Definitions

All questions related to laboratory structure and work completed during the year 2019 (entire year) unless otherwise stated in the question.

All questions relate to histopathology only (including routine immunohistochemistry) – where possible and not overly time consuming, please do not include details for Cytology, molecular pathology or any other disciplines unless otherwise stated.

Please complete all questions where possible – if precise data is unavailable please provide an estimate.

If unable to complete all questions, please provide a partial response (just completing the data that you can).

If you are unable to provide data on any of the questions please record this along with a brief reason in your question response, this should include any data that would take too long to collate and would otherwise prevent you from replying to the Freedom of Information request. This will help us better understand which information requests are reasonable and will inform any future requests for information.

Although not marked as mandatory, all questions should be considered mandatory.

Where numerical data is requested (e.g. number of samples per year) please enter this as a number.

If you have multiple histology laboratories within your organisation please submit separate responses for each.

Digital Pathology: This includes all forms of digital systems used in the diagnostic process as listed below:

  • **Telepathology**: The use of remote digital microscopes – live video/robotic microscopy in the diagnostic process
  • **Whole slide Imaging (WSI)**: The use of scanned images of slides (virtual slides) in the diagnostic process
  • **Image Analysis**: The use of tools (artificial intelligence or otherwise) to aid with certain aspects of the diagnostic process – for the purposes of this questionnaire this should be limited to those systems that automate an aspect of the diagnostic process only (automated counts of ER/PR/Her2/Ki-67 etc.) as opposed to digital annotation of slides or measurement between marked points on a digital slide

Primary diagnosis: for the purposes of this questionnaire, this refers to the initial pathologist assessment of a biopsy and has been separated from additional IHC and molecular tests requested

Secondary diagnosis: For the purposes of this questionnaire this refers to the process of seeking a secondary pathologist assessment (internal or external)

Section 1: Respondent/response details

Q1: Respondent/response details:
- Name of hospital Trust: UHNM
- Address of hospital Trust: refer to the attached letter
- Name of laboratory providing histology services: Royal Stoke University Hospital Histology laboratory
- Address of laboratory providing histology services:
    Histology Department
    Pathology
    Main Building
    Royal Stoke University Hospital
    University Hospitals of North Midlands NHS Trust
    Newcastle Road, Staffordshire, ST4 6QG

Section 2: Breast Cancer Reporting

Q2: Do you perform diagnostic reporting of breast cancers in the house?   **Y**
- If Y, what types?   All

Q3: What are the steps involved in diagnostic reporting once a tissue sample has been received? Please tick as appropriate.
- Tissue preparation ✓
- Primary diagnosis by pathologist ✓
- Molecular test ✓
- Secondary diagnosis (opinion) ✓
- MDT ✓
- Other - please specify

Q4: How many breast cases do you receive per year?
- <100
- 100-500
- 500-1000
- 1000+ (please specify an approximate number) ✓ 2443/annum (2019)

Q5: What % of breast samples received constitute breast cancers?
- <25%
- 25-50% ✓ 41%
- 50-75%
- 75-100%

Q6: What % of breast samples come from Breast Cancer Screening? What % of breast cancers come from Breast Cancer Screening Program?
- <25%
- 25-50% ✓ 28%
- 50-75%

- 75-100%

Q7: What are the additional tests performed for characterisation of breast cancers? Select all that apply:
- Estrogen receptor IHC ✓
- Progesterone Receptor IHC ✓
- Her2 Receptor IHC ✓
- Her2 Receptor FISH ✓
- Ki67 IHC ✓
- OncotypeDx ✓ Not performed in house. Requested directly by Clinicians.
- Others (please specify) ✓ E Cadherin, CK14, P63, Smooth Muscle Myosin

Q8: Which of the below tests are routinely performed? For non-routine/conditional tests, please specify the conditions for these tests to be performed.
- Estrogen receptor IHC ✓
- Progesterone Receptor IHC ✓
- Her2 Receptor IHC ✓
- Her2 Receptor FISH ✓ performed when HER2 IHC is 2+ borderline (approx 25-30% of breast cancers)
- Ki67 IHC ✓ currently in development not routine as yet
- Oncotype Dx ✓ requested by clinicians directly. Not performed in house
- Others (please specify)

Q9: What is the cost per patient for the following tests?
The costs for these tests are built in to the specimen band price and therefore there is no price per test

- Estrogen receptor IHC - (approximately £35)
- Progesterone Receptor IHC- (approximately £35)
- Her2 Receptor IHC – (approximately £115 including 25% HER2 FISH)
- Her2 Receptor FISH – as above. HER2 FISH included in cost per test for HER2 IHC
- Ki67 IHC - unknown at present as mid-workup.
- OncotypDx – not paid for by Pathology. Not tested or requested in pathology so unsure of costs.
- Others (please specify)

If cost per patient is not available, please provide whatever cost breakdown is available (total number of patients + total cost of testing OR total cost of all tests per patient OR routine cost of IHC/FISH + number of cases tested etc.). Please specify the type of costs provided.

Q10: What is the average turnaround time for following steps? Is there any mandated target for each step? If so, what % of cases exceed the target?
- Preparation of diagnostic biopsy

Average 7 Day turnaround time is 3 days

- Primary Diagnostic Reporting
  Average 7 day TAT reporting is 2 days
  Average 10 day TAT reporting is 8 days

- IHC testing - HER2 IHC:
  89% of cases tested for HER2 have a TAT of 7 days or less. The average total TAT is 5 days.

- Other molecular testing – HER2 FISH:
  98% of cases tested in house for HER2 FISH have a TAT of 10 days or less. The average total TAT is 7 days
  NICE guidance recommends there is a HER2 status result within 14 days of the specimen being taken.

NOTE: where numbers for breast malignancies are unavailable, overall numbers will be accepted (please indicate).

Q11: What percentage of cases exceed a 7 day turnaround time and 14 days respectively?
We don't record against a 14 day target.
For 7 days 10.8% exceed 7 day turnaround time.
For 10 days 26% exceed 10 day turnaround time.

Section 3: Use of digital/computational pathology

Q12: Did your histology laboratory use any form of digital/computational pathology in 2019   Yes but only for training and validation purposes against the RCPath 'Best practice recommendations for implementing digital pathology' document.

- If [N] to the above question are you planning to introduce digital pathology in the near future (please provide details)?

NOTE: If your histology laboratory does not currently use any form of digital/computational pathology, the remainder of this section can be left blank. Please proceed to Section 4.

Q13: What was digital pathology used for in your laboratory during 2019?
- Research
- Training ✓
- Primary diagnosis
- Secondary diagnosis (second opinion)
- Telepathology (Requestor)
- Telepathology (Consultant)
- Preparing cases for review at multi-disciplinary team meetings
- Other (please detail)

Q14: Please indicate which of the listed systems were used in your histology laboratory in 2019. If a software suite is used please indicate the features used from the suite.

- Telepathology
- Whole Slide Imaging ✓
- Image analysis
- Conventional (analogue) light microscopy ✓
- Voice recognition system for reporting ✓
- Digital case requesting (ICE) system
- Digital dissection macro imaging systems ✓
- Voice recognition system for dissection ✓
- Specimen tracking system
- Pathology reporting software
- LIS/LIMS/PACS ✓
- Other (please detail)

Q15: If whole slide imaging was used in your laboratory in 2019 please provide the following details on system configuration.

- Number of scanners (and manufacturer)   1 Roche DP200
- PACS/ Image management systems provider
- Current size of digital slide archive
  - Total number of cases - To date 238
  - Number of years - 12 months
  - Estimated retrospective digitization rate (%) – 100%
- Number of slides routinely scanned per week
  - Of these, how many are on-demand - 0%
- Number of slides routinely scanned at 40x
  - For diagnostic reporting - 0
  - For other purposes - 1874 (training and validation purposes only)
- Other (please detail)

Section 4: Future use of digital/computational pathology (only to be filled if Section 3 does not apply)

Q16: Which of the following reasons best describes why you have not used or increased your use of digital pathology?

- High costs
- Lack of evidence surrounding clinical effectiveness
- Staff training requirements
- Disruption to current workflows
- Lack of existing digital infrastructure
- Other (please specify) ✓ Securing a funding source