SydPath
ST VINCENT'S PATHOLOGY

SYDPATH MOLECULAR HAEMATOLOGY REQUEST FORM

RCPA
The Royal College of Pathologists of Australasia
Accredited for compliance with NPAAC Standards and ISO 15189

NATA
ACCREDITATION No 2115

PATIENT DETAILS

Family Name _____

Given Name _____

Sex ☐ M ☐ F DOB _____

Address _____

_____

Medicare No: _____

CLINICAL HISTORY (Must be completed)

Please send relevant pathology results such as bone marrow report, blood film, karyotype, FISH and histopathology.

REQUESTING PHYSICIAN/PATHOLOGIST

Name _____

Hospital / Lab: _____

Provider No: _____

Phone _____

Fax _____

Email _____

Signature ✗ _____ Date _____

SAMPLE TYPE

☐ Bone Marrow (1-2mL EDTA)

☐ Blood (4mL EDTA)

☐ FFPE (lymphoid only – please fill in details below)

☐ DNA (min. 15uL >20ng/uL; specify source) _____

☐ Other (please specify): _____

Collector Surname: _____ Collection Date: _____

Collector's Signature ✗ _____

I certify that I established the identity of the patient named on this request form, collected and immediately labelled the specimen(s).

HOSPITAL STATUS OF PATIENT AT SPECIMEN COLLECTION OR DATE OF SERVICE

☐ Private patient in a private hospital or approved day hospital facility

☐ Private patient in a recognised hospital

☐ Public patient in a recognised hospital

☐ Outpatient of a recognised hospital

FFPE REQUIRED INFORMATION

Please send paraffin block or 10 unstained 5um sections on uncoated slides

Original Pathology Laboratory: _____

Block Identification Number: _____

Approval to Exhaust Block: ☐ Yes ☐ No

NEXT GENERATION SEQUENCING DNA ASSAYS

Myeloid Panel (MBS eligible 73447 at diagnosis, disease relapse of suspected myeloid malignancy). Indication:

☐ Essential Thrombocytosis

☐ Polycythaemia Vera

☐ Primary Myelofibrosis

☐ Myelodysplastic Syndrome

☐ Acute Myeloid Leukaemia

☐ Other Suspected Myeloid Disorder: _____

Lymphoid Panel (MBS eligible 73448 at diagnosis, disease progression or progression or relapse of suspected lymphoid malignancy). Indication:

☐ Suspected Lymphoid Disorder: _____

NOTE: The requesting clinician is required to ensure the patient understands the indications, benefits and limitations of NGS testing. This includes the possibility of incidental findings including results that may be suggestive of variants of germline origin. Germline variants can have significant implications for the patient and their family. Please contact the laboratory if additional information is required or to access our policy regarding the management of incidental findings.

INVOICING PROCEDURE

☐ Bill Hospital / Pathology Provider

☐ Bill Medicare (Patient **must sign** below. Non-rebatable components will be billed to the pathology provider unless specified)

MEDICARE ASSIGNMENT (Section 20A of the Health Insurance Act 1973)

I offer to assign my right to benefits to the approved pathology practitioner who will render the request pathology service(s) and any eligible pathologist determinable service(s) established as necessary by the practitioner.

Patient signature ✗ _____ Date _____

Or if patient unable to sign:

☐ *I authorise the approved pathology practitioner who will render the requested pathology services, and any further pathology services which the practitioner determines to be necessary, to submit my unpaid account to Medicare, so that Medicare can assess my claim and issue me a cheque made payable to the practitioner, for the Medicare benefit. Verbal consent was provided (no signature available)*

☐ Bill Patient (Patient **must sign** below. Please contact laboratory if you would like more information on pricing)

Patient signature ✗ _____ Date _____

I agree to accept responsibility for the full payment of this test

PRINT

Level 6, Xavier Building - St Vincent's Hospital Victoria Street, Darlinghurst NSW 2010

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ADDRESS & CONTACT DETAILS

Please send specimen and completed form to:

SYDPATH SPECIMEN RECEPTION - LEVEL 6, XAVIER BUILDING

ST VINCENT'S HOSPITAL VICTORIA ST DARLINGHURST NSW 2010

Telephone: +61 2 8382 9269/9266

Fax: +61 2 8382 2943

Email: molecular.haem@svha.org.au

Website: www.sydpath.com.au

MYELOID PANEL 49 GENES:

ABL1, ANKRD26, ASXL1, BCOR, BCORL1, BRAF, CALR, CBL, CEBPA, CSF3R, DDX41, DNMT3A, ETNK1, ETV6, EZH2, FLT3, HRAS, GATA1, GATA2, IDH1, IDH2, IKZF1, JAK2, KIT, KRAS, MPL, MYD88, NF1, NPM1, NRAS, PHF6, PPM1D, PRPF8, PTPN11, RAD21, RUNX1, SETBP1, SF3B1, SH2B3, SRSF2, STAG2, STAT3, STAT5B, TET2, TP53, U2AF1, UBA1, WT1, ZRSR2*

** FLT3-ITD variants may not be reliably detected by this assay. An orthogonal assay should be separately ordered to test for these variants.*

LYMPHOID PANEL 61 GENES:

ABL1, ARID1A, B2M, BCL2, BIRC3, BRAF, BTK, CARD11, CCND1, CCND3, CD19, CD28, CD79A, CD79B, CDKN2A, CREBBP, CXCR4, DDX3X, DNMT3A, EGR2, EP300, ETV6, EZH2, FBXW7, FOXO1, FYN, ID3, IDH2, IRF8, JAK3, KLF2, KMT2D, KRAS, MAP2K1, MEF2B, MYC, MYD88, NFKBIE, NOTCH1, NOTCH2, NRAS, PAX5, PIM1, PLCG1, PLCG2, PTEN, PTPRD, RHOA, RPS15, SF3B1, SGK1, SOCS1, STAT3, STAT5B, STAT6, TCF3, TET2, TNFAIP3, TNFRSF14, TP53, XPO1

Patient Information: Next Generation Sequencing (NGS) for Blood Disorders

What are genetic tests for blood disorders?
DNA, located in our cells, contains genes that provide instructions for our body's development and maintenance. As cells constantly renew, errors, or "mutations" can occur.

Not all mutations cause a problem, but some mutations can lead to blood disorders like leukaemia and lymphoma. Your haematologist may recommend testing to look for specific mutations associated with blood disorders in your cells.

What is Next Generation Sequencing (NGS)?
NGS is a test that looks for many mutations at once. Older methods were only able to test one gene or one mutation at a time. There are many reasons to use this test, but also some limitations and risks you should know about.

Why is NGS done for blood disorders?
There are four main reasons NGS may be done in blood disorders:

1. **To help diagnose a blood disorder.**
2. **To assist in predicting how a blood disorder may behave, including chances of response to different treatments and survival.**
3. **To identify mutations that can be targeted with specific treatments.**
4. **To monitor treatment response over time (for certain mutations).**

Your doctor will use these results, along with other tests, to investigate and manage your blood disorder.

What are the benefits of NGS?
Testing many genes at once helps doctors get a more complete picture of your blood disorder, making it easier to provide advice and identify the best treatment specifically for you.

What are the possible results of an NGS test?

1. **No mutations identified:** Finding no mutations doesn't completely exclude a blood disorder, as NGS can't test every gene
2. **Relevant mutation identified:** A mutation is found which is known to have an association with a blood disorder.
3. **Suspected inherited mutation identified**: Some people are born with mutations. This type of mutation may be passed on to your children or found in other family members.
4. **Mutation of uncertain significance identified**: Sometimes mutations are identified that are not known to be associated with disease, or their role in disease is unclear.

What are the limitations of NGS?
NGS doesn't check every gene. It mainly looks for mutations commonly seen in people with blood disorders. That means you might need other more specific genetic tests to help your haematologist manage your condition.

Are there any risks associated with NGS?
It is possible that NGS may identify a mutation you were born with or have inherited. If an inherited mutation is suspected based on your results, your haematologist may recommend further testing for both you and your family. They may also refer you to a special counselling service for further advice and / or testing.

Not everyone wants to know their genetic information. It is important to discuss your wishes with your haematologist before having this test.

How is NGS testing done?
You will be asked to provide a blood, bone marrow or biopsy sample for testing. If an inherited mutation is suspected, skin or hair samples may be required.

Will it cost anything?
Medicare covers the cost of this test in most cases (that is, there is no cost to you). If for some reason you will incur any costs or are not entitled to Medicare, your haematologist will discuss this with you prior to testing.

How is my genetic information protected?
Your test results are kept secure, following strict Australian privacy rules. Your results are confidential and will only be used by health care staff directly involved in your care. Your results will not otherwise be shared except with your explicit consent, unless the law requires otherwise. Further information on how your information is kept private and secure can be provided by the SydPath laboratory.

How long will it take to get results?
The results should be ready about two weeks after the lab receives your sample. It's best to go over the results with your haematologist at your next appointment since genetic test results can be complicated.

What if I have more questions?
For any clinical questions, talk to your doctor. If you have questions about the NGS testing in general, you can email the SydPath laboratory: molecular.haem@svha.org.au