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Medical Director: Denise A. Wells, MD

HLID#: **PATIENT NAME:**
PATIENT ID#: **DOB:** **SEX:**
NPI: **ORDERING PHYSICIAN:**
SPECIMEN TYPE:
COLLECTION DATE: **RECEIPT DATE:**
REPORT DATE: **ICD Code:** **UNITS:** 1 BCR-ABL RQ-PCR
CLINIC ID#:
CPT: 81206/81207
ACCOUNT:

Name I.D.

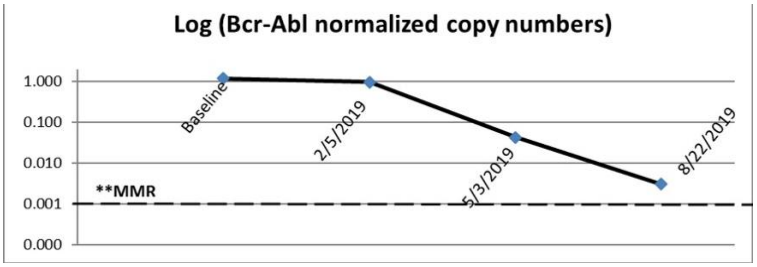
MOLECULAR ANALYSIS REPORT

Specimen Type:

Clinical History/Indications: A xx–year-old fe/male with a clinical history of CML.

Bcr-Abl RT-PCR Results: LOW POSITIVE

Date	HLID#	Specimen	Bcr-Abl NCN	% Residual Disease (IS*)	% Reduction	Log Reduction
Baseline		PB	1.187	~100.0	Baseline	Baseline
2/5/2019		BMA	0.970	96.81	18.28	0.1
5/3/2019		PB	0.043	4.30	96.37	1.4
8/22/2019		PB	0.003	0.30	99.75	2.6



NCN (normalized copy numbers): 0.003 (0.30% residual disease IS*)

Quantitative assay units: BCR/ABL transcript levels are reported as a ratio of fusion gene transcript / ABL reference gene transcript according to the 'Europe Against Cancer Program' standardized protocol. *International Scale

Analysis/Conclusions:

The specimen tested low positive for BCR/ABL fusion transcript which is associated with the presence of the t(9;22) translocation resulting in a small derivative chromosome 22 known as Philadelphia (Ph) chromosome, associated with CML, ALL and/or AML.

- **The quantitative BCR-ABL NCN value of 0.003 (0.30% residual disease IS*) is reduced by 99.75 % (log reduction 2.6) in comparison to the patient baseline specimen (xxxxx).**
- Clinical and histological correlation is required for definitive diagnosis.

The leukemia cell line K562 has a Bcr-Abl NCN value of 1.000 which approximately equals 100 % positivity in comparison to FISH analysis.

Control gene amplification indicated adequate RNA quality in this specimen.

This multiplex test can detect the m-bcr (minor breakpoint cluster region) e1-a2 transcript encoding the 190 kDA (p190) protein and the M-bcr (major breakpoint cluster region) b2a2 (e13a2) and b3a2 (e14a2) transcripts encoding the 210 kDA (p210) chimeric tyrosine kinase protein with a sensitivity level of > 1 in 10e5 transcripts (0.001 %). Single fusion transcript levels for m-bcr and M-bcr only can be analyzed upon request.

Method:

RNA is isolated from the sample provided and converted into cDNA using reverse transcriptase and amplified by real-time polymerase chain reaction (RQ-PCR) for the major and minor BCR-ABL fusion genes. Primer sequences were used according to the 'Europe Against Cancer Program' standardized protocol [Gabert J et al. Leukemia 2003 (17): 2318-2357]. According to the randomized trial (> 1000 CML patients) by Hughes et al [New England Journal of Medicine, 2003, 349: 1423-1432] a *log reduction* of *3 or higher* of the quantitative BCR-ABL values by 12 months of therapy is associated with negligible risk of disease progression during the subsequent 12 months when patients are treated with Gleevec. *Alignment with 'international scale' materials were used to allow consistent and comparable quantitative data for routine monitoring of assay performance using the international standard (*IS) [White HE et al Blood. 2010 Aug 18]. **Residual disease ≤ 0.1% IS has been defined as a Major Molecular Response (MMR)** [Hughes et al. Blood 2006; 108:28-37]. Although molecular testing is highly accurate, rarely false-positive and false-negative diagnostic errors may occur. DW/MRL/BZ

Electronically signed by: Barbara K. Zehentner, Ph.D., HCLD (ABB), Director of Molecular Analysis - 08/23/2019 17:31 PT