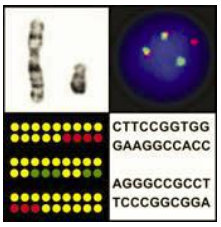

UW Cytogenetics and Molecular Genetics Services

Information for Medical Providers, July 2020

UPDATED ASSAY: Quantitative RT-PCR for *BCR-ABL1* p210 (Major) and p190 (minor) fusion transcripts

We're excited to announce the transition of our Major and minor *BCR-ABL1* assays to the FDA-cleared QuantideX® assay. The QuantideX® qPCR assay is a robust and precise test for the quantification of *BCR-ABL1* and *ABL1* transcripts in total RNA extracted from whole blood. We have additionally validated this test to include bone marrow specimens (see specimen types below). The Major (p210) assay is intended to measure *BCR-ABL1* to *ABL1*, expressed as a log molecular reduction (MR) from a baseline of 100% on the International Scale (IS), in t(9;22) positive CML patients during monitoring of treatment with Tyrosine Kinase Inhibitors (TKIs). The minor (p190) assay measures *BCR-ABL1* to *ABL1*, expressed as a percent ratio (% normalized copy number) in t(9;22) positive CML and ALL patients. These changes are scheduled to go into effect **August 10, 2020**. For more information please call 608-262-0402.

WHAT IS DETECTED (no change from previous assays)

- MAJOR (p210): two *BCR-ABL1* fusion transcripts (e13a2 and e14a2) and *ABL1* (an endogenous control)
- MINOR (p190): one *BCR-ABL1* fusion transcript (e1a2) and *ABL1* (an endogenous control)

SPECIMEN TYPES (no change from previous assays)

- Whole blood in EDTA anticoagulant (purple top) tube, ≤ 72 hours old : **preferred**
- Bone marrow in EDTA anti anticoagulant (purple top) tube, ≤ 72 hours old: acceptable
- Whole blood or bone marrow in sodium heparin anticoagulant (green top) tube, ≤ 72 hours old: acceptable, but not preferred

MAJOR (p210) LINEAR RANGE AND ANALYTIC SENSITIVITY (improved from previous assay)

%IS[1]	100.0 (baseline)	**50.0**	**32.0**	**10.0**	**3.2**	**1.0**	**0.32**	**0.1 (MMR[3])**	**0.032**	**0.01 (DMR[4])**	**0.0032**	**0.002 (LOD[5])**	0.001
MR[2]	0.0	**0.3**	**0.5**	**1.0**	**1.5**	**2.0**	**2.5**	**3.0**	**3.5**	**4.0**	**4.5**	**4.7**	5.0

The linear range of this assay is in **bold red font**. Only specimens within the liner range are able to be accurately quantified (limit of quantitation, or LOQ). Specimens with values above or below the LOQ cannot be accurately quantified; therefore, they will be reported as "positive (above LOQ)" or "low positive" respectively (see Table 1 below).

1. %IS is the percent ratio of *BCR-ABL1* to *ABL1* expressed on the International Scale. This was previously referred to as "IS-NCN".
2. Molecular reduction (MR) is a logarithmic decrease from the common baseline of 100% IS or MR0. This was previously referred to as "Log reduction".
3. MMR= Major molecular response
4. DMR= Deep molecular response
5. LOD= Limit of detection (analytic specificity)

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TABLE 1. UPDATED RESULTS REPORTING FOR MAJOR (p210) ASSAY

***BCR-ABL1* fusion transcript**	**Previous result**	**Updated result**
Detected within limit of quantitation (LOQ)	POSITIVE	POSITIVE
Report includes:	% residual disease (IS-NCN) Log reduction	%IS[1] Molecular reduction (MR)[2]
Not detected	NEGATIVE	NEGATIVE
Report includes:	Copy number of *ABL1* and molecular response status	Sufficient *ABL1* to ensure test LOD is maintained.
Detected below the limit of quantitation (LOQ)	LOW POSITIVE	LOW POSITIVE
Report includes:	Percent residual disease (IS-NCN), Log reduction (extrapolated beyond quantifiable range)	Detected below LOQ (<0.002%IS/>MR4.7)
Detected above the limit of quantitation (LOQ)	N/A[3]	POSITIVE
Report includes:	N/A[3]	Detected above LOQ (>50%IS/<MR0.3)

1. %IS is the percent ratio of BCR-ABL1 to ABL1 expressed on the International Scale. This was previously referred to as “IS-NCN”.
2. Molecular reduction (MR) is a logarithmic decrease from the common baseline of 100% IS or MR0. This was previously referred to as “Log reduction”.
3. The previous assay did not have an upper LOQ specified.

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