East Lancashire Hospitals NHS Trust
A University Teaching Trust

Cellular Pathology User Guide

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Section 1: General Information

Location

The Cellular Pathology laboratory is located on Level 0, Royal Blackburn Teaching Hospital, Haslingden Rd, Blackburn BB2 3HH.

Andrology services are currently provided from a suite at Burnley General Teaching Hospital. Please see the Andrology user manual for full details.

Clinical Services

The department provides:

- Histopathology including immunohistochemistry, frozen sections services and immunofluorescence
- Diagnostic cytology
- Andrology – refer to the andrology user information page.

Opening hours

The department is open from 8 am to 5pm Monday to Friday. There is no service outside of these hours.

Key personnel and contact information

General enquiries

Cellular pathology enquiries line - 01254 732621 (82621)

Results are available on the ICE and GP systems - please check these systems before ringing the department. Please check for reports under NHS, Hospital numbers and other PID before contacting us.

Clinical advice

Clinical advice is available between 8.45 and 5pm Monday to Friday. If you require clinical advice please contact (01254) 732621 or extension 82621 if ringing from within the hospital. Advice about cases reported externally can be directed to the reporting pathologist where their contact details are within the report.

Complaints

Any complaints about the service should be directed to the Lead Biomedical scientist in the first instance on 01254 732438 or via e-mail. They can also be raised via the Customer Relations Team by phone on 01254 733700.

Clinical Staff		Extension
Dr Rupesh Wahane	Consultant Histopathologist and Clinical Lead	01254 732621
Dr Laszlo Hegyi	Consultant Histopathologist	
Dr Neil Sahasrabudhe	Consultant Histopathologist	
Dr Santhi Kumar	Consultant Histopathologist	
Dr Sunita Rajaram	Consultant Histopathologist	
Dr. Qurratulain Chundriger	Consultant Histopathologist	
Dr Syeddah Mujtaba	Consultant Histopathologist	
Dr. Anila Chughtai	Consultant Histopathologist	
Dr Iskander Chaudhry	Consultant Histopathologist	
Dr Durgesh Rana	Consultant Cytopathologist	
Dr Rashmi Ratnakaran	Consultant Histopathologist	
Dr Sonali Timaniya	Consultant Histopathologist	
Nadira Narine	Consultant Biomedical Scientist	
Dr Nivedita Samanta	Clinical Fellow	
Dr Godwins Echejoh	Clinical Fellow	
Dr Aditi Rohan Sawant	Clinical Fellow	
Departmental Management		
Craig Rogers	Lead Biomedical Scientist	01254 73 82438
Directorate Staff		
Clinical Director	Dr Yacoob Nakuda	
Pathology Directorate Manager	Amanda Southworth	84162
Pathology Operations Manager	Pamela Henderson	84173
Pathology IT Manager	Samuel Bolton	82473
Pathology Quality Manager	Tina Cuthbertson	83103
Practice Education Facilitator (PEF)	Claire Shepherd-Cutler	84350

Priority of samples

Cancer/2WR/FDS (faster diagnosis standard

All samples for the suspicion of cancer should be labelled as 2WR, FDS, or a red cross as per ELHT policy.

Urgent

Urgent should only be used when samples are clinically urgent but not suspected of cancer.

Routine

All samples not on an urgent or cancer pathway.

Please note that inappropriate marking of samples, either as high priority or routine, significantly impacts the laboratory and can create workflow problems resulting in significant reporting delays.

Labelling of requests and samples

Use the request form provided by the ELHT laboratory, printed ICE requests or endoscopy (Solus) forms.

If sending the sample to an external service e.g. HMDS, MFT, Genomics, use destination request form and follow their sample collection requirements. They may be different to ELHT.

All fields on the histology/diagnostic request card or ICE request must be completed to ensure appropriate investigation of the specimen. All samples must comply with our specimen acceptance policy.

Missing information or requesting errors will result in a delay to specimen processing and reporting and may affect patient safety. Correct patient and specimen information is vital for us to provide a quality service to our users.

All information provide should be relevant and clearly legible.

Any specimens deemed to be high risk or potentially high risk should be clearly labelled as such to protect the health and safety of all staff.

Labelling

THERE MUST BE 3 MATCHING IDENTIFERS BETWEEN THE REQUEST CARD AND EACH SPECIMEN POT.

Accurate labelling is essential for Get it Right First Time (GIRFT) and to produce an quality result. Legibility is essential.

The following mandatory information must be provided for us to accept the specimen:

Essential Patient Identifiers:

Surname and Forename
Unique identification number – Hospital or NHS number
Date of birth

Use addressograph labels were possible – hand written forms must be checked before sending as errors in unique numbers can create unnecessary clinical incidents and safety issues.

Essential Clinical Details:

Infection risk status – to ensure health and safety of all staff
Specimen type and site – must match on specimen pot and request card
Relevant clinical information – to ensure all necessary investigations are performed. Sample type is not clinical information. Lack of information may delay diagnosis.
Consent – clear indication of any patient requirements e.g. return of material, burial, etc.
Date/time taken – essential to ensure proper fixation of high risk specimens
Clinician – please include the full surname and initials of the requesting clinician. Surname alone is not acceptable and leads to data entry errors.

If the report is needed for specific MDT date, this must be indicated so that the samples can be prioritised correctly.

Where samples do not meet the acceptance criteria, they may be returned to senders for correction or staff may be asked to attend the laboratory to correct the errors. This will delay any result.

Sample containers

All specimens for routine histopathology (except frozen section material) must be immersed in a wide-mouthed container of formalin fixative as quickly as possible after excision.

The container must be of sufficient size to allow the specimen to be surrounded by fixative. Ideally the volume of fixative should be at least 10x the volume of the specimen. If multiple specimens are taken from the patient at any one session, they must be put into separate containers and labelled accordingly.

Specimen containers for theatres are available from the laboratory during working hours.

Formalin filled 60ml screw-topped plastic containers are available for small biopsies such as skin, tru-cut and endoscopic biopsies. There is also a range of containers of different sizes available from the laboratory on request.

Please ensure that all containers have their lids either screwed on tightly or snapped on completely around the whole circumference of the container before transporting to the laboratory.

ELHT use 10% Neutral Buffered Formalin provided by Genta Medical Ltd.

High risk specimens

High risk specimens i.e. suspected category 3 pathogen specimens such as Coronavirus, TB, and blood borne virus specimens should be sent clearly marked to the laboratory as 'HIGH RISK'. The specimens should be double bagged before being sent to the laboratory.

Specimens will be fixed for 48 hours before being processed and this will extend the time for reporting. High risk specimens are not suitable for frozen sections

If the specimen is suspected to be ‘HIGH RISK” the request form and the specimen pot should be clearly marked with high risk stickers. The specimens should be double bagged before transport to the laboratory. Specimens will be fixed for 48 hours before being processed. Please not that an IR1 may be raised if high risk samples are not clearly identifiable.

Frozen section

The laboratory should be informed at least 1 working day before the operation takes place due to specialist nature of the service. The laboratory must be informed of unscheduled frozen sections as soon as possible. This is to ascertain the availability of a Consultant Histopathologist for tissue diagnosis.

The specimen should be sent to the Department immediately after excision in a dry specimen container (i.e. without fixative). Please inform the department if there is likely to be a significant delay or cancellation as we do not provide an out of hours service. A telephone extension number indicated clearly on the request form is mandatory so the report can be phoned through as soon as available.

Specimens for frozen section need transporting urgently to the laboratory. High risk specimens (including Coronavirus or tissues at risk from Coronavirus e.g. head and neck) are not suitable for frozen sections. There is no facility to perform frozen sections out of hours.

Whole Genome Sequencing (WGS)

The department does not currently offer a regular service for Whole Genome Sequencing due to the limited availability of equipment. Requests should be made well in advance (>7 days) as processing a WGS sample means that the frozen section service must be halted for 24-48 hours. Liaison between surgical teams is essential.

Packaging labelling and dispatch

All histology specimens need to be transported to the lab as soon as possible. Once in formalin the process of fixation preserves the tissue. Specimens should be stored at room temperature.

The mislabelling and poor packaging of specimens is a major risk to patient safety.

All specimens should be transported in the relevant fixative or transport medium in approved containers.

All specimen pots should be tightly sealed and transported using specimen bags where possible. The request card should be placed in the pocket of the specimen bag, separate to the sample in case of spillage.

Sample transport

Please note that Histology/diagnostic cytology samples are not suitable for the hospital Pod system.

Samples collected at Burnley General Teaching Hospital (BGTH).

Samples collected in locations at BGTH should be sent to RBTH via the lab reception at BGTH. There is no Cellular Pathology dept at BGTH and no facility to open or examine sample containers.

Bags/boxes of samples will be signed for at BGTH between **09:00** and **17:00**, but individual cases/pots need not be checked as all samples are checked on receipt at RBTH.

Please note that samples arriving in the laboratory at BGTH after 17:00 will not be signed for.

Samples collected at Royal Blackburn teaching Hospital (RBTH)
Hospital samples can be delivered to the laboratory between 8 and 5pm

GP/community samples
These are collected from surgeries on the regular runs.

Specimen storage

If there is a delay in transporting a sample, specimens in formalin must be stored at room temperature, not refrigerated. Fresh samples

Specimen	Storage
Neutral Buffered Formalin	Room temperature
Dry or fresh fluid samples	Fridge
Transport medium (CytoLyt and PreservCyt collection fluid)	Fridge
Michel's medium	Room temperature

Specialist samples:

Skin Biopsy for Immunofluorescence
Skin biopsies for immunofluorescence (IMF) should be placed in Michel's transport medium before being transported to the laboratory at the earliest opportunity. This is available from the laboratory at RBTH. **Skin specimens for immunofluorescence should not be placed in formalin**

In the absence of Michel's transport medium, saline or wet gauze can be used to transport IMF biopsies. Please inform the laboratory if this is the case.

Ideally peri-lesional skin should be submitted for examination. Samples for **Epidermolysis bullosa** investigations need to be sent with a St. John's Institute of Dermatopathology request form. Samples are forwarded via the Cellular pathology Department to St. John's.

Please note that our IMF service is not currently covered by our UKAS accreditation.

Alopecia biopsies
Samples for the investigation of alopecia must be clearly marked as they require specialist processing and reporting. These are sent externally for reporting.

Muscle biopsies
Muscle biopsies are sent directly to Neuropathology at Royal Preston Hospital directly from theatre. For further information please contact the Neuropathology laboratory.

Ophthalmic specimens
Ophthalmic specimens are sent to Manchester University NHS Foundation Trust for reporting. For further information please contact their laboratory.

Foetal and peri-natal specimens (placenta)
Foetal and peri-natal specimens are sent directly to Diagnostic Paediatric Histopathology Service In Royal Manchester for reporting. For further information please contact their laboratory.

Synovial/joint fluid samples
Synovial/joint fluid samples are collected in lithium heparin tubes and sent to the Manchester Cytology Centre for analysis. Please contact them on telephone numbers 0161 276 5115/5116/6727 for Lithium Heparin bottles and/or request forms.
Their user guide is available on: https://mft.nhs.uk/app/uploads/2023/05/Synovial-fluid-user-manual-2023.pdf

Reporting of results

Reports are issued only after authorisation by a pathologist and will be available on ICE or GP systems. Hard copies are available for those areas that request them but these will be phased out over time.

Turnaround times are monitored by the department.

The department works to the target of reporting 90% of cases within 10 days. Compliance against this is monitored monthly. In some instances, it may be necessary to take extra blocks and/or apply specialised staining techniques to clarify or confirm the diagnosis. In such cases results will take longer.

Priority		Expected Turnaround time
2week wait	Patients on cancer pathways should be marked as 2-week wait. The ELHT Policy is a Red Cross (x). Using different symbols E.g. asterisks and dots may result in the sample not being identified as 2-week wait. Escalating cases that have not been correctly marked leads to delays in diagnosis.	90% within 10-days of collection
Urgent Specimens	Urgent cases, where the immediate clinical management of the case depends on speedy tissue diagnosis. Please telephone the Histopathologist to discuss the case. The request form should be clearly marked “URGENT” preferably in red ink.	90% within 10-days of collection
Routine	Cases with no suspicious or concerning clinical information, not on the above pathways. Failure to provide relevant clinical information will result in case being triaged as routine priority which may significantly delay reporting.	90% within 10-days of collection

Large specimens require adequate time to fix before investigations can be started in order to provide optimum accuracy.

Cellular Pathology is a manual discipline and turnaround times are directly affected by staffing levels. If samples are sent off site then the TAT will be increased. Both these will extend the expected times above.

Externally reported cases
In response to service pressures, the department will use external reporting services or colleagues within the Lancashire and South Cumbria Pathology Service to report cases.

The external reports are issued by a pathologist but need transcription and authorisation in pathology at ELHT before they are available on ICE or GP systems. This is an additional step and may add to the turnaround time.

Additional testing and review
If clinicians require additional work not performed by the department, then they must request this in writing, usually to the reporting pathologist. If the test is external or not part of the repertoire, there is likely to be a cost for this.

Photography
Photography of surgical specimens or slides can be performed in selected cases but must be requested in writing by clinicians. Capacity to photograph cases depends on the availability of Consultant Pathologists.

Uncertainty of measurement
All types of measurements have some inaccuracies and therefore measurement results can only be estimates of the quantities being measured.

Cellular Pathology specimens are collected in unique circumstances and as such there will always be some measure of uncertainty.

Our reports are mainly qualitative in nature, i.e., they may not yield a numeric result and a value for uncertainty cannot be derived in all cases. Some measurands e.g. weights and measurements in a macroscopic description do not give prognostic information and assessment of the uncertainty of measurement is inappropriate.

Differences in patient preparation, specimen collection technique, transportation and storage time, and analytical process all contribute to uncertainty

Our department regularly monitors its work with internal quality control and participation in external quality assurance schemes.

Factors affecting the performance of tests and diagnosis
- Time taken for the specimen to be placed in formalin once excised from the body
- Total immersion in formalin (ideally there should be 10x the fixative to specimen)
- Time taken for the specimen to arrive in the laboratory (Please send specimens in a timely manner)
- Quality of clinical information
- Failure to follow the specimen labelling policy
- Not correctly labelling requests as urgent or cancer pathway will result in a delay
- Failure to follow instructions for the specific specimen requirements e.g frozen sections/IMF will result in a frozen tests not being performed.
- Not contacting the laboratory in advance for a frozen section may mean it cannot be performed, due to a lack of availability of technical staff and/or Consultant staff.

Section 3: Cytology

Cytology samples are traditionally divided into two categories

- Gynaecological samples (e.g. cervical smears) and
- all other samples (diagnostic cytology).

Services Available at ELHT

ELHT only process and report on diagnostic non-gynaecological cytology samples. Samples for cervical cytology are collected from GP surgeries and processed at the Manchester Cytology Centre. The contact details for the lab are:

Manchester Cytology Centre
First Floor, Clinical Sciences Centre
Manchester Royal Infirmary
Oxford Road, Manchester
M13 9WL

Urgent & general enquiries Tel: 0161 276 5111
Cyto.pathology@mft.nhs.uk

Please also see their webpage:
https://mft.nhs.uk/app/uploads/2024/03/CERVICAL-SAMPLE-TAKER-INFORMATION-PACK-Jan-24-1.pdf
ELHT has no access to results for cervical cytology.

Diagnostic cytology

High Risk Samples

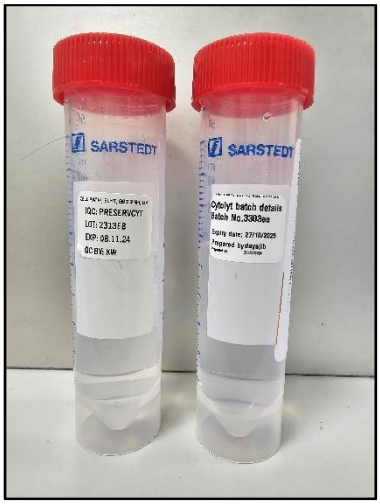
Direct spreads are **NOT** to be sent for high risk specimens

Specimen Containers

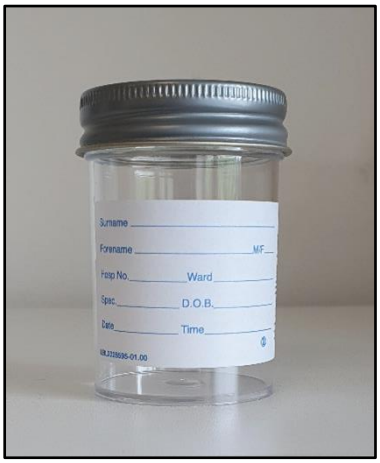
All diagnostic cytology samples should be collected either fresh, into CytoLyt or PreservCyt (transport media) in a red-top universal container. The containers of CytoLyt and PreservCyt can be requested from the laboratory. **The only exceptions are the EBUS samples which are collected into formalin pots.**

Please send specimens in the appropriate container (as shown below), ensuring that the lid is screwed on tightly and that the container is labelled with both patient and specimen details. If possible please avoid covering the volume scale on the side of the container in order to help us quantify the sample.

__DO NOT__ SEND SAMPLES IN BORIC ACID CONTAINER. THIS IS NOT AN APPROPRIATE COLLECTION MEDIUM



Red top PreservCyt and CytoLyt solutions.



Sterile container

Sterile container

Collection of Serous Fluids

Body Cavity Fluids (Includes: pleural/ascitic/peritoneal fluid/peritoneal washing/pericardial)

- Around 50mls of fluid should be collected into a sterile, dry container with a screw cap for transport to the laboratory (**Note**: no other transport medium or fixative is to be added to the sample as this can cause interference with adherence to the slide and quality of staining).

- The fluid should be delivered to the laboratory as soon as possible to minimise cell deterioration, so that cell preservation is not compromised.

  If there is a delay in delivering the sample, please refrigerate around 4 C.

Collection of Cyst Fluids

- Cyst fluids should be collected into a red-top universal tube filled with 30ml of CytoLyt to prevent deterioration of the sample.

- The sample should be delivered to the laboratory as soon as possible to minimise cell deterioration, especially if not collected in CytoLyt.

  If there is a delay in the delivering the sample, please refrigerate at around 4 C.

Collection of Urinary Tract Samples

Includes: voided / catheter / urethral washings / Ureteric and renal pelvis/ileal conduit samples

- Collect urine in a 50ml red-top universal tube containing 30ml CytoLyt to prevent deterioration of the sample (see above section on specimen containers). Fill the pot where possible to ensure specimen adequacy.

- **BORIC ACID IS NOT SUITABLE FOR URINE SAMPLES FOR CYTOLOGICAL ANALYSIS.**

- If the patient is collecting the specimen outside of a clinic surgery then please provide them with a clean, dry container with a screw top. **Tubes containing CytoLyt are NOT to be sent home with patients. The urine they collect should be transferred into CytoLyt before transporting to the Laboratory.**

- **Note:** the first sample voided in the morning is **unsuitable** for cytological analysis. An adequate sample is voided either mid-morning or randomly.

- State the method of collection (voided, catheter etc) on the request form.

- The sample should be delivered to the laboratory as soon as possible to minimise cell deterioration, especially if not collected into CytoLyt.
  If there is a delay in delivering the sample, please refrigerate at around 4 C.

Collection of Respiratory Tract Samples

Bronchial Washings/Lavage/Trap/ Bronchoalveolar Lavage

- The specimen should be collected in a red-top universal tube containing 30ml of CytoLyt to prevent deterioration of the sample.

- **Please note: we do not currently provide a service for differential white blood cell counts on bronchoalveolar lavage samples.**

- The sample should be delivered to the laboratory as soon as possible to minimise cell deterioration, especially if not collected into CytoLyt.

  If there is a delay in delivering the sample, please refrigerate at around 4 C

Bronchial Brush Samples

- Place brush into a red-top universal tube filled with 30ml of CytoLyt **as soon as possible** to prevent deterioration of the sample. **Do not** wait until the end of the procedure, as this causes the brush to dry and makes interpretation difficult.

- Ensure the brush is fully immersed in the CytoLyt

- The sample should be delivered to the laboratory as soon as possible to minimise cell deterioration.

  If there is a delay in delivering the sample, please refrigerate at around 4 C

Endobronchial Ultrasound FNA (EBUS FNA)

- EBUS FNA samples should be collected in a yellow-top formalin pot.

Collection of Pancreaticobiliary Samples

Endoscopic Ultrasound FNA (EUS FNA)

- EUS FNA samples should be collected into a red top PreservCyt container
- Cyst fluids requiring cytology should be collected into a red top PreservCyt container.
- Cyst fluids requiring Biochemistry analysis of glucose/amylase/CEA must be collected as below:

Test required	Container type	Volume required	Timeline
CEA and amylase	Plain universal container	1 ml	ASAP
Glucose	Yellow top fluoride tube	0.5 ml	Must be delivered immediately as the test is to be performed within 6 hrs of collection.

Biliary Brush Samples

- Place brush into a red-top universal tube filled with 30ml of PreservCyt **as soon as possible** to prevent deterioration of the sample. **Do not** wait until the end of the procedure, as this causes the brush to dry and makes interpretation difficult.

- Ensure the brush is fully immersed in the PreservCyt.

- The sample should be delivered to the laboratory as soon as possible to minimise cell deterioration.

Collection of FNA Samples

Includes: Breast lesions/Axillary lymph nodes/Thyroid/Head and neck lesions, salivary glands and lymph nodes/Any other lesions. See above for EBUS and EUS FNA SAMPLES

- Please take precautions to avoid contaminating the sample with substances such as Ultrasound Jelly, which makes the cells difficult to visualise. Please wipe away ultrasound jelly from site of FNA before inserting the needle.

- The aspiration is to be expelled in a red-top universal container containing 30ml CytoLyt as detailed above. A small amount of saline can be used to rinse the needle into the container.

- Please note that if two samples from different sites on the same patient, please try to distinguish clearly which specimen is from which site. For example, Pot 1: Right Breast FNA, Pot 2: Right Axillary FNA.

- For each FNA site, a minimum of 2 passes is recommended. Both passes must be put into the same container.

- For separate FNA sites, e.g left and right or upper and lower, then each FNA site sampled must be placed in a different container. Containers must be appropriately labelled as to site and side.

- **If there is a delay in delivering the sample, please refrigerate at around 4 C**

Collection of Head and Neck Rapid Clinic FNA Samples

- For samples from the Head and Neck (excluding high risk samples) we request that a direct spread of the sample onto a slide is provided. Instructions for how to do this are found below.

- A slide must be created from the first pass of the FNA only. The needle should then be rinsed in the CytoLyt.

- All subsequent passes are to be expelled entirely into CytoLyt, as described above.

- Please deliver specimens from the head and neck clinic, including those from Radiology, directly to the Histology lab as soon as possible. This is a rapid turnaround service.

- Please make clear on the request form that the sample is from the rapid head and neck clinic to ensure that it is processed and provisionally reported immediately.

Making Direct Spreads

A small drop of the aspirate is to be expelled onto a glass slide. Using a second (spreader) slide, spread the drop gently but swiftly to create a tongue-shaped preparation. Demonstrations of this technique can be arranged by contacting the department.

All slides must be **clearly labelled** with the patient details, and transported to the laboratory in a slide mailer box.

PLEASE NOTE THAT DIRECT SPREADS SHOULD **NOT** BE DONE FOR HIGH RISK SPECIMENS.

Collection of Cerebrospinal Fluid (CSF) Samples

- CSF should be collected into a 50ml red-top universal tube filled with 30ml CytoLyt to prevent deterioration of the sample. Samples collected in a sterile container will be accepted but any delay in transport will contribute to deterioration and compromise cytological interpretation.

Serous fluids must be collected in a sterile container

FNA samples, bronchial samples, cyst fluids, CSF samples must be collected in CytoLyt

EUS FNA samples must be collected in PreservCyt

EBUS FNA samples must be collected in formalin

Summary of sample containers and volume requirements

Sample type	Container/Fixative	Total volume
Urine	CytoLyt	At least 40 mls
Bronchial brushes	CytoLyt	Enough to completely cover brush
Bronchial washes	CytoLyt	As much as possible
Serous effusion	Sterile/fresh	At least 50 mls
Fine needle aspirations (including breast)	CytoLyt	At least 2 passes per site – each site in a different container
EBUS FNA samples	Formalin pot	Entire needle rinses
EUS FNA samples	PreservCyt	Entire needle rinses
Pancreatic cyst fluid for CEA and amylase	Plain universal container	1 ml
Pancreatic cyst fluid for glucose	Yellow top fluoride tube	0.5 ml – must be delivered immediately
Biliary brushes	PreservCyt	Enough to completely cover brush
All miscellaneous fluids	Sterile/fresh	As much as possible

CSF and cyst fluids	CytoLyt	As much as possible

Ordering specimen pots and request forms

Users that have consumables supplied by pathology can order the following from our stores:

Specimen pots (formalin-filled and dry)
Cytology collection media
Michel's transport media (IMF samples)
Request forms

Please e-mail: gppathologysupplies.rbh@elht.nhs.uk