

Title: User Handbook

Subject: Organisation & Management

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Author Suzanne Ferra/Fiona Denham

Authorised by Krista De Four

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1. Introduction

1.1 Purpose

This handbook is intended to serve as a quick user guide to the services available from the Cellular Pathology Laboratory based at St Thomas' Hospital. It is aimed for use by all staff groups involved with Histological or Cytological investigations.

1.2 ABOUT US

1.2.1 *Histopathology Laboratory*

Histopathology provides a comprehensive tissue diagnostic service to Guy's and St. Thomas' Hospitals, district general hospitals networked within the South East London Cancer network and local general practitioners. It serves the regional cancer centre and is also a national and international referral centre for expert opinion. The specialist diagnostic and scientific teams aim to deliver a high quality service with cutting edge diagnostic techniques through close links with the cytogenetics and molecular diagnostics department. Multidisciplinary team meetings (MDM) are held across both sites enabling close integration of clinical teams and specialist pathologists.

Areas of expertise include:

- Adult and Perinatal / Paediatric autopsy
- Bone, joints and synovial (BJS)
- Breast
- Cardiovascular System (CVS)
- Endocrine
- General
- Gastrointestinal
- Gynaecology
- Haematopathology
- Liver
- Perinatal
- Renal (Adult and Paediatric including Transplantation)
- Respiratory
- Urology

The laboratory works in conjunction with the St. John's Dermatopathology Laboratory, also at St. Thomas' Hospital (skin samples), and Oral Pathology (head & neck and maxillo-facial samples) at Guy's Hospital.

Frozen sections

In addition to processing fixed tissue, the department offers a frozen section service at both Guy's and St Thomas' sites, incorporating receipt of fresh tissue for diagnostic purposes, enzyme histochemistry, research, clinical trials and tissue banking. At Guy's Hospital, this service is based in the Head & Neck/Oral Pathology laboratory.

Immunocytochemistry and molecular pathology

Within the laboratory there is a immunohistochemistry laboratory which is a referral centre for HER-2 and PD-L1 testing. The laboratory also employs in-situ hybridization (ISH).

The laboratory also offers clonality testing (PCR) on FFPE samples, as well as on blood and other body fluid samples – this service is based within the Molecular Oncology laboratory at Guy's.

Renal histopathology

The dedicated renal histopathology service offers attendance at wards at St Thomas' Hospital for assistance with biopsy collection and an on call Saturday service. Renal biopsies from Guy's Hospital are handled by Histopathology staff in the Head & Neck/Oral Pathology laboratory to ensure timely processing.

1.2.2 Cytopathology Laboratory

Gynaecological cytology

The cytology department is fully converted to Liquid Based Cytology (LBC) and performs processing and reporting for inner South East London on behalf of NHS Cervical Screening Programme. Samples are sent to Northwick Park Hospital for molecular diagnostic testing for Human Papilloma Virus (HPV).

Non Gynaecological Cytology

This includes evaluation of body cavity fluids and brushings from various sites in the body. The ability to prepare cell blocks and treat fluid specimens like tissue blocks has improved the detection of primary and metastatic cancer and the ability to determine the primary site of origin of metastatic cancer.

As well as a full non-gynaecological cytology service (specimen receipt to reporting) at St Thomas' Hospital, the department also provides the non-gynaecological laboratory service at King's College Hospital (KCH); reports for all KCH specimens are issued by the KCH Cellular Pathology service.

Fine Needle Aspiration Cytology

The department supports a comprehensive FNA service for Guy's, St Thomas' and King's College Hospitals. Pathologists and senior BMS staff attend clinics, ward, intra-operative and image guided FNA's to assess adequacy and ensure sufficient material is collected for ancillary testing like microbiology, immunocytochemistry, flow cytometry and cytogenetics. This approach allows for a rapid, confident and complete diagnosis reducing the need for a surgical biopsy in a large number of cases and shortening the overall diagnostic pathway of the patient.

Andrology Testing

This includes routine analysis for infertility cases and evaluation of post vasectomy specimens.

2. CONTACT US

The Cellular Pathology department is located on second floor of the North Wing, St Thomas' Hospital. All visitors should access the department via the main entrance and report to reception where they will be directed to a named individual.

2.1 Contact address

CELLULAR PATHOLOGY DEPARTMENT
2nd Floor, North Wing
St. Thomas' Hospital
Westminster Bridge Road
London
SE1 7EH

2.2 Telephone enquiries

Histology Enquiries Tel 0207 188 2912 Fax 0207 188 2948
Cytology Enquiries Tel 0207 188 2916 Fax 0207 188 8989
FNA and Andrology Appointments Tel 0207 188 2941

2.3 Ordering LBC kits

2.3.1 Lambeth

Use GP supplies ordering form and send to Viapath CSR:

Email: Viapath.CSR@nhs.net

Address: CSR

North Wing

5th floor

St Thomas Hospital

Westminster Bridge Road

London SE1 7EH

Telephone: 020 7188 8008

2.3.2 Southwark

Email: <http://purchasing/enquiries/customers/contactus.aspx>

Address: King's College Hospital Procurement department

Unit 1

KCH Business Park

129 Coldharbour Lane

London

SE5 9NY

Telephone: 020 3299 9000 Ext: 37878

Fax: 020 3299 9000 Ext: 33218

2.3.3 Lewisham

Email: paul.skipsey@gstt.nhs.uk

Address: Essentia GP Stationary Services

Guys & St Thomas' NHS Foundation Trust

St Thomas' Hospital, Lambeth Wing, Lower Ground

Lambeth Palace Road

London SE1 7EH

Telephone: 0207 188 7188 ext 53077

Fax: 0207 188 3902

2.4 Order of semen analysis kits

To order semen analysis kits (specific sample container & request form):

Email: customersupport@viapath.co.uk

2.5 Hours of opening

The department is open from 09:00 – 17:00, Monday to Friday (except bank holidays). Saturday mornings and bank holiday service are available for urgent renal biopsies.

2.6 Clinical advice and interpretation

Phone the general enquiries number and the secretarial staff will put you through to the Consultant Pathologist reporting the case you require.

2.6.1 Histology Enquiries:

Tel 0207 188 2912

Fax 0207 188 2948

2.6.2 Cytology Enquiries:

Tel 0207 188 2916

Fax 0207 188 8989

2.7 Staff contact details

Clinical Lead

Dr. Mufaddal Moonim mufaddal.moonim@gstt.nhs.uk Ext 89728

Cytology Clinical Lead

Dr Ashish Chandra ashish.chandra@viapath.co.uk Ext 82946

Gynae Cytology Lead

Dr Padma Menon padma.menon@gstt.nhs.uk Ext 82935

Hospital Based Programme Coordinator

Dr Ali Kubba Ali.Kubba@gstt.nhs.uk Ext 83691

2.8 Consultants and Specialties

Consultants	Speciality	Extension
Dr Mudher Al-Adnani	Perinatal	82918
Dr Paul Cane	Breast, Respiratory	82933
Dr Ashish Chandra	Cytology, Urology	82946
Dr Fujun Chang	Gastrointestinal, Cytology	82924
Dr Giuseppe Culora	Gynaecology, Cytology	82925
Dr Harriet Deere	Breast, Gastrointestinal	82927
Dr Simi George	Perinatal, Gastrointestinal	82917
Dr Baljit Gill-Barman	Gastrointestinal, Infectious/Tropical disease, Cytology	88507
Dr Anna Green	Haematopathology	50885
Dr Mike Green	Gastrointestinal, General	83085
Dr Robert Hangartner	Renal	82956
Dr Amanda Herbert	Cytology	82926
Dr Catherine Horsfield	Renal, Urology	82907
Professor Sebastian Lucas	Infectious/Tropical disease	82945
Dr Ula Mahadeva	Gastrointestinal, Infectious/Tropical disease, Cytology	82934
Dr Andreas Marnerides	Perinatal	82917

Dr Emma McLean	Respiratory, Cytology	82926
Dr Padma Menon	Gynaecology, Breast, Cytology	82935
Dr Mufaddal Moonim	Haematopathology, Endocrine, General, Cytology	89728
Dr Ranmith Perera	Renal	82940
Prof. Sarah Pinder	Breast	89727/84260
Dr Alexander Polson	Gynae, Urology	89729

2.9 Section Leads

2.9.1 Service Delivery Manager

Ms Krista De Four Krista.defour@viapath.co.uk Ext: 82955

2.9.2 Operations Managers

Diagnostic Cytology: Soma Pillay Soma.Pillay@Viapath.co.uk Ext: 82905
 Cervical Cytology: Suzanne Ferra Suzanne.Ferra@viapath.co.uk Ext: 82905
 Histology (Acting): Ruth Sardinha ruth.sardinha@viapath.co.uk Ext: 81717
 Tissues Sciences Office: Parvinder Bahia Parvinder.Bahia@viapath.co.uk
 Ext: 82953

2.9.3 Quality Manager

Mrs Fiona Denham Fiona.Denham@viapath.co.uk Ext: 82937

Quality officers:

Histology Effie Georgaki Effie.Georgaki@viapath.co.uk Ext: 82931
 Cytology Rana Ebadi-Askari Rana.ebadi-askari@viapath.co.uk Ext: 82904

2.9.4 Training Officers

Histology Karen Boniface karen.boniface@viapath.co.uk Ext: 82931
 Cytology Michelyn Duldulao Michelyn.duldulao@Viapath.co.uk Ext: 82904

2.9.5 Health and Safety Officer

Histology Juliet Kaggwa Juliet.kaggwa@viapath.co.uk Ext: 82931
 Cytology Emma Shumba Emma.Shumba@viapath.co.uk Ext: 82904

2.10 Complaints

Complaints may be made directly to the department, via PALS or via Viapath Customer Services. Complaints are handled according to the Viapath Compliments, Comments, Concerns and Complaints Procedure located at <http://www.viapath.co.uk/customer-service>.

2.11 Protection of patient information

All patient information is handled under the terms of the Data Protection Act 1998. All personal information received by Viapath is dealt with according to the Viapath Privacy, Data Protection & Cookie Policy which is available at <http://www.viapath.co.uk/privacy-policy>.

3. HISTOPATHOLOGY INFORMATION

The majority of specimens for histological investigations must be placed in 10% neutral buffered formalin as soon as possible following removal to ensure that the tissue sample is preserved as much as possible to its life like state. The fixative acts as a preservative arresting the deleterious effects of putrefaction and autolysis. It also hardens and alters the tissue chemically in such a way that it is not harmed by the effects of processing and allows for histological tests to be performed.

3.1 Fixative

3.1.1 Formalin

Specimens are normally received in a fixative which if received from Guy's and St. Thomas' Hospitals will be in **10% neutral buffered formalin**.

Formalin is a clear fluid with a pungent toxic vapour.

There is a small stock of filled and labelled formalin pots in Specimen Reception. The greater bulk of fixative pots are stored in the Solvent Store. Please check for leakages, pots stored beyond their expiry date, and handle carefully using gloved hands. If you spill any formalin wipe it immediately with a De-Formalizer pad and wash the affected area with water and wash your hands.

3.1.2 Renal biopsies

Renal biopsies must be collected in **10% formal saline** for routine Histology and glutaraldehyde for Electron Microscopy.

3.1.3 Hazards

Formalin is a hazardous substance and care is to be taken when in use. Beware of spills and inhaling vapour, as formaldehyde is a toxic agent that may cause mild to severe irritation of skin and mucous membranes. Wear gloves when opening a specimen pot, tighten the lid when closing, and place the labelled specimen pot into a plastic pathology specimen bag. Wash off any spills with copious amounts of water.

3.2 Special fixatives

Samples for testicular biopsies in Bouin's fixative are occasionally received and transferred into 10% neutral buffered formalin during biopsy cut-up.

Bouin's is a yellow fluid.

Occasionally other fixatives are required. These are available on request at Histopathology specimen reception.

Specimen Reception Ext 82920 Pharmacy Ext 85030

3.3 Stock specimen containers

New stocks of filled formalin pots can be obtained from Specimen Reception. Guy's Hospital Pharmacy supplies Guy's Hospital theatres with formalin pots. The MLA in Specimen Reception delivers filled formalin pots to North Wing theatres on the 2nd Floor on a weekly basis (Friday) together with empty specimen containers. All containers carry a specimen label and hazard sign.

Specimen Type	Fixative	Container
Biopsies	10% buffered formalin	Small plastic jar 60 ml
Cervical biopsies	10% buffered formalin	Universal container 30 ml or Small plastic jar 60 ml
Routine Histology	10% buffered formalin	Universal container 30 ml
		Small plastic jar 60 ml
		Large jar 350 ml
		Plastic buckets 1.8, 2.5, 5 and 10 litre.
Renal biopsies	10% formal saline	Small 10ml container
Amputations	No fixation	Unclosed 60 litre Griff Bins
Foetus	No fixation – send to Mortuary	
Placenta	10% buffered formalin	2.5 litre plastic bucket
Bone marrow trephine	10% buffered formalin	Small plastic jar 60 ml or Universal container 30 ml
Testicular biopsies	Bouin's fixative	Universal container 30 ml
Jejunal biopsies	Normal saline – sent to Guy's	(For viewing villi under dissecting microscope) Universal container
Gouty tophus specimens	Absolute alcohol	Small plastic jar

3.4 Unfixed tissue

Some tissues samples are sent unfixed due to clinical requirement or for rapid diagnosis. These include frozen sections, enzyme histochemistry, suspected gout, and suspected lymphoma samples.

Placentas from babies that require a post-mortem examination should be sent unfixed to the Mortuary. Ext: 83195

For chromosomal investigations send a sample to Cytogenetics Department Ext 81715.

These specimens must be transported immediately to the laboratory in a closed labelled container and handed to a member of laboratory staff. Any biohazard should be indicated on the card and specimen. Any indication of infection type would be advantageous.

All unfixed histology and cytology material must be regarded as infectious (category one) specimens and must be handled in the appropriate class I safety cabinet.

3.5 Frozen sections

All frozen sections **must** be pre-booked with the department **24 hours in advance** as a Consultant Pathologist and BMS have to be made available.

To make a booking contact the Histopathology Office on ext: 82912 number below and give:

- Patient details,
- The estimated time of frozen section,
- Theatre details,
- Contact number
- Site (St Thomas' or Guys Hospital)

If there is a delay in operation contact the Histopathology laboratory and indicate the new time of frozen section. Specimens must be delivered immediately to the histopathology laboratory, (2nd Floor North Wing St Thomas's Hospital).

Staff from Histopathology also perform frozen sections at the Guy's Hospital site. Bookings are made via the Histopathology Office on Ext 82912.

Frozen sections at Guy's Hospital should allow for additional transport time. Specimens must be delivered to the Frozen Section Room in Histopathology at Guy's (2nd Floor, Borough Wing) and must **NOT** be delivered to Guy's Central Pathology reception.

All skin and Mohs frozen sections should be booked directly with St. John's Dermatopathology Laboratory, Ext. 86327.

3.6 Cancer pathway requests

When requesting Histology on patients that are on a cancer pathway, please select 'Urgent cancer pathway' if submitting an EPR request form. If submitting a manual request form, please record 'urgent cancer pathway' on the form.

3.7 Request forms and labelling

- All histology samples are to be sent with a request form, either generated by EPR or using the Viapath Histology/Cytology request form.
- For specimens to be accepted by laboratory staff all details on the specimen pot must match those on the request form, including the nature of specimen.
- The sender will be contacted when histology samples are received without an appropriate request form. Testing will be delayed until a form is received in the laboratory. This will be logged as an incident where testing is delayed and patient care has been compromised on to the Trust Datix Electronic IR1 form.

3.7.1 Viapath paper request form

This should only be used when the EPR system is not available.

Failure to complete details on a request form or specimen pot will mean a delay in issue of a result, and result in laboratory staff contacting the sender and requesting them to attend at the laboratory and fill in or correct the missing details.

Please use computer generated labels that accompany patient notes.

The following details must be given on the request form:

- Patient's full name (forename and family name)
- Date of Birth / age
- Hospital number
- Sender address codes: Consultant, destination, date and time taken
- Funding details: indicate if NHS, private, or contract funding
- Clinical details: sufficient relevant clinical details including treatment and length of episode. Note any specific histopathology tests required.
- Specimen details: specimen type. If more than one specimen from same patient, indicate the pot number and the specific specimen site.
- Contact name/ number: The requesting clinician must sign and give a contact Telephone / bleep number.

3.8 Specimen labels

Fill in the specimen pot details using **a ballpoint pen or permanent marker**, not a fibre-tip pen where the ink will run should a spill occur.

All details should be filled, and where more than one specimen is taken, pot numbers and specimen information should match the details on the request card. At least two forms of personal ID must match, full name, and date of birth (and/or hospital number) together with the nature of specimen. **A discrepancy will result in a delay in processing and could impact on patient management.**

3.9 Specimens that should be pre-booked (24 hours notice)

Type of specimen	How to be received	Who needs to be contacted
Rapid Frozen section	Unfixed (dry pot) URGENT	Inform the laboratory 24 hours prior Ext 88468
Rectal suction Biopsies (for Hirschsprung's)	Unfixed on saline moistened gauze	Inform the laboratory 24 hours prior Ext 88468
Muscle biopsies	Unfixed (dry pot) Specimens should be wrapped in saline soaked gauze	May need BMS assistance, contact Enzyme Histochemistry Stefan Buk at King's 020-3299-1957
Nerve biopsies	Unfixed (dry pot)	May need BMS assistance, contact Enzyme Histochemistry Stefan Buk at King's 020-3299-1957
Lymphoma / lymph nodes for lymphoma	Unfixed (dry pot)	Inform the laboratory Ext 82912 <i>(Tissue needs to be selected for Cytogenetics and snap freezing)</i>

3.10 Histology Turnaround Times

Sample Type	Turnaround Times	Comment
Frozen sections	Up to one hour	Fresh tissue is usually prepared, sectioned and stained within 20 minutes. A report will be issued immediately. Clinical staff are encouraged to be present in the laboratory where possible.
Urgent specimens	1-2 working days	State urgent on the request form. When an urgent biopsy is received during early to mid morning the specimen may be prepared and reported on the same day. <i>Discuss with the speciality consultant before sending.</i> Specimens arriving in the afternoon or of other size will require a longer processing time and will be prepared for reporting the following morning by 11am.

Sample Type	Turnaround Times	Comment
		Please indicate clearly who is to be contacted for a phoned report. Where further complex testing is required, a provisional opinion will be given.
Routine specimens	2-7 working days	Specimens of small to medium size received on day one will normally be processed, sectioned and stained by midday on day two, and reported by late afternoon on day two. At the time that the report is entered onto the pathology computer database and authorised by the Consultant Pathologist it becomes available on the Trust Results Reporting Service, EPR and at host terminals to authorised personnel.
Large excision specimens	3-10 working days	Depending on size and degree of fixation, and if further testing is required, a result is normally issued within ten working days

3.11 Notes

Results are available on RRS for up to 999 days.

The department is closed at the weekend and consequently results on specimens received on Friday will only be available by Monday or Tuesday at the earliest. Specimens from bone will require decalcification prior to processing and this will extend the report time, usually by two to four days. Specimens from complex tumours may require immunocytochemistry or molecular studies, usually requiring a further 3-4 days.

3.12 Specimen deliveries to the laboratory

3.12.1 St. Thomas'

Specimens are to be received in the Histopathology laboratory no later than 4.45pm.

Clearly mark all urgent specimens and any known biohazard such as HIV positive specimens.

Portering staff will collect specimens from designated sites and deliver directly to Cellular Pathology or to the Pathology Central Specimen Reception (CSR).

Specimens received in CSR are sorted and delivered to Cellular Pathology immediately. Specimens may be delivered directly to the department.

Routine **out of hours** (17.00-09.00) specimens should be delivered to CSR, or left in formalin at a collection point for the next morning collection.

3.12.2 Guy's Hospital

Specimens from Guy's Hospital are delivered to Central Pathology Reception, 4th Floor, Southwark Wing. Specimens are then delivered to St. Thomas' CSR and forwarded on to Cellular Pathology. Urgent specimens should be marked accordingly.

Please send Ear/Nose/Throat specimens to Oral Pathology at Guy's Hospital, (see below for contact details).

A written log of all Histology specimens (specimen tracking log) has been distributed throughout the GSTFT site by the portering service. This notes all relevant details, particularly date and time of collection. Log records are maintained for one year.

3.12.3 Muscle biopsies

Testing is carried out at the Institute of Psychiatry (see below for details)
Call for BMS assistance 0203 299 1957

4. SPECIALIST SERVICES

4.1 Dermatopathology

Provides a specialist service for skin specimens in association with the St. John's Dermatopathology Laboratory.

Dermatology specimens are to be sent directly to St Johns Dermatopathology. Samples may be received in the main Histopathology laboratory but will be redirected to St. Johns Dermatopathology.

Other specific dermatology specimens will also be redirected as appropriate.

4.1.1 Contact:

St John's Dermatopathology
2nd Floor, Block C, South Wing
St. Thomas' Hospital
Dermatopathology Main Laboratory Ext 86327
Dermatopathology Laboratory Manager Ext 85160

4.2 Centre for Ultrastructural Imaging (Electron Microscopy)

The EM Unit at Guys provides a diagnostic and research electron microscopy service by prior arrangement. Specimens for electron microscopy should be less than 1 mm sq. and be fixed in glutaraldehyde, obtained from the EM Unit.

In an emergency, tissue can be fixed in formalin but results will be inferior.

4.2.1 Contact:

Electron Microscopy
Lower Ground Floor, New Hunts House

Guy's Hospital
020 7848 6950

4.3 Head & Neck/Oral Pathology

Provides services with a special interest in pathologies of the head and neck. For further information contact:

4.3.1 Contact:

Head and Neck/Oral Pathology
4th Floor, Tower Wing
Guy's Hospital
Clinical Lead: Professor Eddy Odell
Operations Manager: Claire Lock

Ext 84365
Ext 81754

4.4 Histochemistry

Provides a service for surgical muscle (myopathies), nerve and rectal (Hirschprung) biopsies. BMS assistance is available on request at muscle biopsies.

4.4.1 Bookings / Information/ Contact

Clinical Neuropathology
1st floor ANC building
King's College Hospital
Denmark Hill, SE5 9RS
Muscle biopsies: Mr Stefan Buk (Institute of Psychiatry) 0203 2991957
Consultant Pathologist, Dr. Harriet Deere Ext 82927

4.5 Renal Histopathology

Based at St. Thomas Hospital this unit provides a specialist service for the clinical renal diagnostic and transplant teams. BMS assistance is available at renal biopsy from staff based at Guys Hospital. Prior booking enables staff to plan workload. Regular Clinicopathological (MDM) meetings are held. Renal biopsies may be booked at St. Thomas. The Renal Laboratory supplies formal saline in 5ml containers and glutaraldehyde in 5ml containers to the clinical teams.

4.5.1 Contact:

Renal Histology Laboratory
2nd Floor North Wing
St Thomas' Hospital
Renal Pathologist: Dr. Robert Hangartner Ext 82956
Renal BMS Ext 82906/ 82931 **Bleep 2811**
(9am to 5pm Monday to Friday only)

4.6 Soft Tissue Tumours

Provides a specialist service for soft tissue tumours.
For further information contact

Dr. Eduardo Calonje

Ext 86408

Specialist work may occasionally be referred to an outside laboratory. A list of these laboratories is available on request.

5. CERVICAL CYTOPATHOLOGY INFORMATION

5.1 Quality Statement

The Cytology laboratory is a CPA accredited department and all cervical liquid based cytology (LBC) samples are processed and screened following NHS Cervical Screening Programme guidelines and the regional Quality Assurance Reference Centre recommendations. The department participates in the regional gynaecological and technical EQA schemes and the performance of all screening staff is assessed quarterly as per NHSCSP guidelines. The management and staff within the department are committed to providing a quality service to our users. We aim to continually improve our service through internal audit and feedback from users. If you do have a complaint or concern about any aspect of the service, this should be addressed to the Operations Manager on 0207 188 2905.

5.2 Specimen collection and transport

The laboratory is fully converted to processing and reporting LBC tests. The laboratory reports ThinPrep® LBC samples. These should only be collected by trained sample takers. They should undergo training (including taking LBC samples) and regular updates as recommended in the NHSCSP publications Quality Assurance Guidelines for the Cervical Screening Programme (1) and Resource Pack for Training Smear Takers (2). The British Society for Clinical Cytology video Taking Cervical Smears (3) should also be available in screening clinics contributing to the NHSCSP Training in sample collection for primary care staff is available on request from the cytology training leads at the local Primary Care Trust. Instruction sheets on sample collection are available from CCG nursing leads.

The person taking the sample is responsible for collecting a sample of cells from the full circumference of the transformation zone, having visualised the cervix.

NB. Please do not use ThinPrep vials after the expiry date as these will be rejected.

A courier service will deliver LBC kits and collect LBC samples. If there are any issues relating to the courier service please, contact Viapath customer support at customersupport@viapath.co.uk.

5.3 Arrangements for Cervical screening Cytology service for Inner South East London.

The laboratory has a large capacity for LBC sample processing and reporting and delivers the cervical screening Cytology service on behalf of Guy's and St Thomas's Hospital, King's College Hospital and University Hospital Lewisham.

5.4 LBC sampling kits

LBC kits are distributed by different areas for the 3 different Trusts, outlined below:

Guy's and St Thomas Trust – Viapath procurement and Citysprint

King's College Hospital Trust – King's College Hospital procurement department.

University Hospital Lewisham – Independent Trust procurement team.

The monitoring of each area is the responsibility of the teams involved. The Cytology laboratory also monitors stock use and buffer levels.

5.5 Sample storage/transportation

Liquid based Cytology vials contain Presercyt; a methanol-based, buffered, preservative solution. This must be stored as recommended:

Follow rules for flammable liquids; Keep away from heat, spark, open flames and other sources of ignition. Keep container tightly closed in a cool, well-ventilated place. Store away from incompatible materials. Keep out of the reach of children.

Storage temperature:

Without cytologic sample: 59-86°F (15-30°C)

With cytologic samples, for up to six weeks: 39-99°F (4-37°C)

Check sample container is finger-tight before packaging for transportation. The samples require to be transported in an LBC sample bag (supplied by Viapath) which will contain any leaked sample. CitySprint couriers collect samples and transport these to the laboratory. These samples must only be transported by affiliated couriers.

Basic shipping requirements:

DOT- UN1993

IATA- UN1993

IMDG- UN1993

TDG- UN1993

Please note that leaked samples and samples stored in unsuitable conditions may be rejected.

5.6 Completing the request form

- Where Possible the clinic should use the **T-Quest or EPR system** for generating a Cervical Cytology Request Form. When these are not available a normal Viapath version of the HMR101 request form

should be used. The request form should be completed in full with all information PRINTED legibly. Relevant clinical information should be printed clearly on the form. The NHS number should be used whenever possible as this is the unique patient identifier. The following information must be included on the request form:

- Full patient name, including previous name
- Address and date of birth
- Name and address of smear taker if not GP
- Name and address of GP
- GP's code
- Code for source of smear
- Date of taking sample, time of taking, date of last test, date of LMP
- Reason for smear; routine call, routine recall, clinically indicated or previous
- abnormal cervical tests
- Specimen type; Liquid Based Cytology (LBC) sample, vault sample
- Cervix visualised yes / no
- Condition; pregnant, post-natal, IUCD, taking hormones
- Clinical data including previous treatment such as radiotherapy, LLETZ,
- cone biopsy, local ablative treatment.

Any further requests can only be made while the specimen vial is with Cytology. The vials are disposed of 4 weeks after the test has been received.

Please note that requests with missing data or discrepancy may be rejected. Requests with minor discrepancies may be accepted after confirmation of correct details.

Samples taken at an inappropriate interval, before the woman has been formally invited for screening, or if the woman is older than 65 may be rejected as out of programme.

5.7 Taking a sample

Please refer to National sample taker guidelines (NHSCSP publication 23: Taking samples for Cervical Screening available via NHSCSP website: www.cancerscreening.nhs.uk).

**If the sample is not taken correctly the results will be invalid.
The use of lubricant may render the test inadequate.**

5.8 Patient Consent.

At first invitation the cervical screening programme (CSP) should be discussed with the patient, included limitations. Once the patient consents to entering the CSP they do not need to be asked for consent for each subsequent cervical Cytology test.

For patients who wish to be removed from the CSP a signed disclaimer must be gained after thorough discussion with the patient to highlight the risks associated with this.

Consent to use patient sensitive data for the CSP does not need to be sought from the patient-annual signing to section 251 of the social care act supersedes the requirement for individual patient consent.

5.9 Sample labelling

The label on the sample vial should record the forename, surname, date of birth and NHS number/Hospital number to allow matching of the vial with the request form in the laboratory. After collection and labelling, the sample and request form should be placed in separate sections of the plastic specimen bag provided before dispatch to the laboratory. Vials should not be batched and should be dispatched to the laboratory as soon as possible to avoid increasing the turnaround time of the test.

Samples that have not been adequately labelled or where the form and label do not match cannot be processed and will be discarded (following London QARC guidelines). The requester will be informed by letter if a sample is rejected.

5.10 Vaginal vault samples

These are not considered part of the NHS cervical screening programme. The vault can be identified as a scar line with corners at either end. A Cervix-Brush® should be used to sweep over the entire area in a clockwise direction, making sure that this includes both of the corners of the vault. The broom is then rinsed or placed into the LBC vial, depending on the system being used. Additional information on vault samples can be found in section 5.22.

5.11 Vulval samples

These are not considered part of the NHS cervical screening programme. Once the sample has been collected using the Cervix-Brush® it is rinsed or placed into the LBC vial, depending on the system being used.

5.12 Report generation and distribution

Printed reports are sent to the surgery or clinic where the sample was collected.

Copy reports are sent to Call/Recall agency at the Primary Care Trust (PCT) and the woman's GP (when the GP practice is not the source of the sample). Unidirectional links are in operation between the laboratory and the PCTs to allow electronic transmission of the cytology report.

The laboratory aims to provide a screening report within 7 to 10 days from the date the smear was taken, to comply with the national target of 98% report letters received by women within 14 days of sample collection. General Practitioners and Clinics will be informed via the HBPC and the

Screening Commissioner if there are delays due to staff shortages. Under these circumstances urgent, hospital clinic and follow-up cases will be prioritised.

5.13 Results

The laboratory will not issue results to patients. Only completed authorised results will be posted to the sample taker, with a copy to the general practitioner if his/her name and address is provided on the request form.

5.14 Urgent referrals for further investigation

Any test reported as suspected invasive carcinoma or suspected glandular neoplasia requires urgent referral for further investigation, as these are possible cancer cases. The laboratory will contact the sample taker by phone and arrange to email the report via NHS mail so that referral process can commence as soon as possible. A failsafe system is in place to ensure that the report has been received and the patient referred.

5.15 Prioritising the workload

The majority of samples received by the laboratory are taken as part of the NHS cervical screening programme. The national screening office has advised that laboratories should make the final report available to women within 14 days of sample collection. The laboratory adheres to this national target.

5.16 Audit

The department participates in the Trust audit programme and has a rolling programme of audit projects.

5.17 Cervical screening management protocol

- Commence cervical smears after 24.5 years old.
- No need to screen women under the age of 24.5 years. However, within this age group, there may be a clinical indication to take a cervical test.
- Continue routine 3 yearly recall between the ages of 25 – 49 years inclusive
- Continue routine 5 yearly recall between the ages of 50 – 64 years inclusive.
- Cease smears at age 65 years, only screen those who have not been screened since age 50, or those who have had recent abnormal tests.

Additional (unscheduled) smears are **NOT** justified in any of the following situations:

- On taking or starting to take an oral contraceptive

- On insertion of an IUCD
- On taking or starting to take hormone replacement therapy
- In association with pregnancy – neither antenatally nor postnatally, nor after termination.
- In women with genital warts
- In women with a vaginal discharge
- In women with cervical/vaginal infection
- In women who have had multiple sexual partners
- In women who are heavy cigarette smokers
- One year after the first ever negative smear

Abnormal vaginal, postcoital, postmenopausal or intermenstrual bleeding should be assessed clinically and managed appropriately by a referral to gynae. A cervical Cytology test is not an appropriate test to manage dysfunctional bleeding.

Where there is a strong clinical suspicion of malignancy, refer to gynaecologist.

5.18 Evidence of transformation zone sampling

A lack of endocervical cells and/or immature metaplastic squamous cells is not taken on its own as a criterion for sampling adequacy (unless the patient is being followed up for a previous glandular abnormality or at the discretion of the Cytopathologist).

5.19 Failsafe for early recall & colposcopy referral

The laboratory sends cervical screening results electronically to PCSE (Capita); these codes update the Health Authority computer. When the laboratory advises early recall, the suggested interval acts as a marker for the Health Authority computer to initiate fail-safe operations (i.e. invitation letters, reminder letters and GP notification letters of defaulters). If a report recommends referral to colposcopy, the colposcopy department will be informed directly by the laboratory and they will arrange an appointment for the woman. The laboratory operates a Failsafe System that is designed so that if a patient does not have the necessary follow up from colposcopy attempts are made to rectify this.

5.20 HPV testing

The laboratory has implemented year 2 HPV testing protocols for triage and Test of cure since 2014. It is important for the sample taker to highlight on the request form if a patient is eligible for Test of Cure HPV testing, or has had previous treatment (LLETZ, cone biopsy) for CIN in the last 10 years.

The HPV test is performed at Northwick Park Hospital using DNA extraction and PCR amplification with labelled probes to identify if High Risk HPV DNA is present/not present. The test detects 14 subtypes of high risk HPV.

5.21 Cervical Screening Management Summary

REPORT	MANAGEMENT
Negative	Routine recall ie. <ul style="list-style-type: none"> • Ages 25-49 every 36 months • Ages 50-64 every 60 months unless no screening history or previous abnormality then every 36 months After 65 with at least two previous negative samples then cancel recall
Inadequate because endocervical cells are absent with a history of endocervical abnormality	Repeat smear in 3 months Endocervical and ectocervical sampling is recommended
1st Inadequate 2nd Inadequate 3rd Inadequate	Repeat in 3 months Repeat in 3 months Refer for colposcopy
Borderline changes Low grade (Mild) dyskaryosis	HPV test for triage: HPV detected-refer to Colposcopy HPV not detected-routine recall
Follow-up after borderline changes: 1st Negative (taken at 6 months) 2nd Negative 3rd Negative	Repeat in 12 months Repeat in 12 months Routine recall
High Grade (Moderate) dyskaryosis	Refer for colposcopy
High Grade (severe) Dyskaryosis	Refer for Colposcopy
Suspected invasive carcinoma	Urgent colposcopy referral
Suspected glandular neoplasia	Urgent colposcopy referral
Follow-up after treated CIN	HPV test for TOC: HPV detected-refer to Colposcopy HPV not detected-routine recall
Follow-up after untreated CIN 1	3 tests 12 months apart then routine recall.
Follow-up after untreated CIN 2/3	2 tests 6 months apart then annual tests for 9 years then routine recall.
Follow-up after treated CGIN	HPV test for TOC: HPV detected-refer to Colposcopy HPV not detected-12 month recall
Follow-up after treated cervical cancer	Recall at discretion of gynaecologist

5.22 Vault sample guidance

(patients who have undergone total hysterectomy)

Guidance from the NHSCSP and the National Colposcopy Quality Assurance Group is that the follow up of women who had a total hysterectomy would become the responsibility of the gynaecologist. It is not possible to record any samples taken after a complete hysterectomy and the responsibility for follow up and failsafe of these women will reside with the gynaecologist.

5.23 Gynaecologist responsibility

Dr John Tidy, Chairman of the National Colposcopy QA group issued a letter in March 2008 to clinicians regarding the arrangements and responsibilities.

Follow up of women undergoing complete hysterectomy should be in line with national guidance summarised below:

- For women who were on routine recall and no CIN was present in the hysterectomy specimen then no further vaginal vault cytology is required.
- For women not on routine recall and with no CIN in the hysterectomy specimen the gynaecologist may need to arrange appropriate investigations. These may include colposcopic examination of the vaginal vault or vaginal vault cytology.
- For women who undergo hysterectomy and are found to have completely excised CIN it is still recommended these women should undergo vaginal vault cytology at 6 and 18 months following hysterectomy.
- In women who undergo hysterectomy and have incompletely excised CIN then follow up should be conducted as if the cervix was still in situ.
- Women who undergo radical trachelectomy as part of conservative management of cervical cancer should remain under the care and guidance of the treating gynaecologist. Future follow up will be determined by the treating gynaecologist and the woman will be deemed to be no longer within the National Screening Programme.
- If the gynaecologist discharges a woman who still requires vault cytology to her GP's care, the gynaecologist must ensure that appropriate written guidance on future treatment requirements is provided to the Practice.

Please note - Women who undergo a subtotal hysterectomy will remain within the National Screening Programme and will be recalled by the NHAIS (Exeter) System.

6. NON GYNAECOLOGICAL CYTOLOGY

The staff in the laboratory will be pleased to advise on any aspect of sample collection.

6.1 Patient Consent

Patient consent must be gained before any procedure can commence. This is the responsibility of the patient's clinician/consultant to complete.

The patient will also need to consent to their medical/clinical history being disclosed for their onward care.

6.2 Specimen collection

Specimens by and large are fresh samples and should be delivered immediately to specimen reception (2nd floor, North Wing, STH). Cells will deteriorate rapidly at room temperature, but this process can be slowed by storing the specimen at 4°C in a fridge prior to dispatch to CSR. Specimen containers and request forms may be ordered via GP Supplies, CSR department (ext 81174).

- **Fluids**

This includes pleural, pericardial and ascitic fluids, cyst aspirates, peritoneal, bronchial and biliary washings, lavages and drain fluids. All fluids need to be placed in a standard universal container and sent unfixed to the lab. If large amounts of fluid are present a suitable quantity should be sent to the lab after the whole specimen has been well mixed. Exudates often tend to clot and cells are trapped within this. If a clot is noticed in a fluid, please also send this along with the fluid.

- **Brushings**

These include brushings from bronchial, biliary, mucosal and other sites. Please prepare one smear by moving the brush in a circular pattern on a glass slide. Spray fix this immediately so as to prevent air drying artefact. Then place the brush tip in a ThinPrep vial and ensure that the material on the brush is mixed with the fixative. Send both samples to the lab, ensuring that the slide is securely placed in a plastic slide carrier.

NB. Please do not use ThinPrep vials after the expiry date.

- **Smears**

This usually consists of prepared smears from nipple discharge or fine needle aspiration specimens which have been done without pathologist / BMS assistance. Smear the material thinly onto two slides and leave one to air dry and immediately spray fix the other. Label and then place the slides securely in a plastic slide carrier.

Please note that both fixed and air dried smears are needed for diagnostic purposes. If an appointment for a FNA is needed please see section below.

Incorrect collection of sample may result in the laboratory being unable to process the test.

6.3 Specimen labelling

6.3.1 Slides

Use a lead pencil only to label the frosted end of each slide with the following details. **Ink and fibre-tip pens should not be used as the ink will be lost during the staining process.**

- Name of the patient
- Hospital No / Date of birth
- Whether fixed or air dried

6.3.2 Specimen pots

Populate the pre-printed form on universal containers / specimen pots with the following details;

- Full name of patient
- Hospital No
- Date of birth
- Type of sample
- Date & time of collection

6.4 Completion of request form

All samples must be accompanied by a request form that is completed legibly and accurately with all patient, sender and clinical details. The specimen type e.g. 'FNA left thyroid' must also be recorded. Either EPR or Viapath Histo/ Cytopathology paper forms may be used. If requesting via EPR, please ensure that the EPR label is attached to the specimen container.

The sample and the request form must be placed into a plastic 'biohazard' 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.

Incorrectly labelled samples or incomplete request forms will delay the processing of the sample and impact on patient management, however the department endeavours to process all samples if possible.

6.5 Urgent specimens

Specimens marked as 'urgent' will be reported within 24 hours after receipt by the laboratory. However, this may only be a provisional report pending

further ancillary tests. **It is recommended that the requesting clinician discuss such specimens in advance with the cytopathologist. Please ensure that appropriate contact details are documented on the request form.**

6.6 Routine specimens

The turnaround time for non-gynae reporting is between 7 to 10 working days but this will vary depending on the specimen type and if additional clinical information or ancillary tests are required e.g. immunocytochemistry, flow cytometry, FISH or molecular studies.

FNA specimens received in the laboratory will be reported within 5 working days.

6.7 Results

Non-gynae results are available on the RRS / EPR in the time frames mentioned above.

Paper reports are printed and sent out daily, addressed to the consultant or clinical team who requested the test.

To discuss a cytology report with a consultant cytopathologist, contact the department between 9.00 and 5.00 pm on 020718 82915 / 89189

6.8 Fine Needle Aspiration (FNA) clinics

Fine needle aspiration is a reliable method of determining the nature of lumps and bumps. This involves aspirating a lump using a fine needle and then testing the material removed. Clinics are run by Consultant cytopathologists and are one stop clinics where a diagnosis / provisional diagnosis is determined while the patient is in clinic. This allows material to be collected in one setting for ancillary testing (microbiology, cell blocks, flow cytometry, cytogenetics and molecular diagnostics). A joint one stop clinic (USG guided FNA) is also being run between pathology and dental radiology for head & neck cancer and thyroid patients.

FNA clinics: There are several FNA clinics per week, details are given below;

Guy's & St Thomas' Hospitals

Day	Clinic	Time
Monday	FNA Clinic, Dept of Cellular Pathology, 2nd floor North Wing, St. Thomas' Hospital	2-4 pm
Tuesday &	Endobronchial Ultrasound (EBUS) FNA clinic, Chest Clinic, 1 st Floor,	Tues - 9am-1pm, 2-

Day	Clinic	Time
Thursday	Lambeth wing, St Thomas' Hospital	5pm Thurs - 2-5pm
Tuesday & Thursday	Head & Neck ultrasound Clinic, FNA Clinic Room No: 0303032; 3 rd Floor, Tower Wing, Guy's Hospital	1-4.30pm
Wednesday & Friday	Ultrasound Clinic, 1 st Floor, Lambeth Wing, St Thomas' Hospital	9am-12.30pm
Wednesday	Ultrasound FNA Clinic, X-ray Department, 2 nd Floor, Tower Wing, Guy's Hospital	9.15-11.30am
Thursday	Endocrinology FNA Clinic, 3 rd Floor, Lambeth Wing, St Thomas' Hospital	9am-1.30pm
Thursday	ENT Outpatients, 3rd Floor Southwark Wing, Guy's Hospital	2-5 pm
Friday	ENT/ General outpatients, 2nd Floor Southwark Wing, Guy's Hospital	11-12.30 pm

- **Ward based FNA service:** This is a routine service provided by the cytopathologists with or without BMS assistance during working hours (9-5 pm). Please ring FNA appointments (ext 82941) to arrange this.
- **Intra-operative FNA service:** This is a routine service provided by the cytopathologists with or without BMS assistance during working hours (9-5 pm). Please ring FNA appointments (ext 82941) to arrange this.
- **On- site assessment for image guided FNA:** USG guided FNA is provided by radiology and clinical departments across both hospital sites. These are routinely supported by biomedical scientists (BMS) who assess specimen adequacy during the procedure. If a cytopathologist is required for a case, please ring FNA appointments (ext 82941) to arrange this.

King's College Hospital

BMS support is also provided for the following FNA clinics at KCH:

Day	Clinic	Time
Monday & Tuesday	Ultrasound (radiology), 2 nd Floor, Denmark Wing, King's College Hospital.	Mon- 2-4pm Tues - 9-9.45am
Tuesday	Dental Institute, Ground Floor, King's College Hospital	9.30am-1pm

6.9 Andrology service

The Semen Analysis request form and specimen container needs to be obtained from the GP surgery. Section PART A needs to be completed by the requesting doctor, and PART B needs to be completed by the patient. The specimen container is a unique sterile container and it is mandatory that this be used.

Semen analysis is carried out for sub-fertility investigation and for post vasectomy checks.

Patients should be instructed to abstain from coitus or masturbation for a minimum of two days and a maximum of 7 days prior to the specimen being produced.

The sample needs to be collected in a sterile container which can be obtained from individual GP practices.

The specimen should be produced by masturbation (stimulation by hand) directly into the specimen container supplied. It is helpful if you warm this container in your hands for a couple of minutes first. No other container must be used.

It is important not to use an ordinary condom to collect the sample or to use lubrication of any sort as this will adversely affect the test. It is important that the entire specimen is collected in the specimen container; incomplete samples may not be suitable for testing. There are no facilities in the cytology department for on-site specimen production.

The specimen has to be delivered to the laboratory by the patient. Appointments are given as per time slots and it is important for the patient to be informed that they need to produce the sample a maximum of thirty minutes prior to their time slot to ensure the specimen is not more than a hour old when analysis has begun. Instructions to the patient are provided on the back of the reverse side of the request form as well.

The specimen should be delivered to the laboratory as soon as possible and not more than 1 hour after production. It should be kept warm (eg. in an inside pocket) whilst being transported to the Cytology laboratory (2nd floor, North Wing, St Thomas Hospital).

Excessive cold (less than 20°C) or heat (greater than 37°C) will adversely affect the test results.

Please note that the laboratory logs the specimen under the provider's (man's) name and date of birth. Staff will ensure that the patient has completed the request form adequately before the patient leaves.

This service is by appointment only.
Andrology appointments: 0207 188 2941

Samples delivered outside of appointment hours or delivered without appointment will not be processed. Sample collected in an incorrect way or in an incorrect container may render the test results invalid.

6.10 Contact details

Dial 020718 before extension if calling from outside the hospital.	
Appointments (FNA clinics/andrology)	82941
Enquiries about specimen collection/delivery	82904
Enquiries about results/discuss report with a cytopathologist	82915/89189

6.11 Non-gynaecological sample collection

Sample	Fixative	Container	Special instructions
Bronchial lavage Bronchial wash Bronchial trap Bronchoalveolar Lavage	Unfixed	Clean, dry container with screw cap	
Brushings: Bronchial Oesophageal Gastric Bile duct, etc.	Spray fix smear Brush in Cytolyte vial		See section 6.1
CSF	Unfixed	Clean, dry container with screw cap/ Universal container	Contact the laboratory in advance to notify staff of imminent arrival of sample (Ext 82904). Sample must be delivered to the laboratory by 3:30pm as it is prepared upon receipt.
Fluids Body cavity fluid Cyst fluid Aspirates	Unfixed	Clean, dry container with screw cap/ Universal container	Send the sample to the laboratory as soon as possible to minimise cell deterioration
FNAs	FNA CLINIC BY APPOINTMENT ONLY		
Semen Analysis	Unfixed	BY APPOINTMENT ONLY	
Sputum	Unfixed	Clean, dry container with screw cap	Collect first deep cough after waking, before brushing teeth or eating. Patient may be induced to provide a deep cough sample.

Sample	Fixative	Container	Special instructions
Urine			
Routine	Unfixed	Universal container	The second voided mid-stream urine of the day should be collected. Important to state the collection method i.e. voided, catheter specimen, ileal conduit
Crystals	Unfixed	Universal container	Deliver to lab immediately
Dysmorphic red blood cells and casts	Unfixed	Universal container	Deliver to lab immediately

7. REFERENCES

1. NHSCSP Publication No 1, Achievable Standards, Benchmark for Reporting. Criteria for Evaluating Cervical Cytopathology, October 1995, May 2000 and April 2013.
2. NHSCSP Publication No 8, Guidelines for Clinical Practice and Programme Management, December 1997
3. NHSCSP Publication No 20, Colposcopy and Programme Management 2004
4. Quality assurance guidelines for the cervical screening programme. NHSCSP Publication No 3; Sheffield, January 1996.
5. Resource pack for training smear takers. NHSCSP Publication No 9 Sheffield, July 1998
6. Service specification 25 Cervical screening, April 2013
7. Guidelines for cytology procedures and reporting in breast cancer screening. NHSBSP Publication No 22; Sheffield September 1992
8. European Committee for Standardization. Medical Laboratories – Requirements for quality & competence (ISO 15189:2012). Clause 5.4.2. October 2012.