**Referring Renal Biopsies to the RVI**

**Contents**

[1.0 Purpose of procedure 2](#_Toc38288727)

[2.0 Principle of Procedure 2](#_Toc38288728)

[3.0 Personnel 2](#_Toc38288729)

[4.0 Health & Safety 2](#_Toc38288730)

[5.0 Summary of significant changes 3](#_Toc38288731)

[6.0 Critical Control Point 3](#_Toc38288732)

[6.1 Critical Control Point Table 3](#_Toc38288733)

[7.0 Sample / Equipment / Reagents / QC 3](#_Toc38288734)

[7.1 Sample 3](#_Toc38288735)

[7.2 Equipment 4](#_Toc38288736)

[7.3 Reagents 4](#_Toc38288737)

[7.4 Internal Quality Control 4](#_Toc38288738)

[7.5 Inter laboratory Comparison (External Quality Assurance) 4](#_Toc38288739)

[8.0 Procedure 4](#_Toc38288740)

[8.1 Centres without stereomicroscope access or BMS staff competent in renal assessment and dissection. 4](#_Toc38288741)

[8.2 Centres with access to stereomicroscope and BMS staff competent in renal assessment and dissection. 5](#_Toc38288742)

[9.0 Criteria relating to Procedure 6](#_Toc38288751)

[9.1 Limitations 6](#_Toc38288752)

[9.2 Validation 6](#_Toc38288753)

[9.3 Verification 6](#_Toc38288754)

[9.4 Troubleshooting 6](#_Toc38288755)

[9.5 Reference Ranges / Intervals 7](#_Toc38288756)

[9.6 Uncertainty of Measurement 7](#_Toc38288757)

[9.7 Contingency 7](#_Toc38288758)

[10.0 References 7](#_Toc38288759)

[10.1 Relevant Standards and Accrediting Bodies 7](#_Toc38288760)

[10.2 Departmental and Trust policies 7](#_Toc38288761)

[10.3 Forms 7](#_Toc38288762)

[10.4 Related Documents 7](#_Toc38288763)

**Referring Renal Biopsies to the RVI**

1. Purpose of procedure
	* 1. Fresh renal biopsies are often referred to the RVI. The purpose of the procedure is to provide a diagnostic procedure to give information on type, activity and intensity of disease.
2. Principle of Procedure
	* 1. The principle of the procedure is to always ensure the correct sampling and delivery techniques are employed.
3. Personnel
	* 1. All trained and competency assessed Scientific and Technical staff can perform this procedure and must comply with the conditions contained in this document. Specific tasks will be determined by competency assessment.
		2. Tasks are performed by BMS staff competent in renal assessment and dissection.
		3. Staff in training must be supervised by a competent member of staff.
4. Health & Safety
	* 1. Good laboratory practice is essential when performing all procedures. Staff undertaking this procedure must be aware of and operate in accordance with all current departmental and Trust Health and Safety documentation and policies. CPRE049 Fresh specimens relates.
		2. All appropriate Personal Protective Equipment (PPE) must be worn at all times. The list is not exhaustive but examples would include gloves, laboratory coats and goggles.
		3. All personnel performing this procedure must be familiar with current associated COSHH and Risk assessments.
		4. All staff must ensure compliance with all appropriate mandatory health and safety training e.g. Infection Control.
		5. All accidents and incidents must be reported in accordance with current department and Trust policies.
		6. All waste must be removed in accordance with current department, Trust and Newcastle University policies and procedures as appropriate. All personnel must be familiar with these policies and procedures before performing this procedure.
		7. Pathology material should be stored and retained in accordance with current department, Trust and national policies/guidelines.
5. Summary of significant changes
	* 1. Updated to new format to comply with ISO15189.
6. Critical Control Point
	* 1. Critical Control Points are listed in this table and referenced throughout the procedure.
	1. Critical Control Point Table

|  |  |  |  |
| --- | --- | --- | --- |
| **Critical Control Point (CCP) reference** | **Critical control point** | **Risk** | **Reduction measure** |
|  | Correct sampling of the tissue. | Can compromise diagnosis. | Clarify the type of renal biopsy. Any doubt check with Pathologist. |
|  | A minimum amount of 10 glomeruli is required to deem the specimen adequate. | Insufficient glomeruli can compromise diagnosis. | Accurate microscopic analysis is crucial. Advice should be sought from a colleague or Pathologist if in any doubt. |
|  | Sample needs to be placed in the correct reagent. | Incorrect reagent can compromise diagnosis. | Always check sample type. |

1. Sample / Equipment / Reagents / QC
	1. Sample
		1. Renal core biopsies received fresh and wrapped in gauze dampened with Phosphate Buffered Saline 7.2pH. Specimen transported urgently to RVI Cellular Pathology.
		2. Specimen pot and form packaged according to UN3373 guidelines.
	2. Equipment
		1. Gauze or Cell Path tissue wrap (order code: EBB-0106-10A)

Stereomicroscope

Microscope slides

Forceps or orange stick

Ruler

Scalpel

Cryostat

Small white pill box

Plastic IMF bag

* 1. Reagents
		1. All reagents received must undergo pre-acceptance testing (CCP 6.1.1), refer to slide production for these documents.
		2. Phosphate buffered saline 7.2pH

10% neutral buffered formalin

Glutaraldehyde 2%

Sorenson’s Phosphate Buffered Sucrose

Optimal Cutting Temperature Compound (OCT) freezing medium

* 1. Internal Quality Control
		1. A control section made of composite pieces of tissue is stained first every morning prior to any test cases. Slides are assessed at the QC stage to ensure the staining procedure has been successful.
		2. Action to take in an IQC failure must be documented.
	2. Inter laboratory Comparison (External Quality Assurance)
		1. Participates in the Renal Pathology UKNEQAS EQA scheme.
1. Procedure
	1. Centres without stereomicroscope access or BMS staff competent in renal assessment and dissection.
		1. Write macroscopic description of tissue on histology request form including:
2. Number of cores.
3. Length of cores.
	* 1. Wrap tissue in fine gauze or tissue wrap and dampen with Phosphate Buffered Saline ph7.2. Specimens must not dry out in transit or be sent floating in saline.
		2. Place tissue in specimen pot labelled with:

a. Patient name

b. Date of Birth

c. Hospital number

* + 1. Package specimen pot and form according to UN3373 guidelines
		2. Send package via taxi/ courier urgently to:

Specimen Reception

Cellular Pathology

Level 3 New Victoria Wing

Royal Victoria Infirmary

Victoria Road

Newcastle upon Tyne

NE1 4LP

* + 1. Inform RVI, Cellular Pathology of imminent arrival of specimen and provide contact details in order to complete chain of custody (0191 2824565)
	1. Centres with access to stereomicroscope and BMS staff competent in renal assessment and dissection.
		1. On receipt of renal:
1. Assess glomerular content under stereomicroscope
2. If insufficient glomeruli present ask clinician to repeat biopsy if clinically appropriate
3. Identify nature of renal core:
4. Recent transplant (less than 12 months since transplant). Point 8.2.2
5. Native (patient’s own kidney). Point 8.2.3
6. Old transplant (more than 12 months since transplant). Point 8.2.3
	* 1. **Recent Transplant biopsies**

a. Check that clinical details do not mention recurrent glomerulonephritis- If they do go to point 8.2.3

b. Write macroscopic description of tissue on histology request form including:

i. Number of cores

ii. Approximate number glomeruli present

iii. Length of cores

iv. State if further biopsies requested and if so whether they were provided by clinician

1. Place core in specimen pot containing 10% Neutral Buffered Formalin.
	* 1. **Native Renal and Old Transplant renal**
	1. Write macroscopic description of tissue on histology request form:
		1. Number of cores
		2. Approximate number glomeruli present
		3. Length of cores
		4. State if further biopsies requested and if so whether they were provided by clinician
	2. Sample core for:
2. Immunofluorescence (3-4 mm containing at least 3 glom) and place in specimen pot containing Michel’s medium (ensure this is done first to minimise risk of contamination with fixatives)
3. Electron microscopy (1-2 mm containing 1-2 glom) and place in specimen pot containing glutaraldehyde
	1. After 60 minutes transfer into Sorenson’s Phosphate Buffered Sucrose.
4. Paraffin process (remainder of tissue) and place in 10% Neutral Buffered Formalin
	* 1. Label all specimen pots with:
5. Patient name
6. Date of Birth
7. Hospital number
8. Tissue type
9. For EM specimens indicate time into Glutaraldehyde and into Sorenson’s Phosphate Buffered Sucrose
	* 1. Package specimen pots and form according to UN3373 guidelines
		2. Send package urgently to RVI, Cellular Pathology
		3. Inform RVI, Cellular Pathology (0191 2824565) of imminent arrival of specimen and provide contact details in order to complete chain of custody
		4. Send specimens via taxi/ courier urgently too:

Specimen Reception

Cellular Pathology

Level 3 New Victoria Wing

Royal Victoria Infirmary

Victoria Road

Newcastle upon Tyne

NE1 4LP

* + 1. If there are any concerns with any renal specimens please contact RVI, Cellular Pathology on 0191 2824565 in the first instance.
1. Criteria relating to Procedure
	1. Limitations
		1. Not applicable.
	2. Validation
		1. Not applicable.
	3. Verification
		1. Sampling of renal biopsies will be audited using the renal biopsy assessment form.
	4. Troubleshooting
		1. When the amount of tissue available is limited, please consult with the renal Pathologist as to the prioritisation of sampling.
	5. Reference Ranges / Intervals
		1. Not applicable.
	6. Uncertainty of Measurement
		1. Measurement of uncertainty of the assay is assessed regularly, according to the Departmental Measurement of Uncertainty Guide located in Q-Pulse, with the data stored on Q-Pulse and discussed IN CPQM020. The data can be made available to users on request.
	7. Contingency
		1. Please refer to the Departmental Business Continuity Policy (CPMP015 - Business continuity).
2. References
	* 1. Not applicable.
	1. Relevant Standards and Accrediting Bodies
		1. The laboratory complies with all legislative requirements for practice and is assessed appropriately by external bodies such as United Kingdom Accreditation Service (UKAS), the Human Tissue Authority (HTA), Medicines and Health Regulatory Agency (MHRA) and the Home Office for evidence of conformity.
		2. For the full UKAS accredited scope of tests, assessed for conformance to ISO 15189 standards please refer to the UKAS website. A link to this is available through the Laboratory Medicine website.
	2. Departmental and Trust policies
		1. CPPO001 – Health and Safety Policy
		2. CPPO009 – Good Laboratory Practice
		3. COSHH015 – Reporting of Accidents and Incidents Policy
		4. HIHS022 – Disposal of Waste
		5. CPQM001 – Quality manual
		6. HIQP008 – Quality improvement – error logging
		7. CPQM020 – Measurement Uncertainty in Cellular Pathology
	3. Forms
		1. HILF237 - Special stains Daily QC sheet.
		2. HILF341 – Renal biopsy assessment form.
	4. Related Documents
		1. CPRA014 - Handling hazardous chemicals
		2. HIHS001 - COSHH - Chemicals Inventory
		3. CPRA049 Fresh specimens