12 LIST OF FACTORS KNOWN TO AFFECT THE PERFORMANCE OF THE EXAMINATION AND ON INTERPRETATION OF RESULTS

There are a number of factors known to affect the performance of the examination and interpretation of results. This list is not exhaustive:

- Failure to follow the sample acceptance policy may result in a delay in producing a report.
- Failure to supply relevant clinical information may result in a delay in producing a report.
- Failure to mark as Urgent may result in a delay in producing a report.
- Failure to place a routine specimen in 10% Neutral Buffered Formalin may result in a delay in producing a report, but more importantly may compromise specimen quality and subsequent histological examination and diagnosis.
- Specimens placed in the incorrect fixative solution could seriously damage the specimen and render it non-diagnostic.
- Specimen for frozen section placed in 10% Neutral Buffered Formalin, would result in a frozen section not being performed and therefore a rapid diagnosis would not be established.
- Skin IMF specimen placed in 10% Neutral Buffered Formalin, would result in immunofluorescence not being performed on the specimen.
- Failure to mark for MDT may result in a delay in producing a report and then it may not be discussed at the required meeting but at a later meeting.
- Failure to contact consultant/laboratory in advance for a frozen section may result in a delay or even a scenario where it cannot be performed, due to a lack of availability of technical staff and/or Consultant staff.
- Failure to follow sample production instructions for Andrology semen samples may result in analysis not being performed on the specimen.

12.1 Measurement Uncertainty in Cellular Pathology

- All types of measurement have some inaccuracy due to bias, imprecision and operator variation, and therefore measurement results can be only estimates of the values of the quantities being measured. In histopathology reports, usually qualitative data are of greater significance, however in certain situations quantitative measurements become critical of diagnosis and prognosis.
- Measurements can be made with either:-
    - A ruler, for example, macroscopic measurements of tissues, tumours and excision margins.

- Eyepiece graticule in a microscope, for example, measuring microscopic distances in tissue sections.

- There will be a degree of variation in all such measurements and it is this uncertainty that should be considered when interpreting the final histology report. Where tumour sizes and excision margins have been measured there is a level of uncertainty in the measurement step. For macroscopic tumour measurements we have calculated this to be +/- 2.3mm. In order to minimise such uncertainty we have a number of steps and assurances in places:-

  - Ensuring tumours are only measured in the largest dimension.
  - For tumours of a size close to the limits of different tumour staging we are aware that inaccuracies could upstage tumour.
  - Understanding that it is not possible to measure more accurately than to nearest millimetre.
  - Measuring to nearest millimetre with a UKAS calibrated ruler.
  - Discussion at MDT is actively encouraged regarding measurements close to staging limits.
  - Final assessment of staging is a clinical decision based on multiple information sources.

- In cervical cytology the examination of the sample is used to indicate the presence or absence of disease. Where biological variation in samples occurs, this can lead to difficulties in interpreting results. Where there is genuine doubt as to whether cells changes are abnormal an equivocal report 'Borderline changes' is issued.

  - In Andrology, analysis of semen samples is a test which shows biological variability between samples from the same patient. Every semen analysis parameter is subject to some uncertainty. Measurement uncertainty can come from the measuring instrument, from the item being measured, from the environment, from the operator, and from other sources. Measurement uncertainties can be estimated using statistical analysis of a set of measurements. The use of good practice such as traceable calibration, careful calculation, good record keeping, and checking can reduce measurement uncertainties

  - Within the NHSCSP the sensitivity and specificity of the test is well understood and documented. All laboratories and screening individuals are monitored and expected to achieve sensitivities in excess of 90% for all abnormalities and more than 95 % for high grade abnormalities