


<b>Unique Identifier</b>	MI-Hist-CPP-Histology User Guide	<b>Version No.</b>	14	
<b>Approval</b>	N Katsafados Neil Wrathall	<b>Date of Issue</b>	As per QPulse Document record	
<b>Author</b>	Catherine Billington	<b>Frequency</b>	As per QPulse Document record	

# HISTOPATHOLOGY USER GUIDE 2025

## CONTENTS

• <b>Overview</b>
• <b>Contact details of key members of staff</b>
• <b>The location of the laboratory</b>
• <b>Opening Times of the Histopathology Laboratory</b>
• <b>Services offered by the Histopathology Laboratory</b>
• <b>Disposal of unwanted Formalin</b>
• <b>Consent</b>
• <b>Instructions for requesting Tests</b>
• <b>Instructions for Transportation of samples</b>
• <b>Reporting of results</b>
• <b>Clinical advice and interpretation</b>
• <b>Opinion Service</b>
• <b>Comments / Complaints procedure</b>
• <b>Data Protection</b>
• <b>Quality Assurance and Accreditation</b>
• <b>Names and addresses of referral Laboratories</b>
• <b>References</b>

## OVERVIEW


Histopathology services are provided by the Christie Pathology Partnership.

**The information in this user guide relates to Histopathology Services.**

Expert clinical and scientific advice is available on the investigation of patient pathological specimens, the diagnostic report and on any further investigations which may be required.

Authorised results will be available to view on CWP. All request forms should be filled in correctly with all relevant clinical details.

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Contact details shown below (during normal working hours):

### CONTACT DETAILS OF KEY MEMBERS OF STAFF


The contact number for the histopathology department is 0161 446 3290.

The full contact details of all laboratory personnel can be found on the staff directory.

**NB all telephone numbers should be prefixed with 0161 when calling from outside Manchester**

Medical Staff	Name	Telephone	E-mail
Consultant Histopathologist	Dr Sudha Desai	446 3571	<a href="mailto:sudha.desai1@nhs.net">sudha.desai1@nhs.net</a>
Consultant Histopathologist	Dr Bipasha Chakrabarty	446 3907	<a href="mailto:bipasha.chakrabarty@nhs.net">bipasha.chakrabarty@nhs.net</a>
Consultant Histopathologist	Dr Lia Menasce	446 3273	<a href="mailto:lia.menasce@nhs.net">lia.menasce@nhs.net</a>
Consultant Histopathologist	Dr Patrick Shenjere	446 3274	<a href="mailto:p.shenjere@nhs.net">p.shenjere@nhs.net</a>
Consultant Histopathologist	Dr Paula Hyder	446 3292	<a href="mailto:paula.hyder@nhs.net">paula.hyder@nhs.net</a>
Consultant Histopathologist	Dr Pedro Oliveira	956 1161	<a href="mailto:pedro.oliviera1@nhs.net">pedro.oliviera1@nhs.net</a>
Consultant Histopathologist	Dr Anshuman Chaturvedi	446 7071	<a href="mailto:a.chaturvedi@nhs.net">a.chaturvedi@nhs.net</a>
Consultant Histopathologist	Dr Angelia Ong	446 8533	<a href="mailto:angelia.ong@nhs.net">angelia.ong@nhs.net</a>
Consultant Histopathologist	Dr Sangeeta Verma	446 8025	<a href="mailto:sangeeta.verma@nhs.net">sangeeta.verma@nhs.net</a>
Consultant Histopathologist	Dr Rola Salama	Ext 1687	<a href="mailto:rola.salama@nhs.net">rola.salama@nhs.net</a>
<b>Scientific staff</b>			
Histology Service Manager	Ms Catherine Billington	446 3289	<a href="mailto:catherine.billington3@nhs.net">catherine.billington3@nhs.net</a>
Biomarker Analytics (formerly BTR) Clinical Scientist	Mrs Elizabeth Elliott	446 3211	<a href="mailto:elizabeth.elliott17@nhs.net">elizabeth.elliott17@nhs.net</a>
Biomarker Analytics Office	Mrs Elizabeth Elliott	446 3221	<a href="mailto:the-christie.receptors@nhs.net">the-christie.receptors@nhs.net</a>
Histology Office	Emma Herring	446 8540	<a href="mailto:the-christie.pathology.office@nhs.net">the-christie.pathology.office@nhs.net</a>

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## THE LOCATION OF THE LABORATORY

The Histopathology laboratory is situated within the Pathology Department (Department 45) located at the Wilmslow Road end of the 1<sup>st</sup> floor corridor, above the Wilmslow Road entrance. Follow the silver signage for Pathology. Alternatively, you could download the Christie app for real time navigation on your phone. Search for 'The Christie' on the App Store or Google Play.

## OPENING TIMES OF THE HISTOPATHOLOGY LABORATORY

Please note: There is **NO** out of hour's service for Histopathology. Specimens arriving on Saturday, Sunday or bank holidays will not be processed until the next normal working day

Monday to Friday 07:00 – 17:00	Routine service - Please ensure that samples for routine requests are sent to the laboratory within these hours
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## SERVICES OFFERED BY THE HISTOPATHOLOGY LABORATORY


- Routine Histopathology
- Special Stain Histopathology
- Immunocytochemistry
- Breast and Gastric Receptor staining and analysis

Histopathology offers a diagnostic service for oncology surgical specimens taken in Theatre at The Christie with a frozen section service provided during routine hours. The department also processes peritoneal washings for Gynae specimens, so that they can be reported in conjunction with the surgical specimen. Histopathology also provides a review and opinion service for surgical samples taken at external hospitals.

MDT review of Christie patients could cause the pathologist to return to any previous histology cases and request extra tests to be carried out, which may not have been indicated either by the clinical status of the patient or that the test may not have been available at that time. As Histology blocks are stable in the longer term, this allows further testing to be carried out.

The laboratory carries out H&E staining, a variety of special stains, a limited number of in-situ hybridisation probe staining and a large repertoire of immunocytochemistry staining of the prepared surgical specimens. The current test repertoire of the Histopathology Department can be found in the Schedule of Accreditation issued by the United Kingdom Accreditation Service (UKAS) and can be accessed via the following link: [8697 Medical Single \(ukas.com\)](https://www.ukas.com/8697/Medical/Single).

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Due to the complex nature of the surgical samples and a move towards personalised medicine, the department may need to send material away for further molecular or genetic testing.

The department also provides a Breast and Gastric receptor analysis service for external laboratories, which refer their work to the department. The Breast Tumour Receptor service performs immunohistochemistry (IHC) and analysis on paraffin embedded tissues for breast and gastric receptors, including HER2, Oestrogen Receptors (ER), Progesterone Receptors (PR), Ki67, PD-L1 22C3 and Androgen Receptor (AR). The Breast Tumour Receptor Service also offers non-routine testing by special request for trials and other research

### **HER2**

- HER2 IHC cases showing >10% strong, complete membrane staining of invasive cancer cells are regarded as HER2 positive.
- Less than 10% of cells with strong complete membrane staining or greater than 10% of invasive cells are with moderate membrane staining are forwarded for assessment by FISH.
- Current HER2 testing guidelines are followed which recommend a two-tier service using IHC to detect HER2 protein expression with analysis of equivocal HER2 (2+) cases by FISH to detect gene amplification.
- HER2 FISH, using an approved dual colour assay, to determine HER2 status for the use of adjuvant trastuzumab (Herceptin) therapy, in support of NICE guidance in early breast cancer (see Cytogenetics User Guide).

### **Gastric HER2**

- If HER2 testing in advanced gastric or gastroesophageal cancer by IHC and FISH is required. **Please refer all cases of gastric tumours directly from the pathologist to avoid delay in testing.**
- Further information on arrangements for HER2 testing can be obtained from Dr Mansoor (was.mansoor@nhs.net), Medical Oncologist at The Christie

### **PD-L1 22C3**


- to identify patients for treatment with pembrolizumab (UKAS accreditation approved: [8697 Medical Single \(ukas.com\)](http://8697.Medical.Single.ukas.com))
- PD-L1 22C3 is a Companion Diagnostic for Gastric or GOJ Adenocarcinoma, where a CPS  $\geq$  10 identifies gastric or GOJ adenocarcinoma patients for treatment with KEYTRUDA® (pembrolizumab).

**Referrals for FISH only are welcome**

**Enquiries regarding testing for all cell markers by IHC or FISH are welcome.**

<b>Biomarker Analytics Test</b>	<b>Target Reporting Time (Calendar days)</b>
Immunohistochemistry	7 days
FISH	14 days

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- Turnaround times are assessed as time of receipt in the laboratory to release of report for HER2 IHC & HER2 FISH.
- Turnaround times are dependent on the time taken for the sample to reach the laboratory from the requestor

### ***Technical background to Breast and Gastric Analysis***

HER2 signals are counted in 20 to 60 non-overlapping invasive cancer cell nuclei by at least two analysts and over three or more distinct tumour fields. Additional cells are scored in borderline cases.

- A ratio of 1.80-1.99 or a ratio  $<2.0$  and average HER2 gene copy number between 4.0 and 6.0 will be reported as 'Borderline but Not Amplified' and include a clear statement that the tumour is HER2 Negative.
- A ratio of  $>2.0$  and/or mean HER2 copy number  $>6.0$  will be reported as Positive.
- Monosomy or partial monosomy of chromosome 17 leading to a dual probe ratio  $>2.0$  will be reported as 'Positive with Monosomy'

#### References:

(Rakha EA et al. J Clin Pathol 2014;0:1-7). Aneusomy i.e. deletions / gains (polysomy) are common in breast cancer and measurement of chromosome number is critically important (ref Walker et al, J Clin Pathol 2008)


IVD/CE marked. PD-L1 IHC 22C3 pharmDx can be used for qualitative immunohistochemical assessment using monoclonal mouse antibody. It is used in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) gastric or gastroesophageal junction (GOJ) adenocarcinoma. PD-L1 protein expression in gastric or GOJ adenocarcinoma is determined by the Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumour cells, lymphocytes, macrophages) divided by the total number of viable tumour cells, multiplied by 100

The Histopathology department works closely with the MCRC Biobank and samples fresh surgical tissue for inclusion in consented trials and research projects. We also provide a service to process material taken for trials directly into paraffin wax blocks. Archived paraffin wax blocks can also be retrieved for use in Trials.

### **DISPOSAL OF UNWANTED FORMALIN**

Out of date or unused formalin (from trials etc.) can be brought to the Histology lab for disposal. The formalin should be decanted into a 5l plastic container and labelled as waste Formalin. (an empty container and waste label can be acquired from Histology if necessary, and formalin can be decanted in Histology under fume extraction, NB we do not have the staff to carry out this task for other departments)

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## CONSENT

It is the responsibility of the requesting clinician to obtain consent from the patient for the collection, processing and retention of specimens.

## INSTRUCTIONS FOR REQUESTING TESTS

All specimens must be fully labelled and accompanied by a completed Histology or Breast Receptor request form. Inadequately or incorrectly labelled samples will not be processed. The Breast Receptor form must be accompanied by an authorised Histology Report.

It is necessary to comply with the guidelines below for both the Request form and the sample to avoid potentially compromising the integrity of the samples taken and reduce any potential risk to testing required to produce the final histopathology report and therefore patient safety.

### THE REQUEST FORM:

#### Essential:

1. Forms should be labelled with an addressograph label showing patients full name, hospital number, date of birth and NHS Number
2. All relevant clinical information **MUST** be included.
3. High risk status **MUST** be indicated where appropriate on the form.
4. The type of sample
5. The site from which each sample was taken.
6. The legible name of the person making the requests to enable contact from the laboratory in case of queries.
7. Requestor's contact number.
8. Details of previous treatment required to inform subsequent Histology report.


#### Desirable:

1. The consultant name / initials.
2. The location of where the sample was taken.
3. The time the sample was taken.

### THE SAMPLE:

- Samples should be placed in appropriately sized specimen containers filled with 10% Neutral Buffered Formalin. The sample **MUST NOT** be crammed into a container that is too small. This will distort the specimen and prevent adequate fixation.
- Bone Marrow Trephines should be placed into a 60ml pot containing AZF to allow for correct preservation of the sample for further testing
- Samples for frozen sections need to be placed into a sterile 60ml sized pot without fixative and transported immediately to the Histopathology laboratory for receipt and processing.

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- Fluid for peritoneal washings should also be brought to Pathology as soon as possible. If this is not possible then the fluid must be refrigerated until it can be transported to the laboratory

Essential:

1. Each sample must be labelled with an addressograph label giving full name, date of birth and hospital number.
2. The type of sample.
3. Where there are multiple samples relating to one request form, each must be clearly labelled on the sample container with:
  - a. The type of sample
  - b. Location of site
4. Each sample must also be recorded and written on the request form **EXACTLY** as it is written on each container for unequivocal traceability.
5. The legible name of the person making the requests to enable contact from the laboratory in case of queries.

Desirable:

1. The location of where the sample was taken.
2. Date and time the sample was taken.

**URGENT SAMPLES**

- Requests to process samples urgently should be **CLEARLY WRITTEN** on the Histology form.
- **31/62** target stickers should be affixed to the form, if appropriate.

**NON-COMPLIANCE:**

**1. Incorrectly labelled samples**


- a. Will either be returned to surgical theatre along with the request form so that the correction can be made, or the requestor will be asked to attend the laboratory to make the correction. It is the responsibility of the person making the correction to ensure the details are correct.

**2. Unlabelled samples**

- a. The specimen **will not** be processed until it has been labelled. A note will be made on the final report that the specimen was received unlabelled, and that the laboratory cannot take responsibility for actions taken as a consequence of the report issued.
- b. The Laboratory staff will attempt to contact the requestor to allow correction / completion of the labelling. Where there is conflicting information the person taking the specimen will be asked to re-label it. If the name is correct but other details are incorrect the specimen can be sent back for correction.

Details of any acceptance issues are recorded in the laboratory for patient safety and audit purposes

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### Verbal Requests:

Verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time are not received in Histology, a written Histology card or letter/review request is always received.

## INSTRUCTION FOR TRANSPORTATION OF SAMPLES

**Histopathology samples should NEVER be sent via the pneumatic tube system; they should be delivered to Pathology Reception by hand.**

Various personnel within the Trust will be involved in transport of specimens to and from the laboratory. In order to protect their own and others safety the following guidelines should be followed.


- Cover any cuts and grazes with a waterproof dressing.
- Touch specimen containers as little as possible, washing hands as soon as practicable afterwards.
- Diagnostic samples must be sealed in the plastic bag and request form put into the open pocket of the bag. This is particularly important for fresh specimens, and peritoneal fluids, which need to reach the laboratory as soon as possible.
- Carry all specimens in the trays or boxes, where provided, never in pockets.
- If a specimen leaks into a tray or box, tell the laboratory reception staff and they will refer the specimen to a member of Histology staff.
- If a specimen is dropped or broken, do not touch it or try to clear up the mess. Stay with the specimen to prevent other people touching it and send someone to the laboratory for assistance. If you spill the fixative onto your clothing, you must remove it at once and then wash your hands and put on clean clothing.
- Report the accident to a supervisor as soon as possible.
- Keep specimen containers upright at all times.

**Histology specimens should never be transported in the POD system, as they are irreplaceable.**

## REPORTING OF RESULTS

Histology specimens must be fixed and processed before the resulting slides can be reported by the Consultant Pathologist. This process can take several days, the expected TRT for Histology results would ideally be 10 working days or less. **However, due to the complexity of the patient samples received here at the Christie, this may take longer as a result of sending samples for complex molecular testing in referral laboratories.**

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### Turnaround Times.

Turnaround times for the internal surgical and external referred cases in 2024 are as follows:

<b>TURNAROUND TIMES 2023</b>	Average	Target
Performance Internal Cases 1- 10 Days	49%	90%
Performance Outside Cases 1-10 Days	71%	90%

Breast/Gastric Receptors are reported within 7 days for IHC and 14 for FISH. (For further info on FISH see Cytogenetics user guide).

**Please note** that the primary method for transmission of reports is to the Clinical Web Portal (CWP).

### Uncertainty of Measurement

All test results are subject to a degree of uncertainty of measurement. This may be due to a range of factors, including:

- Biological variation within individuals
- Analytical measurement imprecision
- Pre-analytical factors

If you require more information regarding the effects of these factors on the outcome of an individual test result, please contact the lab on 0161 446 3290.

### **CLINICAL ADVICE AND INTERPRETATION**


Clinical advice on examinations and interpretation of results is available by contacting a Consultant Histopathologist or Specialist Registrar via telephone.

For Biomarker Analytics interpretation queries please contact Elizabeth Elliott or a member of the Biomarker Analytics team on 0161 446 3211

### **OPINION SERVICE**

The Histology Dept. also provides an opinion service, which can be accessed by sending relevant blocks/slides with a covering letter providing all relevant clinical information to the Pathology Office. Blocks and slides should be packaged appropriately according to current postal regulations, and will be returned as soon as possible after reporting.

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## COMMENTS / COMPLAINTS PROCEDURE

Any complaints or concerns about any aspect of the service should be raised initially with the Histology Service manager, Ms Catherine Billington, tel: 0161 446 3289

We are keen to know about any problems arising from the laboratory service. Feedback from our users will help in our constant efforts to improve our service; a user satisfaction survey is available.

## DATA PROTECTION

The Christie Pathology Partnership (CPP) is committed to deliver a first class confidential service ensuring that all patient information is processed fairly, lawfully and transparently. Confidential information about patients can only be used for healthcare and relevant business purposes. All staff are required to comply fully with The Trust [Governance Operating Framework](#) for handling of patient confidential information.

In addition to this all HCPC registered staff follow the HCPC confidentiality guidance for registrants


The CPP also follows the Synlab group [Privacy Policy](#)

## QUALITY ASSURANCE AND ACCREDITATION

### QUALITY STATEMENT:

The laboratory examinations, procedures and reports of test results are compliant with the requirements for quality and competence in medical laboratories according to United Kingdom Accreditation Service against the International Standard ISO15189:2022. UKAS **Registration Number: 8697**. A list of accredited tests can be accessed on the UKAS website. The department participates in all appropriate National External Quality Assurance Schemes (NEQAS) where available. Documentation relating to Internal Quality Control and performance in NEQAS are available for scrutiny by users of the service. Performance is monitored and subject to rigorous control, to ensure that analyses are accurate, precise and results are comparable with other laboratories. A list of accredited tests can be accessed on the UKAS website.

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## TRAINING:

The department is approved by the Institute of Biomedical Sciences (IBMS) as a **Training Laboratory** for:

- i. **Pre-Registration training towards the CERTIFICATE OF COMPETENCE**  
Valid to 1<sup>st</sup> February 2029
- ii. **Post-Registration training in CELLULAR PATHOLOGY**  
Valid to 1<sup>st</sup> February 2029
- iii. **Support Staff training towards the CERTIFICATE OF ACHIEVEMENT**  
Valid to 14<sup>th</sup> December 2028


All our Biomedical Scientists and Clinical Scientist are registered with the Health & Care Professions Council (HCPC).

Certain IHC tests are not accredited by UKAS – see list below:

2SC	CXCL13	OCT 2
ALK-ETOP (D5F3)	D2-40 (Podoplanin)	PD-1 (CD274)
Annexin	FH	PD-L1 (SP263) Lung
AR	HNF1 $\beta$	Perforin
$\beta$ -Catenin	ICOS	PTEN
$\beta$ F1 (T cell Receptor)	Ig G	PRAME
BAP-1	Ig G4	RB358 (Retinoblastoma)
BOB-1	INSM-1	ROS-1
BRAF	LEF1	SATB2
CAIX	Lysozyme	SDHB
Caldesmon	Mast Cell Tryptase	SF-1
Calponin	MIC-2	SOX11
Cathepsin K	MITF (C5.D5)	SOX2
CD163 (MRQ-26)	MUC-4	STAT6
CD22	Myo D1	TIA-1
CD38	Napsin A	Tyrosinase
CD42b	Nectin	Uroplakin II
CD44	NK1C3 (CD63)	Uroplakin III
Claudin	NKX3.1	Vimentin

The laboratory also regularly monitors the UKAS accreditation status of the referral laboratories used for specialist testing.

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## NAMES AND ADDRESSES OF REFERRAL LABORATORIES

### SPECIAL TESTING

<b>HSL Advanced Diagnostics</b>	Health Services Laboratories, 60 Whitfield Street, London, W1T 4EU for BCL2 (Clone E17), DBA44, Galectin, p24, SALL4, Sox-2
<b>Leeds General Infirmary</b>	Department of Microbiology, The Old Medical School, Thoresby Place, Leeds LS1 3EX for PCR testing
<b>MCGM</b>	Genomic Diagnostic Laboratory, Manchester Centre for Genomic Medicine, (6th Floor) St Mary's Hospital, Oxford Road, Manchester, M13 9WL  GIST, BRAF, EGFR, KRAS
<b>MRI</b>	Department of Pathology, Clinical Sciences Building, Manchester Royal Infirmary, Oxford Road, Manchester, M13 9WL for Adipophilin (ADFP), Annexin, CA125, CD33, CEA (Polyclonal), Gastrin, Glucagon, H. pylori, Hep B, HSV-1, IgA, Insulin, MOC-31, Myoglobin, Pax-2, PGP9.5, Polyoma, RCC, Somatostatin, MMR Panel
<b>MRI Virology</b>	Department of Virology, Clinical Sciences Building, Manchester Royal Infirmary, Oxford Road, Manchester, M13 9WL for PCR testing
<b>RMCH</b>	Consultant Paediatric Histopathologist, Level 4, Royal Manchester Children's Hospital, Oxford Road, Manchester, M13 9WL for BCOR, Brachyury, CD13, Fli-1, GLUT-1, NSE, NUT-1, TLE-1
<b>RNOH Stanmore</b>	Histopathology Department, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, HA7 4LP for CAMTA1, FOSB, SMARCA4
<b>Salford Royal</b>	Histopathology Department, Salford Royal NHS, Eccles Old Road, Salford, M6 8HD for H3K27me3, SSTR2, Treponema pallidum
<b>MFT</b>	Histopathology Department, Clinical Sciences Building Wythenshawe Hospital, Southmoor Road, Manchester, M23 9LT for TTF-1 (SPT24)

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<b>2<sup>ND</sup> OPINIONS</b>	
Prof. C Fletcher	Director of Surgical Pathology, Brigham & Women's Hospital 75 Francis St, Boston Massachusetts 02115, USA
Prof. Manuel Sobrinho-Simões	IPATIMUP, Rua Roberto Frias S/N, P 4200-465 Porto, Portugal
Prof. Juan Rosai	Centro Consulenze Anatomia patologica, Centro Diagnostico Italiano (CDI), Via Saint Bon, 20, 20147 Milano, Italy
Dr Jaime Eduardo Calonje	Histopath. Dept, St Thomas' Hospital Westminster Bridge Road, London SE1 7EH
Prof Cyril Fisher	Histopath. Dept. Royal Marsden Hospital, Fulham Road, London SW3 6JJ
Dr Raf Sciot	Dienst Pathologische Ontleedkund, VZ St Rafael, Minderbroedersstraat 12, B-3000 Leuven, Belgium
Dr Carrie Y Inwards	Division of Anatomic Pathology, Mayo Clinic, Rochester, Minnesota 55905, USA
Prof. J Cameselle-Teijeiro	Pathology Dept. Hospital Clinico Universitario, 15706 Santiago de Compostela, Spain
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Dr R McVey: Gynae	MRI
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## 8. References

- LabTestsOnline.org.uk
- United Kingdom Accreditation Scheme: Lab 8697

## 12. Document Locations

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<b>Author</b>	Catherine Billington	<b>Frequency</b>	As per QPulse Document record	

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### 13. Procedure Amendments

This replaces all previous versions of the document.

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