

Non-NAACCR Standard Data Items Biomarkers

Comparative Effectiveness Research Project

NHSCR

PO Box 186

Hanover, NH 03755

(603) 653-6630

<http://dms.dartmouth.edu/nhscr>

Types of BCR-ABL Biomarkers

There are four types of BCR-ABL biomarkers:

- Cytogenetic
 - ❑ Karyotyping
 - ❑ Conventional cytogenetics
 - ❑ Philadelphia chromosome analysis
 - ❑ Chromosomal banding analysis
- Fluorescence in Situ Hybridization (FISH)
- Qualitative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR Qual)
- Quantitative Reverse Transcriptase Polymerase Chain Reaction (RT-PCR Quant)
 - ❑ Real time RT-PCR
 - ❑ BCR-ABL Gene Rearrangement Analysis

Biomarkers: BCR-ABL

- Required for Chronic Myeloid Leukemia (CML)
- Refers to all BCR-ABL transcriptions, including BCR-ABL2
- Biomarker analysis may be used to monitor disease response to therapy and relapse
- Record results of analysis for BCR-ABL t(9;22) (q34;q11) at time of initial diagnosis
- If multiple tests done, use results closest to the diagnosis date

**DO NOT RECORD TEST RESULTS AFTER
INITIATION OF TX**

Coding Instructions

Code	Definition
000*	Negative result OR Not applicable (e.g. information not collected for this case) OR Test not done (e.g., test not ordered and was not performed) OR Unknown information (e.g., not documented in source record) OR Test ordered (e.g., results not in source records)

010 Positive: code only for cytogenetic, FISH, RT-PCR Qual
**used in combination with the corresponding BCR-ABL related date and date flag variables to substantiate reason for coding "000"*

For RT-PCR Quant, record the exact ratio*:

001-998	Ratio of 0.001 to 0.998 (enter exact ratio)
999	Ratio greater than or equal to 0.999

**Units reported as ratio of fusion gene transcript to β -2-microglobulin reference gene transcript.*

Biomarkers: BCR-ABL Date and Date Flag

- Records the date of the BCR-ABL test
- Use date that specimen was obtained and sent for analysis, NOT the report date
- Again, do not record results of this test after initiation of treatment.
- Date Flags: Explains why there is no appropriate value in date fields

Biomarkers: BCR-ABL Date Flags

Code	Definition
10	No information
11	Not applicable
12	Value applicable but unknown
15	Information not available now, but expected later
Blank	Valid date provided, or date not expected to have been transmitted

Comment: This is consistent with part of the initiative of the transformation from the old NAACCR date standards to interoperable dates.

Thank You

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