NHS
North West
NHS Genomic Laboratory Hub

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Dear Colleague,

Change to *BCR::ABL1* testing methodology from May 2023

We are writing to inform you of changes to the *BCR::ABL1* testing methodology utilised by the Haemato-Oncology team at Manchester Genomic Diagnostics Laboratory, North West-Genomic Laboratory Hub (NW-GLH) for patients with CML and Ph+ acute leukaemia.

Testing will move from using in-house designed primers and probes to using commercial kits, supplied by 3B BlackBio Biotech India Ltd (operating as TRUPCR® Europe Ltd). This change means that new diagnosis samples will undergo a qualitative screen for *BCR::ABL1* Major (e13a2 and e14a2), Minor (e1a2) and Micro (e19a2) fusion transcripts and a qualitative report will be issued identifying the transcript type(s) present.

The use of this commercial kit increases the repertoire of transcript types screened for at diagnosis, with the inclusion of e19a2 (µ-BCR). Any sample found to be µ-BCR positive will be forwarded to West Midlands Regional Genetics Laboratory for quantitation. Baseline level quantitation for Major-BCR positive patients will no longer be performed as the international scale (IS) reports against a standardised baseline from the IRIS study; a qualitative report only will be issued for a diagnostic M-BCR sample. We will continue to perform baseline quantification for minor-BCR positive patients following the qualitative screen in the absence of IS calibration in this subtype.

Quantitative testing will only be performed on known patients, therefore detailed clinical information including the transcript type will be essential for referrals from patients who have not previously been monitored at Manchester Genomic Diagnostics Laboratory.

The new quantitative M-BCR assay, which is internally calibrated to the international scale via a secondary WHO standard, has been validated against the previous in-house version to ensure no difference in MRD values was obtained from known positive samples at different disease levels. If you would like more information, please contact michelle.obrien@mft.nhs.uk / 0161 276 4137.

For those users referring patients through HIVE, please use the following M codes relevant to the clinical scenarios:

Disease	Clinical scenario	M code
AML	Suspected *BCR::ABL1* positive AML (qualitative screen)	M80.13
	Known *BCR::ABL1* positive AML (quantitative test)	M80.48
	Known *BCR::ABL1* positive AML, tyrosine kinase domain (TKD) mutation testing	M80.8
CML	Suspected or newly diagnosed CML *BCR::ABL1* multiplex (qualitative screen)	M84.1
	Known CML p190 or p210 (quantitative test)	M84.2
	Known CML rare variant (quantitative test)	M84.23
	Known CML, tyrosine kinase domain (TKD) mutation testing	M84.8
MPN	Suspected MPN, *BCR::ABL1* multiplex (qualitative screen)	M85.11
ALL	Suspected or newly diagnosed ALL *BCR::ABL1* multiplex (qualitative screen)	M91.8
	Known *BCR::ABL1* positive ALL p190 or p210 (quantitative test)	M91.9
	Known *BCR::ABL1* positive ALL rare variant (quantitative test)	M91.79
	Known *BCR::ABL1* positive ALL, tyrosine kinase domain (TKD) mutation testing	M91.11
Acute Leuk other	Suspected acute leukaemia, *BCR::ABL1* multiplex (qualitative screen)	M89.8
	Known *BCR::ABL1* positive acute leukaemia p190 or p210 (quantitative test)	M89.13
	Known *BCR::ABL1* positive acute leukaemia rare variant (quantitative test)	M89.106
	Known *BCR::ABL1* positive acute leukaemia, tyrosine kinase domain (TKD) mutation testing	M89.17
MDS/MPN	Suspected MDS/MPN, *BCR::ABL1* multiplex (qualitative screen)	M224.10

Yours sincerely,

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