
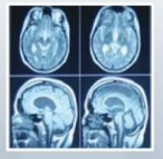


September 26, 2016

QUANTITATIVE MOLECULAR TESTING for BCR-ABL1 mRNA TRANSCRIPTS

Effective: October 3, 2016

The Hematopathology Molecular Laboratory is shifting the Q-PCR assay for BCR-ABL1 follow-up measurement to a more robust methodology and instrument platform, effective October 3, 2016. The reporting format for Q-PCR testing will also change, to meet new clinical and regulatory standards of care. There will be no change in turnaround time or specimen requirements (2 EDTA tubes).

BCR-ABL1 transcripts with a p210 breakpoint (b2a2/e13a2, b3a2/e14a2) will be reported as a qualitative result (positive or negative), the normalized ratio (BCR-ABL1 copy number/ABL1 copy number), and the International Scale (IS) score expressed as a percentage of the IRIS trial standardized diagnostic baseline. The revised limit of detection for this assay will be 4 copies of BCR-ABL1 mRNA per microliter of cDNA, or an IS score of 0.0019%, which will allow reporting of values according to the standardized criteria for a 4.5 log molecular response ($MR^{4.5}$).

BCR-ABL1 transcripts with a p190 breakpoint (e1a2) will be reported as a qualitative result (positive or negative) and the normalized ratio (BCR-ABL1 copy number/ABL1 copy number). The revised limit of detection is 17 copies BCR-ABL1 mRNA per microliter of cDNA, or a normalized ratio of 4.17×10^{-4}.

This test utilizes a laboratory-developed assay methodology which has been previously reported in the scientific literature, and locally validated in the Hematopathology Molecular Laboratory for clinical use.

Any questions regarding this assay or reporting format should be referred to:
Dr. Michel Nasr (Pager: 204-932-1219) e-mail mnasr@dsmanitoba.ca
Dr. Arshad Ahsanuddin (Pager: 204-932-0562) email aahsanuddin@dsmanitoba.ca
Dr. Carmen Morales (Pager: 204-932-0203), email cmorales@dsmanitoba.ca

References:

1. Jennings L, *et al.* Recommended Principles and Practices for Validating Clinical Molecular Pathology Tests. *Arch Pathol Lab Med.* 2009;133(5):743-755
2. Gabert L, *et al.* Standardization and quality control studies of 'real-time' quantitative reverse transcriptase polymerase chain reaction of fusion gene transcripts for residual disease detection in leukemia - a Europe Against Cancer program. *Leukemia*, 2003;17(12):2318-2357.
3. Gabert J, *et al.* Evaluation of candidate control genes for diagnosis and residual disease detection in leukemic patients using 'real-time' quantitative reverse-transcriptase polymerase chain reaction (RQ-PCR) - a Europe against cancer program. *Leukemia*. 2003;17(12):2474-2486.
4. Bradford S, *et al*. "Desirable performance characteristics for BCR-ABL measurement on an international reporting scale to allow consistent interpretation of individual patient response and comparison of response rates between clinical trials." *Blood. 2008*;112(8):3330-8.

dsmanitoba.ca

Suite 1502 – 155 Carlton Street
Winnipeg, Manitoba
R3C 3H8

155, Rue Carlton, suite 1502
Winnipeg (Manitoba)
R3C 3H8

T 204.926.8005
1.866.320.8796 – Toll-free Manitoba only
F 204.940.1761