

Title: Cellular Pathology Handbook of Services

Author: Mark Orrell Authoriser: Saima Rasib Q-Pulse ID: CP-QMS-POL-37 Version: 16

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Cellular Pathology User Guide to Services

1 Introduction

Severn Pathology, North Bristol NHS Trust (NBT) provides a Cellular Pathology service from a laboratory based in Phase two, Pathology Sciences, Southmead Hospital. There is an essential services laboratory (ESL) located in the Bristol Royal Infirmary on the University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) campus.

The Department provides a wide-ranging and comprehensive diagnostic Histopathology, diagnostic Cytopathology and Cervical screening service.

Services offered include consultation with clinical colleagues to assist in the interpretation of reports and provide advice about the collection, handling, fixation and submissions of specimens for investigation.

In April 2019 the department was awarded the contract for the provision of Laboratory Services to support the delivery of the HPV Primary Screening Pathway within the NHSCSP to the population of the Southwest of England. Since March 2020 NBT has processed and reported all cervical samples taken in the Southwest of England. NBT also provides a cervical screening service to Spire Healthcare, the Isle of Man and the Bailiwick of Guernsey. There is currently an annual workload of ~340,000 cervical screening samples. All service users have fully converted to the HPV Primary screening pathway and samples are processed using Hologic Aptima HPV assay, followed by the screening of high-risk HPV detected samples using Hologic Thinprep slide preparation technology. Further details on service provision, supplies and arrangements can be obtained by contacting the cytopathology section.

2 Working Hours

The Department is open to receive specimens and offer technical advice Monday – Friday, 07:00 –18:00. The ESL is open 8.30 to 16.30.

Consultant Pathologists are available for advice and opinion Monday to Friday 09:00 – 17:00. Outside of these hours, a renal on-call service is offered on Bank Holiday. Contact with the appropriate Consultant can be made via switch board. **Please note there is no general Consultant on-call.**

3 Specimen Identification

With the exception of intraoperative frozen section requests, requests for Histology or Diagnostic Cytology can be made on ICE, this is the preferred and safest method of



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requesting pathology.

Where users are unable to access ICE, it is essential that a completed request form accompany the specimen. Specimen containers (not the lid) must be appropriately labelled in accordance with NBT Clinical Governance Policy CG-163: **Pathology Specimen Labelling Policy**.

Specimens MUST bear,

- Patient number (e.g. NHS number, hospital number, ICE number)
- Date of birth
- Family name and first name
- Description of samples

Failure to provide this information may delay or prevent the processing of a specimen

In addition to the above, Histology and Diagnostic Cytology <u>Request forms</u> should bear the following information,

- Patient address with postcode
- Requestor and Consultant name and location
- Date and time specimen was taken
- Biopsy site. This is particularly important if multiple samples are to be sent.
- Relevant clinical details including LMP as appropriate, details of any previous biopsies
- Patient category (NHS / Private / Other)

Request forms for cervical screening should be the printed pre-populated Cervical Screening Management System (CSMS) A4 portrait editable HMR5 form.

Cervical screening forms also need a registered sample taker code. Registration is available at: NHS England — South West » Screening

National guidance on sample acceptance criteria can be found at <u>Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities - GOV.UK</u>

Failure to provide the information may result in delays in producing a report.

4 Health and Safety

4.1 Specimens

- (a) Any patient with or suspected to have any of the following are considered to be an Inoculation Risk.
 - > HIV
 - Hepatitis B
 - Hepatitis C
 - Creutzfeld Jakob



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Tuberculosis

- (b) For the safety of staff, please ensure that investigations are kept to a minimum.
- (c) Forms must be clearly labelled with a "Biohazard Risk" or "Inoculation Risk" sticker with the nature of the risk given on the request form.
- (d) If a patient having an Inoculation Risk is admitted to a trust hospital, the Consultant Microbiologist should be advised as soon as possible.
- (e) Specimen transport from the Brunel building to Cellular Pathology is via the porters.
- (f) In Southmead Hospital, to control and minimise exposure to histology fixative reagents the TissueSafe system is available for use for Theatre samples from the Brunel building.
- (g) Safe transport of specimens from the Brunel Building to Cellular Pathology:-

Cellular Pathology specimens must <u>NOT</u> be placed in the 'POD' transport system

4.2 Formalin

Formalin is a hazardous substance and should only be handled wearing appropriate PPE (gloves, eye protection, apron/ scrubs).

Pots should be stored at room temperature in a safe and upright position to minimise the risk of spillage/ leakage.

Should a spillage occur:

- For small volumes (up to approx. 100ml) ventilate the area where possible and use absorbent material (i.e. paper towel) to clear up spillage.
- For larger volumes (>100ml) Use a spill kit where available following the provided instructions. If no spill kit is available restrict access to the area and call the laboratory immediately for advice (0117 4149800).

4.3 LBC Pots

Contents are flammable so should be stored at room temperature (15-30°C) and away from potential ignition sources.

Spillages can be dealt with using absorbent material i.e. paper towel.

5 Transport

(a) In Southmead hospital, specimen transport to Cellular Pathology is via the porters.



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Please check with your location for details on how this is arranged or by contacting Facilities and Estates.

- (b) Samples from UHBW sites are delivered by porter to Pathology reception on level 8 of the BRI. These samples are then transported to Southmead via regular City Sprint transports.
- (c) Samples from Weston-Super-Mare are delivered to Pathology at WGH and are transported to Southmead via City Sprint transports.
- (d) DDL is under contract to Pathology Sciences NBT provides a routine service to local hospitals and GP surgeries. City Sprint is under contract with UKHSA to provide the transport between UHBW and NBT.
- (e) Cervical Cytology from outside of the NBT transport catchment will be collected by transports operated by UHBW, Gloucester Hospitals NHS Trust or by DDL.
- (f) Transport of urgent frozen section samples from UHBW to Southmead hospital is via ambulance from the BRI. Details can be found on the UHBW intranet site or from theatre managers. Contact the department for further details.
- (g) Specimens labelled with a "Biohazard Risk" or "Inoculation Risk" sticker must be contained within a sealed bag and that samples from different patients must not be placed into the same bag. Specimens from known or suspected COVID-19 patients must be double bagged as per NBT specimen Transport Policy CG-163.
- (h) For emergency transport, contact the Trust Transport Department on 0117 414 5423.

6 Delivery instructions

Histopathology specimens should be delivered directly to Histology sample reception on Level 1 of Phase 2 Pathology Sciences. Outside of opening hours samples should be left in the blue box outside of the reception hatch. Samples should NOT be left at blood sciences reception.

Diagnostic Cytopathology specimens should be delivered directly to cytology sample reception on Level 1 of Phase 2 Pathology Sciences. Outside of opening hours samples should be left in the blue box outside of the reception hatch. Samples should NOT be left at blood sciences reception.

Packages

Specimens must be securely packaged using **UN3373-compliant materials**, which include a leak-proof primary container, a sealed secondary container with absorbent material, and a rigid outer box. Each specimen must be clearly labelled with patient identifiers, specimen type, and relevant clinical details, and accompanied by a completed request form. The outer packaging should display the "**Biological Substance**, **Category B**" label and **UN3373 diamond marking**, and be clearly marked for either Histology or Cytology, including the full address:

Department of Cellular Pathology - Histology/ Cytology



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North Bristol NHS Trust, Pathology Sciences Building, Phase II, Southmead Hospital, Southmead Road, Westbury-On-Trym, Bristol BS10 5NB

Multiple specimens should be individually packaged and identified. Parcels sent via courier or internal transport must be securely sealed and labelled "Pathology - Urgent" if applicable.

7 Supplies

Supplies for use in collection and dispatch of Histology and Diagnostic cytology samples can be ordered through Pathology Sciences.

Southmead E-mail:PathologyConsumablesSouthmead@nbt.nhs.uk

Requests can be made using a pro forma list and supplies are dispatched by the Trust Transport system within 3 days.

Supplies of larger (1L+) pots both with and without formalin are available directly from the Histology laboratory at Southmead hospital or from the ESL laboratory for UHB sites. Please contact the department if you require further information. All formalin supplies should be stored at room temperature in a safe upright position where the possibility of spillage is minimised.

LBC supplies are available from an external company 'CellPath' please contact info@cellpath.co.uk or call 01686 611333.

- ➤ If you have stock that has expired, please contact the appropriate laboratory for disposal advice.
- ALWAYS CHECK YOUR SUPPLIES ARE IN DATE BEFORE USE. Expired reagents may affect results.

8 Key Contacts and Consultant staff

For guidance and advice about any aspects of the work of the department, please use the following contact details.

SMD: Pathology Sciences

Histopathology - Enquiries & Results	0117 41-49890	
Cervical Cytology Queries	0117 41-49823/41- 49889	
Diagnostic Cytology Laboratory Queries	0117 41-49821	

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Diagnostic Cytology Report Queries	0117 41-49890
Head of Department, Dr Tim Bates	0117 34-27622
Secretary: -	0117 41-49890
Laboratory Manager, Saima Rasib	0117 41-49849

BRI: Essential Services Laboratory

Name	Telephone number
Laboratory Enquiries	0117 34-27556
Report Enquiries	0117 41-49890

9 GP Access

- (a) GP enquiries are welcomed and can be made by telephoning during normal working hours (09.00 17.00 hrs).
- (b) Reports are dispatched by hospital postal service (the majority GP practices have direct access to results via computer).

10 Turn around Times

	Expected turnaround times	
Cervical Screening Cytology	98% within 14 days	
Diagnostic Cytology	Preliminary report within 5 days	
Urgent Histology biopsies (clinical urgency agreed by Pathologist)	Preliminary report within 5 days	These turnaround times depend upon the exact nature of the specimen and the requirement for
Routine Histology biopsies	80% Within 7 days	additional processing, testing or opinion. Times may also be extended due to availability of staff
Routine Histology resections	Within 14 days	extended due to availability of stair
Frozen Sections	Within 30 minutes of arriving in the laboratory	Samples sent via Bristol Ambulances from UHBW to NBT might take longer depending on the journey time



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11 Histopathology specimens

- (a) Routine specimens where fresh tissue is not required
 - Should be placed in at least 10 times their volume of fixative (neutral buffered formalin) in an appropriate container. Specimen containers and fixative will be supplied on request. All samples are to be accompanied by a fully completed Request Form or ICE request.
 - Delayed fixation, inadequate fixation (through insufficient volume of fixative), and sample handling (i.e. crush artefact, diathermy etc.) may have a detrimental effect on the initial diagnosis and may invalidate subsequent tests such as immunohistochemistry.
 - Formalin is a hazardous substance and care should be taken when handling (see H&S above). The lids of all specimen containers must be securely applied to prevent leakage.
 - All samples should be transported within specimen transport boxes (i.e. Daniel's boxes or equivalent) wherever possible. Those that are too large to fit into a transport box must be double bagged.
 - Small specimen pots should be placed into the sealed plastic specimen bags with the request form (if applicable) placed in the front envelope of the bag. This is to ensure the request forms are kept clean and avoid being ruined by potential formalin leaks.
 - Large, operative specimens collected during working hours should be sent in a sealed box, or specimen bucket, unfixed to the laboratory with a porter to be received by 17:00. After 17:00, unless prior specific arrangements have been made, place specimen into fixative and transport to the laboratory as usual.
 - Specimens packaged using the TissueSafe system must be refrigerated overnight If it cannot be delivered to the laboratory by 17:00 and delivered as soon as possible the following day.
 - All Inoculation Risk specimens must be fixed in formalin and labelled appropriately.
 - Urgent specimens may be able to be processed (if of a suitable size) within the day it is taken. Specimens must be in the department before 12.30 pm. Please contact the department to discuss.
 - For samples where rapid diagnosis is required for clinical reasons, these should be placed into formalin and promptly sent to the laboratory, marked URGENT, and accompanied by a request form bearing appropriate details. An email clarifying the reasons for the urgent request to the Pathologist associated with the organ system is advised (e.g. the Pathologists who attend the MDT).
- (b) If immunofluorescence studies are required, Michel's transport medium can be



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supplied. Please telephone the department to discuss.

(c) All histology is reported or personally supervised by consultants.

12 Frozen Sections

Frozen sections should only be requested for intra operative diagnosis. Samples for frozen section diagnosis at Southmead Hospital or ESL will be accepted at any time during working hours, 9.00 am to 4.00 pm. Service outside these hours is by prior arrangement only. 24 hours' notice is required to ensure appropriate staff members are available. Failure to provide 24 hours' notice may lead to the specimen being processed as a normal Histological specimen. Please telephone the department with details ext. 49890. For requests originating from areas within UHBristol, please phone the ESL on ext. 27556.

13 Diagnostic Cytopathology specimens

(a) All samples, specimen pots or slides must be clearly labelled and include the patient's name, hospital number, date of birth, collector ID and date and time of collection, including any treatment that the patient is receiving. These must be accompanied by a request form or ICE request which should include relevant medical details, including the sample site. Requests for breast aspiration cytology should state if the patient is pregnant or on contraceptives.

Please contact your trust IT department regarding requesting via ICE.

- (b) All specimens that may be an inoculation risk should be labelled as such (Please see "(3) Health and Safety" above).
- (c) The department aims to be able to issue at least a preliminary report on all cases within 5 days. This does however depend upon the exact nature of the specimen and the requirement for additional processing, testing or opinion. If a rapid result is required specimens should be promptly sent to the laboratory, marked URGENT, and accompanied by a request form bearing appropriate details.
- (d) One-stop clinics in support of the Head & Neck service are held weekly at the Bristol Dental Hospital and are attended by a Consultant Pathologist and BMS in order to facilitate rapid diagnosis.
- (e) Please note that Cerebrospinal fluids (CSF) samples are handled by Neuropathology (see details below).
- (f) Samples are kept for 48 hours after the report is released. If additional tests are required contact by telephone the cytology department to discuss.
- (f) Specimen Collection: the Department requires suitably submitted samples in order to



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produce a diagnostic report. Any reservations about the sample quality (volume etc) will be included in the report.

(g) If the user wants to send samples for different pathology modalities (e.g. Diagnostic Cytology and Microbiology) then the sample should be split when taken and placed into the appropriate container, and submitted with separate ICE requests. Failure to follow this advice runs the risk that the required testing will not be possible.

i) Diagnostic Cytology

Specimen type	Requirements	Quality Measures
Breast Fine Needle Aspiration (FNA)	Breast FNAs should be spread thinly onto a clean labelled slide (see FNA above) and airdried rapidly. Any needle washings should be placed in a sterile universal containing 5ml Cytolyt (available from Cytology x49889)	If the sample is too thick, it may not be possible to obtain a diagnosis. Delay in air drying or fixation affects cellular preservation and can affect diagnosis.

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Specimen type	Requirements	Quality Measures
Breast Fine Needle Aspiration (FNA)	Breast FNAs should be spread thinly onto a clean labelled slide (see FNA above) and air-dried rapidly. Any needle washings should be placed in a sterile universal containing 5ml Cytolyt (available from Cytology x49889)	If the sample is too thick, it may not be possible to obtain a diagnosis. Delay in air drying or fixation affects cellular preservation and can affect diagnosis.
Bronchoalveo lar Lavage (BAL) / Bronchial Washings	Collect into dry, sterile universals. UHB Paediatric BALs: Place sample in a clear plastic specimen bag labelled 'urgent'. Send sample via porter to the Cellular Pathology laboratory (ESL) on level 8 of the BRI. For samples taken on a Friday please ring the Cytology laboratory on 0117 414 9889 to alert us to the arrival.	As samples are sent unfixed, it is imperative that specimens are sent to the laboratory as soon as possible after collection. Samples not sent immediately are at risk of cellular degeneration of bacterial overgrowth, which could lead to an inadequate result. If taken out of hours, please store the samples in a fridge (~4°C) overnight and send on the next working day.
Brushings (bronchial, oesophageal, biliary, gastric)	A minimum of two slides are required. Using pencil, label clean, frosted end microscope slides* with: (a) Patient's surname (b) Patient's forename and (c) Patient's DOB or hospital number. Transfer material from brush onto slides immediately after collection, using a gentle but firm rolling technique. One slide is rapidly air-dried and the other spray fixed. Slides should be allowed to dry, labelled with identification 'fix' or 'dry' and placed in a plastic slide container. We also receive brush tips in 20ml Cytolyt.	Delay in air drying or fixation affects cellular preservation and can affect diagnosis. Fixed slides must immediately be fixed with Cytospray* cytology fixative to prevent airdrying.

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Specimen type	Requirements	Quality Measures
Cyst Fluids	Collect into dry, sterile universals.	As samples are sent unfixed, it is imperative that specimens are sent to the laboratory as soon as possible after collection. Samples not sent immediately are at risk of cellular degeneration of bacterial overgrowth, which could lead to an inadequate result. If taken out of hours, please store the samples in a fridge (~4°C) overnight and send on the next working day.
Fine Needle Aspiration (FNA) & Needle Washings	Using pencil, label up to five clean, frosted end microscope slides* with: (a) Patient's surname (b) Patient's forename and (c) Patient's DOB or hospital number. Place 1 drop of specimen near bottom of each slide and spread gently using another clean slide. Rapidly air-dry the slides, prior to placing in a plastic slide container. NB; If squamous cell carcinoma is suspected, at least one slide should be spray fixed and labelled as such. Flush needle into a bottle containing 5ml Cytolyt and send the needle washings together with the FNA slides (do not send the needle).	If the sample is too thick, it may not be possible to obtain a diagnosis. Delay in air drying or fixation affects cellular preservation and can affect diagnosis. Fixed slides must immediately be fixed with Cytospray* cytology fixative to prevent air-drying.



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Specimen type	Requirements	Quality Measures
Serous Fluids (pleural, ascitic, pericardial, peritoneal lavage/washings)	Collect into dry, sterile universals. Ideal volume is 20ml. Place inside a sealed specimen bag and deliver to the laboratory immediately. Store in fridge if kept overnight.	As samples are sent unfixed, it is imperative that specimens are sent to the laboratory as soon as possible after collection. Samples not sent immediately are at risk of cellular degeneration of bacterial overgrowth, which could lead to an inadequate result. If taken out of hours, please store the samples in a fridge (~4°C) overnight and send on the next working day.
Sputum	Collect into dry, sterile sputum pots. The specimen should be collected before any food is eaten and before teeth are cleaned and should be a deep cough, early morning specimen taken with the assistance of a physiotherapist if needed. Saliva is not adequate.	As samples are sent unfixed, it is imperative that specimens are sent to the laboratory as soon as possible after collection. Samples not sent immediately are at risk of cellular degeneration of bacterial overgrowth, which could lead to an inadequate result. If taken out of hours, please store the samples in a fridge (~4°C) overnight and send on the next working day.
Synovial Fluid	Collect into dry, sterile universals. Samples must be sent to Cytology department as soon as possible.	Incorrect storage can lead to the formation of contaminating crystals.
Urine / Urinary Tract Washings	Place in bottles containing alcohol.* Urine sample should ideally be an aliquot of the whole output, although a midstream sample is acceptable. An early morning sample is not appropriate. Please indicate on the request form if specimen is a catheter or cystoscopy sample.	No alcohol can lead to the degeneration of the cellular content and to bacterial overgrowth and can affect diagnosis.
Vitreous Humour fluid	Collect into dry, sterile universals or syringe (do not send the needle). Samples must be sent to Cytology department as soon as possible.	If unfixed, samples should be received for processing in the lab within two hours of being taken to prevent cellular degeneration of the sample

^{*} Available by contacting Cytology, Southmead Hospital on ext. 49889



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For more in depth detail on Diagnostic Cytology specimens please see Diagnostic Cytology for Handbook of Services (CP-QMS-POL-91) which can be found on the Cytology page of the Severn Pathology website.

ii) Neuropathology

Specimen type	Requirements	
Cerebrospinal fluid (CSF)	Contact Neuropathology who provide this service in support of Neurosciences	0117 41-42400

All samples need to be sent to the laboratory **as soon as possible** and arrive at the laboratory during routine opening hours. If this is not possible store in the fridge and send in on the next working day. Any delay can lead to the cellular content degenerating.

14 Cytopathology - Cervical Screening

All samples for cervical screening must be collected into ThinPrep vials and be sent to the laboratory in the orange bags on the next available transport. Samples should only be taken by staff trained and registered to NHSCSP guidelines. The sample taker must be recorded on the request.

For advice see following links.

<u>Cervical screening: professional guidance - GOV.UK (www.gov.uk)</u> Home - South West Cytology Training Centre (cytology-training.co.uk)

All requests for screening will need to be made via the Cervical Screening Management System (CSMS) IT system by filling and printing the CSMS HMR101 form and including it with the sample. This will ensure correct patient identification, correct patient management and improve efficiency for the whole service.

- a) All samples for cervical screening must be collected into ThinPrep vials and be sent to the laboratory with a typed HMR101 request form.
- b) Cervical screening results are available within 14 days of the sample being taken.

15 Accessing reports

Reports are issued electronically as soon as a case is authorised by the reporting pathology. For the majority of users reports can be accessed via ICE/GP Links. Where electronic links are not available hard copies of reports are sent to the requesting location. This applies to Histology, Diagnostic Cytology and Cervical Cytology. For Cervical Cytology the patient will receive notification of their



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result from CSMS via the post (this is not the responsibility of the laboratory).

16 Referral Services

(a) The department is able to offer technical services to other Cellular Pathology departments. Please contact the Laboratory Manager or Operations Manager to discuss requirements.

Potential users should be aware that the department cannot validate tissue fixation and processing of externally referred tissue blocks.

Techniques used are appropriately verified and subject to appropriate QA and QC.

Please note that the department uses a small number of research use only (RUO) antibodies. These antibodies have been validated in house, to reflect clinical use. These antibodies are never used in isolation and are not the sole means of diagnosis for the cases they are requested on. We are committed to using CE-IVD approved methodologies whenever possible and update our antibody stock when these become available.

(b) On occasion, the department may need to refer work out to other testing centers. Where this is required, the department will select testing centers that are accredited to ISO15189, another recognised standard or meet strict criteria that ensure high quality standards. For details about the referral centers used, please contact the lab.

17 Complaints

In the event that users have to cause to raise a complaint about the service provided, please contact the Clinical Head of Department or Laboratory Manager in first instance, contact details in section 6 of this document. Alternatively, a complaint can be raised using the Trust's procedure available here.

18 Protection of personal information

The Department of Cellular Pathology operates within the Information Governance policies and procedures laid down by North Bristol NHS Trust. Further details are available here.

19 Consent

Several hundred Histopathology and Cytology requests are received in the department each day. For some rare or complex tests patient, specimens may be sent to specialist laboratories elsewhere which have the necessary expertise or an expanded repertoire of tests. In some cases, there will be only one specialist laboratory in the whole country which



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performs a particular test, meaning using referral laboratories is essential.

The department has a policy and procedure in place to govern how we choose these referral laboratories. They are selected for their expertise and their quality standards and regular checks are made on their accreditation status, which gives us assurance that they have procedures in place for the protection of information.

When specimens are sent to a referral laboratory, we need to send some 'patient identifiers' such as name and date of birth. In some tests it is essential to send further clinical information to allow the referral laboratory to interpret the results for the individual patient.

Consent to a specimen being taken and analysed is implied by the patient presenting to the point of specimen collection. The responsibility for obtaining informed consent for the test(s) resides with the individual ordering the test. Informed consent should cover all the tests being done, implications of their results and disclosure of clinical and personal details to personnel (in the requesting organisation and any other healthcare organisations involved in providing the test).

20 External Quality Assurance

The department participates in a wide range of External Quality Assurance and interlaboratory comparison schemes concomitant with the scope of its service. A list of schemes can be provided upon request.