TP53 Mutation Testing Algorithm

Patient diagnosed with chronic lymphocytic leukemia
Peripheral blood, bone marrow, or frozen tissue* Order P53CA / Hematologic Neoplasms, TP53 Somatic Mutation, DNA Sequencing Exons 4-9

Are following conditions known and met?
- B-cell percentage adequate for testing
- White blood cell count >30,000
- Appropriate specimen volume

YES
TP53 testing performed to include the following:
- B-cell enrichment
- DNA extraction
- PCR amplification TP53 exons 4-9
- PCR product sequencing
- Analysis and interpretation

NO
Flow cytometry triage will be performed to verify diagnosis and determine the percentage of B cells**

Meets criteria?
- Diagnosis
- B-cell percentage adequate for testing
- White blood cell count >30,000
- Appropriate specimen volume

YES
TP53 testing performed to include the following:
- B-cell enrichment
- DNA extraction
- PCR amplification TP53 exons 4-9
- PCR product sequencing
- Analysis and interpretation

NO
TP53 testing not performed. Test order canceled

Patient diagnosed with other lymphoid or hematologic neoplasm
Peripheral blood, bone marrow, or frozen tissue* Order P53CA / Hematologic Neoplasms, TP53 Somatic Mutation, DNA Sequencing Exons 4-9

Are following conditions known and met?

Appropriate specimen volume

TP53 testing performed to include the following:
- DNA extraction
- PCR amplification TP53 exons 4-9
- PCR product sequencing
- Analysis and interpretation

Patient diagnosed with nonhematologic malignancy or suspected germline condition
To evaluate for the presence of somatic TP53 mutations for diagnostic or prognostic purposes order TP53Z / TP53 Gene, Full Gene Analysis

* Bone marrow specimens and frozen tissues will not have flow cytometry (CKP53) testing performed, nor will they be enriched for B cells
** CKP53 flow cytometry testing will be performed if:
1. Percentage of B cells is not known
   AND/OR
2. Flow cytometry testing has not been completed at Mayo Clinic within the past 4 days
   AND/OR
3. Flow cytometry testing has not been completed at client site within the past 7 days