (different days) to increase the yield if a lung carcinoma is suspected; these samples should be labelled consecutively 1, 2 and 3 and each specimen sent promptly to the laboratory without waiting for the next specimen to be obtained. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4° Celsius. This should be refrigerated up to a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

9.4. BRONCHIAL/GASTRIC/OESOPHAGEAL WASHINGS & BRUSHINGS

Bronchial brushings are prepared in the clinic and must be fixed immediately in 95% alcohol or spray fixed. The bronchial washings are sent directly to the Laboratory for preparation. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4° Celsius. To obtain a detailed procedure for oesophageal brushings, please contact the laboratory. This should be refrigerated upto a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

9.5. CYTOLOGY OF SEROUS EFFUSIONS

The sampling of fluids from the serous membranes of the pleura, peritoneum and pericardial cavities is performed to ascertain the reason for excess fluid collecting in these spaces. These membranes normally produce only small amounts of fluid to provide lubrication for moving surfaces. There are two basic types of fluid, the transudate and the exudate. Transudates have a low protein and cellular content and may be associated with circulatory disorders.

Exudates have a high protein and cellular content and may be associated with infections or malignant disease.

Collect in a sterile container. If it is not possible to send the sample to the laboratory straight away, you should refrigerate the specimen at 4° Celsius. Anticoagulants should not be added. This should be refrigerated up to a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

9.6. CEREBROSPINAL FLUID (CSF)

The specimen should be sent to the laboratory in a sterile universal container immediately after it has been taken. If it is late in the day, please advise the laboratory of impending arrival to ensure technical cover so that the specimen can be processed on arrival.

9.7. CYST ASPIRATES

Send the maximum volume of fluid in a sterile container as soon as possible after aspiration.

9.8. SYNOVIAL FLUID

The minimum volume is 5ml, which should be presented as soon as possible after collection. Please indicate whether examination for crystals is also required. If it is not possible to send the sample to the laboratory straight away, the sample should be refrigerated at 4° Celsius. This should be refrigerated upto a maximum of 72 hours, after this time the cells will start to degrade making diagnosis difficult.

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10 Handling Gynaecologic Cytology Samples

Handling Gynaecologic Cytology Samples

10.1. CLINICIAN INFORMATION

The processing laboratory now uses HR-HPV mRNA as its primary cervical screening test using the Hologic Aptima assay. This assay is approved for UK cervical screening.

The method of taking the cervical smear has not changed and continues to use the same ThinPrep vial.

We ask that you fully complete the request form ticking the HPV box when requesting a cervical screening test. It is important to provide details of previous smear history.

If you also require a conventional PAPT test you should tick the HPV box and the PAPT test boxes. Note that it is not possible to request a PAPT test in isolation. In this situation the sample will undergo HR-HPV testing followed by a PAPT test and both tests will be charged.

10.2. LABORATORY PROCESSING

Requests for cervical screening received at CPS are referred to A UKAS accredited laboratory for HR-HPV mRNA testing (and preliminary screening if a PAPT smear was requested) and returned to CPS for in-house reporting and issuing of results. All PAPT test smears are examined and reported by a consultant pathologist.

10.3. TURNAROUND TIMES

CPS monitors turnaround time for gynaecologic cytology specimens as one of its KPI.

10.4. ADDITIONAL TESTING

The following additional tests can be requested on the same ThinPrep vial by ticking the appropriate box. These tests will be referred to an accredited laboratory for assessment.

The following additional tests can be performed on the Thin-Prep vial:

- HPV20 HPV DNA testing for 20 subtypes of low/high risk HPV subtypes
- **HPVT** HPV20 with reflex mRNA testing if high risk subtypes detected.
- Chlamydia PCR
- Gonorrhoea PCR
- **7STD** PCR sexual health screening for 7 organisms (Chlamydia, Gonorrhoea, Mycoplasma, Ureaplasma, Gardnerella, Trichomonas and HSVI/II).

The laboratory may also receive swabs for HVS or chlamydia which are sent to an accredited microbiology laboratory.

Note: These results are transcribed into our CPS report format. The date of the original report and the referral laboratory are clearly stated.

10.5. RECOMMENDED ACTIONS

The recommended action is based on the HR-HPV test result or on the combined HR-HPV and PAPT results in situations where both these tests were performed. The recommended actions follow NHSCSP guidelines.

- If **HR-HPV** is requested in isolation and is **NEGATIVE** no further testing is required The sample will not undergo a PAPT test unless this was specifically requested. The **Recommended Action** will be **"Return to normal recall"**.
- If HR-HPV is requested in isolation and is POSITIVE then a PAPT will be performed
- at no additional charge.
- If CYTOLOGY is **NEGATIVE** the recommendation will either be "**Repeat in 12months**" or, if the smear history indicates HR-HPV is persistent, **"Refer for colposcopy"**.
- If CYTOLOGY is **ABNORMAL** the recommendation is to "Refer for colposcopy".

Handling Gynaecologic Cytology Samples

10.6. GYNAE THIN-PREP COLLECTION PROTOCOL A



Broom-Like Device Protocol

Record the patient's full name and DOB on the ThinPrep vial



Obtain an adequate sampling from the cervix using a broomlike device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.



Rinse the broom as quickly as possible into the ThinPrep solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device, do not send this to the laboratory



Tighten the cap so that the torque line on the cap passes the torque line on the vial.



Complete the patient information and medical history on the cytology requisition form.

Place the vial and requisition in a specimen bag for transport to the laboratory.

10.7. GYNAE THIN-PREP COLLECTION PROTOCOL B

Endocervical Brush / Spatula Protocol

Record the patient's full name and DOB on the ThinPrep vial

Obtain an adequate sampling from the ectocervix using a spatula.

Rinse the spatula as quickly as possible into the PreservCyt solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.

Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

Rinse the brush as quickly as possible in the ThinPrep vial solution by rotating the device in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.

Tighten the cap so that the torque line on the cap passes the torque line on the vial.

Complete the patient information and medical history on the cytology requisition form.

Place the vial and requisition in a specimen bag for transport to the laboratory.















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07741 85 55 50

For all enquiries relating to results, courier pickups and urgent consumables or if you need to discuss a result with a pathologist.

Address

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