• Based on recommendations from literature and experts in the field, reports should contain at minimum:

  – Information on specimen tested and pre-analytical parameters
  – Information on test, including key analytical performance parameters
  – Information on acceptance criteria
  – Raw results and IS percent ratio
  – Information necessary to understand how the test is performed and how to interpret the data
  – Clear explanation of terminology
  – All historical data (when available) to further help data interpretation
Limit of detection for quantitative result (LLOQ)
Value of IS conversion factor
Graphical representation of historical data showing MMR cutoff (0.1% on the IS)
Endogenous control gene used
Results validity criteria
Raw results
Percent ratio on the IS
Method used for standardization
Tabular representation of historical data including IS % ratios, CF values and other information not captured in the graphic

Description of test and results interpretation

Explanation of terms used in report
Other Considerations

• Samples with no BCR-ABL1 signal should
  – Not be reported if endogenous control (EC) copy number < cutoff value
  – Be reported as “BCR-ABL1 not detected” if EC copy number > cutoff value (not as “negative for BCR-ABL1”)

• Samples with BCR-ABL1 above limit of detection (LOD) but below limit of quantification (LOQ) should be reported as “positive but below LOQ” or “positive but below linear range”

• For samples with BCR-ABL1 above LOQ, interpretation relative to clinically validated landmarks (e.g. MMR or MR³.0) can only be done for percent ratios on the IS

• Deep molecular responses characteristic of second generation TKIs can only be interpreted for percent ratios on the IS and in the context of ABL1 copy number:
  – MR⁴.0 = either detectable disease <0.01% on the IS or undetectable BCR-ABL1 in cDNA with >10,000 ABL1 copies
  – MR⁴.5 = either detectable disease <0.0032% on the IS or undetectable BCR-ABL1 in cDNA with >32,000 ABL1 copies


