NewGene
Next Generation Diagnostics

NewGene Clinical Services

Utilising the latest technologies to deliver molecular diagnostics and genomic services, NewGene is able to offer significant benefits leading to improved clinical delivery:

- **TURNAROUND** - Clinically relevant turnaround times
- **RESPONSE** - Emerging clinical need can be met with rapid development of new tests
- **SAVINGS** - The high throughput capacity of the technology gives rise to savings in both time and cost
- **QUALITY** - An excellent track record in external quality assessment
- **FLEXIBILITY** - NewGene can develop a bespoke service to meet your specific needs.

All results and interpretation are reported by an HCPC registered Clinical Scientist.
NewGene also works closely with the NHS and pharmaceutical companies on the validation of biomarkers and the development of diagnostic tests.

Haemato-Oncology

NewGene's expertise and service delivery are applied to the support of haematology services with tests available for both blood based cancers and myeloproliferative diseases.

BCR-ABL testing for patients with Chronic Myeloid Leukaemia

The diagnostic hallmark of chronic myeloid leukaemia (CML) is the presence of the Philadelphia chromosome, which results in the fusion of the *BCR* gene on chromosome 22 with the *ABL1* gene on chromosome 9. Long term monitoring of the expression level of the fusion gene reflects the effectiveness of drug treatment and rapidly identifies any relapse in the disease.

CML mutation testing

A small number of patients develop resistance to the standard Imatinib treatment as the *BCR-ABL* gene acquires further mutations such that the drug is no longer able to recognise the mutant protein. Such patients require alternative treatments.
The NewGene CML mutation test includes:

- The multiplex assay detects 20 different mutations in the *BCR-ABL* fusion gene including T315I (c.944C>T)
- The test will detect 90% of patients with a CML mutation
- The remaining 10% of mutations, made up of approximately 50 further mutations are not included in this assay.

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JAK-2 and MPL mutation testing

Janus-Kinase 2 (JAK-2) is a protein kinase that plays an important role in normal haemopoietic growth factor signalling. A point mutation (V617F, c.1849G>T) in exon 14 and additional mutations in exons 12 and 16 of the *JAK-2* gene and exon 10 of the *MPL* gene are linked with myeloproliferative disorders.

There is some evidence that the level of the V617F mutation is related to the progress of disease in myeloproliferative disorders. Quantitative analysis, therefore, may have clinical utility in monitoring disease progression. The NewGene test includes:

- V617F mutation and mutations in exon 12 of *JAK-2*
- Mutations in exon 10 of *MPL* at codons 505 and 515
- Quantitative for *JAK-2* V617F levels between 5% and 100%.

Clonality Testing

Standard histopathological diagnosis of malignant lymphoma can be challenging. The use of a PCR based assay for the identification of clonal populations is a valuable tool as in principle B- and T-cell lymphomas are clonal diseases.

The PCR based test amplifies targeted regions of DNA in the conserved regions of antigen receptor genes that lie on either side of an area within the V-J region. It is this region where programmed genetic rearrangements occur during maturation of all B and T lymphocytes.

The antigen receptor genes that undergo rearrangement are the immunoglobulin heavy chain IGH and light chain genes (IGK) in B-cells, and the T-cell receptor genes TCR in T-cells.
The NewGene test includes:

- Test in either or both of the IGH and TCR genes
- Standardised PCR based test
- Highly sensitive differential fluorescence detection
- Relative quantification.

Other diagnostic testing in haematology

The presence of specific mutations can be diagnostic for the following disorders:

- The V600E (c.1799T>A) mutation in the *BRAF* gene is diagnostic for Hairy Cell Leukaemia
- The D816V (c.2447A>T) mutation in the *cKIT* gene is diagnostic for mastocytosis.

These mutations can be detected in the NewGene *BRAF* and *cKIT* test respectively.

For more information visit our website:
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