**Northern England Haemato-Oncology Diagnostic Service:**

**NEHODS**

A Specialist Integrated Haematological Malignancy Diagnostic Service

**User Guide**

**NEHODS User Guide**

**Contents**

[1.0 Purpose of document 3](#_Toc146286168)

[2.0 Summary of significant changes 3](#_Toc146286169)

[3.0 Introduction 3](#_Toc146286170)

[4.0 NEHODS aims 3](#_Toc146286171)

[5.0 NEHODS objectives 4](#_Toc146286172)

[6.0 NEHODS structure 4](#_Toc146286173)

[7.0 Integrated reporting – Haemosys® 4](#_Toc146286174)

[8.0 Services provided 5](#_Toc146286175)

[8.1 Cytomorphology 5](#_Toc146286176)

[8.2 Cellular pathology 5](#_Toc146286177)

[8.3 Flow cytometry 5](#_Toc146286178)

[8.4 Cancer Genomics 6](#_Toc146286179)

[9.0 Contacting NEHODS 6](#_Toc146286180)

[10.0 Opening times and out of hours 6](#_Toc146286181)

[11.0 Requesting investigations 7](#_Toc146286182)

[Unfixed Tissue Sample 8](#_Toc146286183)

[Unfixed tissue samples - keep biopsy moist with a little normal saline and keep refrigerated between 2-8oC. If possible a portion of the sample should be placed in 10% formalin. 8](#_Toc146286184)

[12.0 Sample requirements and transport 12](#_Toc146286185)

[13.0 Add on tests 13](#_Toc146286186)

[14.0 NEHODS reporting 14](#_Toc146286187)

[15.0 Turnaround times 15](#_Toc146286188)

[16.0 External quality assurance and accreditation 16](#_Toc146286189)

[17.0 Comments, Complaints and Compliments procedure 16](#_Toc146286190)

[18.0 Abbreviations 16](#_Toc146286191)

**NEHODS User Guide**

1. Purpose of document
	* 1. The purpose of this document is to provide users of NEHODS key information about what services are provided how the service is run and how to contact us.
2. Summary of significant changes
	* 1. Revised and updated to current format.
3. Introduction
	* 1. NEHODS provides an integrated diagnostic service covering all aspects of the diagnosis and monitoring of haematological malignancies and related conditions. The service has facilities for flow cytometry, immunohistochemistry, metaphase and interphase cytogenetics studies and a wide range of molecular genetic testing. Further details of the service can be found on the NEHODS webpage - <https://www.newcastlelaboratories.com/lab_service/nehods/>
		2. The NEHODS laboratory is located within the Blood Sciences Department within the integrated laboratory medicine directorate at the Royal Victoria Infirmary. We have a centralised specimen reception for all samples needing work-up for haematological malignancy. All flow cytometry and preliminary genetic work is done in this area and then further testing and reporting takes place in the main genetics laboratories in the Centre for Life. Histopathology work is done in the Cellular Pathology Laboratory, RVI.
4. NEHODS aims
	* 1. The aim of NEHODS is to provide accurate and timely reports for patients with potential and known haematological malignancies as well as other malignant and non-malignant disorders affecting haemato-lymphoid tissue. We integrate morphology, genetics and immunophenotyping to provide a single interpretative report.
5. NEHODS objectives
	* 1. Participate in all relevant external quality assurance (EQA) schemes
		2. Comply with (National Institute for Health and Care Excellence) NICE guidance on reporting haematological malignancies
		3. Provide integrated reports consistent with World Health Organisation (WHO) classification
		4. Support all regional multidisciplinary team meetings (MDT)
		5. Contribute to training of doctors and scientists in haematopathology
		6. Seek feedback from relevant stakeholders (Integrated Laboratory Medicine Directorate, Cancer Services, Clinical Haematology Directorate, Children’s’ Services Directorate, relevant MDTs and the Northern Region Haematology Group (NRHG)
		7. Produce annual report
		8. Provide annual NRHG education day
6. NEHODS structure
	* 1. NEHODS is part of Newcastle upon Tyne Hospitals NHS Foundation Trust. It is managed as part of the Directorate of Integrated Laboratory Medicine with contributions from the Cancer Services and Clinical Haematology directorate. The service is provided by a highly-skilled team of dedicated doctors, scientists and technologists who offer a timely, efficient and cost-effective service to our users. The department also complies with professional standards and participates in all appropriate external quality assurance schemes.
		2. There is a clinical lead for the service in addition to an operational manager. Each individual section has a scientific lead (flow cytometry, cytogenetics, molecular genetics and cellular pathology).
7. Integrated reporting – Haemosys®
	* 1. Haemosys® is a web-based integrated reporting and tracking system. Each hospital trust in the north east and north Cumbria has access to Haemosys. The system allows samples to be booked in at source and when complete allows the publication of results back into the local laboratory information management system (LIMS). Where there is no link between Haemosys® and the LIMS samples are booked in at NEHODS and results are posted or can be printed locally.
		2. Haemosys® allows each individual element of the report to be written and authorised separately on one sample number and once complete the whole case is published back to the LIMS. Interim reports can be published if not all elements of the test are ready to publish.
		3. The system allows clinical audit of any element of the testing and diagnostic process, showing all previous revisions of reports and tests
		4. Images and other documents can be attached to reports
		5. Provides a platform for performing a manual differential cell count
8. Services provided
	1. Cytomorphology
		1. Processing, examining and reporting of peripheral blood, bone marrow aspirate and other liquid samples such as cerebrospinal fluid (CSF), ascitic fluid and pleural fluid. Samples are reviewed by specialist registrars and consultant haematologists.
	2. Cellular pathology
		1. The cellular pathology laboratory processes bone marrow trephine biopsies, lymph node biopsies and other tissues which are fixed, sectioned and stained ready for morphological assessment under the microscope. Many special stains can be performed in addition to immunohistochemistry. Bone marrow trephines are reviewed and reported by haematologists and lymph node biopsies are reported by histopathologists.
	3. Flow cytometry
		1. Multi-parametric flow cytometry requires a single suspension, which can be
		derived from a number of different biological sites such as the peripheral blood, bone marrow, CSF, ascitic fluid, and pleural effusions. This technique allows the immunophenotyping of cells to help in the diagnosis of haematological malignancy. In addition the flow cytometry laboratory also performs a wide range of other haematological tests such as paroxysmal nocturnal haemoglobinuria screening, CD34 enumeration, Eosin-5’-malemide (EMA) analysis in addition to a wide repertoire of immunological studies. For non-NEHODS requests please use the request form here: <https://www.newcastlelaboratories.com/lab_service/flow-cytometry/>
	4. Cancer Genomics
		1. In cytogenetics acquired chromosomal abnormalities are investigated in bone marrow, blood, lymph node and other infiltrated tissue. These tests help establish the diagnosis, monitor treatment and provide prognostic information hereby impacting on
		patient management.
		2. Molecular genetic investigations involve looking at changes or mutations to DNA that patients acquire as part of the malignant process. These can help with diagnosis and prognosis of many haematological malignancies.
9. Contacting NEHODS
	* 1. General NEHODS Enquiries: 0191 282 5028 / 0191 282 5078
		2. Flow cytometry-specific email: nuth.FlowCytometryLab@nhs.net
		3. Genetics-specific email: nuth.cancer.genomics@nhs.net
		4. The full postal address of the laboratory is:

NEHODS Reception
Blood Sciences, Flow cytometry Laboratory
Level 3, Leazes Wing
Royal Victoria Infirmary, Richardson Road
Newcastle upon Tyne, NE1 4LP

1. Opening times and out of hours
	* 1. Standard opening is 08:30 to 17:00 Monday to Friday.
		2. If urgent analysis is required please contact us in advance.
		3. An on-call flow cytometry and cytogenetic service is available Saturdays, Sundays and bank holidays for clinically urgent requests. This is where there is an immediate need to commence treatment and will change patient management. This service is accessed by contacting the consultant haematologist for general/laboratory haematology on call through the Newcastle Hospitals switchboard (0191 2336161). This should be done before the sample is taken. The on-call haematologist will contact a nominated NEHODS haematologist who can coordinate weekend urgent flow cytometry and genetics work.
2. Requesting investigations
	* 1. When sending us a sample please complete the sample request form which can be downloaded from <https://www.newcastlelaboratories.com/lab_service/nehods/> or generated within HaemoSys® with pre-populated patient details and clinical information for those Trusts that are able to book into Haemosys®. There are options on the form to request certain common tests. If a specific test is required please mark this in the clinical details or contact us.
		2. Integrated analysis of samples is critically dependent on clinical information. It is therefore vital that all clinical diagnostic information is clearly stated on the request form. If correct details are not present the interpretation of material and subsequent conclusions made may not be accurate. Information required within clinical details includes:
			1. The clinical question
			2. Full blood count to include haemoglobin concentration, mean cell volume, platelets, white count and full differential
			3. Blood film comments
			4. If lymphoma or myeloma are suspected – the presence of paraprotein, type and quantitation
			5. Relevant examination findings e.g. splenomegaly, lymphadenopathy
			6. Relevant medications e.g. on cytotoxic medication or GCSF
			7. Other laboratory results e.g. liver function, renal function, B12/folate
			8. Treatment received e.g. AML post cycle 2 of DA
		3. A Diagnostic Kit is available from NEHODS comprising:
			1. Transport box, UN3373 PathoShield 8 (pre-labelled with the address above)
			2. Sealable, internal bag with unique tracking number (Please make a note of this)
			3. 3 × 5 ml EDTA tubes – for flow cytometry and/or DNA extraction – please mix well
			4. 1 × 5 ml lithium heparin tube for cytogenetics – please mix well
			5. 2 × 5 slide transport containers

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| --- | --- | --- | --- |
| **NEHODS section** | **Sample type** | **Sample requirement** | **Comments** |
| Haematology Cytomorphology | Peripheral blood | One unstained peripheral blood film | Please send sample as soon as possible after taking.CSF samples should arrive within 24 hours and if delays the sample should be kept refrigerated between 2-8°C.  |
| Bone marrow aspirate | Three fresh, unstained bone marrow aspirate smears and one unstained peripheral blood film |
| CSF | 0.5 mL fresh (universal container) |
| Other fluid (ascitic fluid, pericardial fluid, pleural fluid etc.) | >1 mL fresh (universal container) |
| Cellular pathology | Bone marrow trephine | Fixed in formalin or paraffin block if processed locally | Protect the front face of the paraffin block with tissue paper. Secure packageIf sending us a trephine paraffin block please also send us one H&E slide. |
| Lymph node biopsy | Fresh tissue | Unfixed Tissue SampleUnfixed tissue samples - keep biopsy moist with a little normal saline and keep refrigerated between 2-8oC. If possible a portion of the sample should be placed in 10% formalin.  |
| Extra nodal tissue | Fresh tissue |
| Paraffin block | Fixed in formalin or paraffin block if processed locally | Protect the front face of the paraffin block with tissue paper. Secure package |
| Cytology block | Fixed in formalin or paraffin block if processed locally | Protect the front face of the paraffin block with tissue paper. Secure package |
| Flow cytometry | Peripheral blood | 4 mL in EDTA and one unstained peripheral blood film | Please send sample as soon as possible after taking.Mix wellIf sample is urgent please contact laboratory in advance.All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay, please keep samples refrigerated between 2-8°C |
| Bone marrow aspirate | 5 mL in EDTA (smaller volumes can be accepted) and three unstained bone marrow aspirate smears and one unstained peripheral blood film |
| CSF | 0.5 mL fresh (universal container) |
| Other fluid (ascitic fluid, pericardial fluid, pleural fluid etc.) | Fresh (universal container) |
| Cytogenetics (karyotyping and FISH) | Peripheral blood | 5 mL lithium heparin | Please send sample as soon as possible after taking.Mix wellIf sample is urgent please contact laboratory in advance.All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay, please keep samples refrigerated between 2-8°C |
| Bone marrow aspirate | 5 mL lithium heparin |
| Other fluid (CSF, ascitic fluid, pericardial fluid, pleural fluid etc.) | universal container |
|  | Formalin-fixed paraffin embedded material | Requirements depend on test required :FISH – 3 µM section on superfrost slide with labelled H&E incl. tumour content of labelled region. - send 4 slides for MYC FISH panel. For other tests, send 2 extra slides for each test request.See NEHODS HaematoPathology request form for guidance.  | Assuming NEHODS has block |
|  | Fresh tissue | Sample dependent. | All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay, please keep samples refrigerated between 2-8°C |
| Molecular tests | Peripheral blood | 5 mL EDTA | Please send sample as soon as possible after taking.Mix wellIf sample is urgent please contact laboratory in advance.All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay, please keep samples refrigerated between 2-8°C |
| Bone marrow aspirate | 5 mL EDTA |
| Other fluid (CSF, ascitic fluid, pericardial fluid, pleural fluid etc.) |  |
|  | Formalin-fixed paraffin embedded material | ? See NEHODS HaematoPathology request form for guidance. | Assuming NEHODS has block |
|  | Fresh tissue | Sample dependent. | All unfixed samples should be delivered to the laboratory within 24 hours. If a sample is delayed beyond this point it may not be possible to carry out a full range of investigations. In these circumstances, definitive diagnosis may not be possible. If there is going to be an unavoidable delay, please keep samples refrigerated between 2-8°C |

1. Sample requirements and transport
	* 1. Please check before sending samples:
			1. We need three items of patient identification (including NHS number).
			2. Are all the tubes labelled?
			3. Are all the lids fastened? Leaking specimens compromise analysis and are a health risk.
		2. Samples will be rejected according to the each individual laboratory’s acceptance criteria. [Specimen Acceptance Criteria - Newcastle Laboratories](https://www.newcastlelaboratories.com/quality/specimen-acceptance/) Wherever possible, and especially if the sample referred has arisen from an invasive procedure, NEHODS will contact the referrer to accept samples without a fully complete data set but will add a caveat to any report relating to the sample. The report will indicate that the sample was unlabelled/incorrectly labelled and state that the decision to act on the report resides with the referring clinician.

All samples should be sent to the NEHODS Centralised Specimen Reception for booking in and sample distribution. Samples can be sent by first class post, by courier or via inter hospital transportation. Transportation and packaging of samples should be performed according to the sender’s policy for safe transport of pathological specimens. See HSE guidance on <https://www.hse.gov.uk/biosafety/blood-borne-viruses/transportation-of-infectious-substances.htm>

* + 1. Samples arriving after 13:00 on Fridays may not be processed until the following week. If possible please aim for samples to arrive before this time to allow for timely processing. This is especially important in flow cytometry when delays to analysis may affect sample quality.
		2. It is essential that appropriate labels are attached to request forms and containers where a sample is suspected as being ‘high risk’. All samples from patients exposed to a dangerous infectious pathogen (ACDP category 3 or higher) will be considered a high infection risk. This includes known carriers, people with prior contact to infected individuals and other risk groups such as IV drug users. All samples from patients at High Risk of infection referred should be identified to the laboratory. The sample and request card must be clearly labelled as High Risk
		3. For childhood acute leukaemia samples or if Burkitt lymphoma or acute promyelocytic leukaemia is a suspected diagnosis – please call the laboratory immediately. For Burkitt lymphoma, please also make extra smear slides in view of apoptosis of lymphoma cells during transport.
1. Add on tests
	* 1. Requested by NEHODS
			1. If, according to our professional judgement, if we feel that further tests may be required in order to obtain a correct diagnosis or optimise classification, it is our policy to pass the sample to another section within NEHODS. For example, this may include passing the sample to our molecular diagnostics team to confirm the clonality of a T-cell population, to request FISH for t(11;14) in the case of a clonal CD5 positive B-cell population with a low CLL score or to request a full myeloid panel where this may help in cases of borderline dysplasia.
			2. We feel that this is in the interest of patient care in facilitating a quick diagnosis, negating the need for; further samples being taken and extra hospital appointments.
			3. Most of the add on tests invoked by NEHODS will be around making the correct diagnosis and accurate classification as per the current WHO guidelines and comply with national and international practice and guidance. Occasionally we will also request prognostic markers outside of usual testing strategy where clinical details dictate e.g. Known CLL with rising white count and new lymphadenopathy.
		2. Requested by clinician
			1. If there are changes in the patient’s condition or relevant new information emerges after the specimen is sent, please contact the laboratory so that additional investigations may be initiated if required.
			2. This can be done by email
			3. Investigations on tissue blocks and stored DNA can generally be carried out on archived material without time limit. However flow cytometry requires fresh material and therefore further analysis may not be possible. Please contact the laboratory directly. In addition certain genetic tests may not be possible on stored material. For example in myeloma and lymphoma where the population of neoplastic cells are low we perform cell selection prior to analysis. This selection must be performed at the outset. In addition certain genetic tests require specific processing and may not be possible after the specimen has been handled.
2. NEHODS reporting
	* 1. NEHODS results are available using HaemoSys® - <http://www.haemosys.com>
		2. Please contact the System Administrator to obtain access to HaemoSys®.
		3. HaemoSys® contains a comprehensive user guide within the software which is regularly updated.
		4. Pre-authorised results**:** All users must be aware that results may be entered/saved into HaemoSys® before test results are fully authorised. Users must note that such results are interim and subject to change before authorisation of that section or publication of the final report.
		5. Authorised results**:** Authorised/Completed test results are clearly indicated with HaemoSys®, appearing on the right-hand side of the ‘Test summary’ screen. Authorised results may change depending on results from subsequent tests and prior to the final publication of the integrated report.
		6. Integrated reports**:** Following completion of testing, integrated reports are published on HaemoSys® by the NEHODS clinical team. These final reports are either delivered to the local LIMS system or posted to the referring clinician. These reports are also available for download as pdf within HaemoSys®. These reports should be considered the final report but these can be updated if tests are added. If an integrated report is unauthorised, updated and subsequently re-published this will be marked as superseding a previous report
		7. An interim integrated report can also be requested prior to the reporting of all modalities
		8. Lymphoma NEHODS reports are available through the APEX computer system. Paper reports are sent to the referring pathology departments. Urgent reports can be emailed if required. Please e-mail queries to nuth.cellularpathology.secretaries@nhs.net
3. Turnaround times
	* 1. For urgent samples please state this on the request form and contact the laboratory in advance.

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| **NEHODS Test** | **Timeframe** | **Target Turnaround time from sample receipt** |
| Bone marrow aspirate or peripheral blood morphology | Routine | 72 hours |
| Urgent | 4 hours |
| Flow cytometry | Routine | 72 hours |
| Urgent | 4 hours |
| Cancer Genomics | Routine | 14-21 working days |
| Urgent | 72 hours |
| Bone marrow trephine |  | 10 days |
| Lymph node or other tissue |  | 14 days |
| Integrated report compilation (from completion of all testing) |  | 72 hours |

1. External quality assurance and accreditation
	* 1. We take part in the following external quality assurance schemes:
			1. UK NEQAS for Leukaemia Immunophenotyping (Part 1)
			2. UK NEQAS Leukaemia Diagnosis Interpretation (Part2)
			3. UK NEQAS Paroxysmal Nocturnal Haemoglobinuria
			4. UK NEQAS CD34+ Stem Cell Enumeration.
			5. UK NEQAS Cerebrospinal Fluid CSF Immunophenotyping (not accredited)
			6. UK NEQAS Haematological Malignancy Bone marrow Aspirate Assessment (not accredited).
			7. UKNEQAS ICC & ISH Lymphoid Pathology
			8. UKNEQAS ICC & ISH General Pathology
2. Comments, Complaints and Compliments procedure
	* 1. Any comments concerning the performance of the service should be directed to the NEHODS clinical lead in the first instance. Any complaints which affect patient care will be dealt with according to the Newcastle upon Tyne Hospitals NHS Foundation Trust’s incident reporting procedures.
3. Abbreviations
	* 1. CSF – cerebrospinal fluid
		2. EQA – external quality assurance
		3. LIMS - laboratory information management system
		4. MDT – multidisciplinary team
		5. NEHODS – Northern England Haemato-oncology Diagnostic Service
		6. NICE – National Institute for Health and Care Excellence
		7. NRHG – Northern Region Haematology Group
		8. SIHMDS – Specialist Integrated Haematological Malignancy Diagnostic Service
		9. WHO – World Health Organisation