CML patients receiving TKI therapy

- Every 3 months: BCR-ABL1 quantitative PCR [91065] to assess molecular response
- At 3 months: CBC to assess hematologic response
- At 6 months: Chromosome analysis [14600(X)] or FISH [12070(X)] to assess cytogenetic response. See Table 1. Repeat again at 12 months if no CCyR and again at 18 months if still no CCyR.

**Figure 3. Use of Laboratory Testing to Monitor Response to Tyrosine Kinase Inhibitor (TKI) Therapy in CML Patients**

This algorithm is intended as a guide for using Quest Diagnostics laboratory tests to monitor the treatment response to tyrosine kinase inhibitor therapy in CML patients and is based in part on previous recommendations and published literature. It is provided for informational purposes only and is not intended as medical advice. A physician’s test selection and interpretation, diagnosis, and patient management decisions should be based on his/her education, clinical expertise, and assessment of the patient.

CML indicates chronic myelogenous leukemia; TKI, tyrosine kinase inhibitor, PCR, polymerase chain reaction; FISH, fluorescence in situ hybridization; CCyR, complete cytogenetic response; IS, international scale; MMR, major molecular response; and CMR, complete molecular response.

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**CML patients receiving TKI therapy**

- **BCR-ABL1/ABL1 IS ratio ≤0.1%**
  - MMR or CMR; very low risk of disease progression
  - Monitor with BCR-ABL1 quantitative PCR [91065] every 3-6 months

- **IS ratio >0.1% at any time**
  - MMR not achieved or lost
  - Impact on progression risk unclear
  - IS ratio <10-fold ↑
  - High risk of progression

- **Any 1 of the following:**
  - Partial or no hematologic response at 3 months
  - No cytogenetic response at 6 months
  - Partial or no cytogenetic response at 12 or 18 months
  - Loss of response (hematologic or cytogenetic relapse)

**Resistance Workup**

- **ABL kinase domain mutation analysis [16029(X)]**
  - Any mutation
  - No mutations

- **Resistance to 1 or more TKI likely**
  - T315I
    - Resistance to imatinib, dasatinib, and nilotinib likely; consider other therapy

- **V299L, T315A, or F317L/V/I/C**
  - Resistance to imatinib and dasatinib likely; consider nilotinib

- **Y253H, E255K/V, or F359V/C/I**
  - Resistance to imatinib and nilotinib likely; consider dasatinib

- **Other ABL kinase domain mutations**
  - May respond to change or dose escalation of TKI

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