Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Newly Diagnosed, Non-Metastatic (somatic)

When and what should be tested?

- Treatment eligible
- Stage IB-IIIA
- Stage IIIA with local recurrence
- Newly diagnosed or local recurrence
- Tissue sample preferred
- Liquid biopsy if tissue sample is inadequate for further testing

FDA/NCCN approved*

- Stage IB-IIIA
  - EGFR (exon 19 or L858R)
  - PD-L1
  - ALK rearrangement

Emerging

- Comprehensive NGS panel
  - Sequential single gene testing not preferred due to likelihood of running out of tissue
- MRD

*Prior to finalizing plans for treatment, it is essential to follow approved testing recommendations and await test results

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Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Advanced/Metastatic Disease at Initial Diagnosis (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C or Stage IV
- Test at initial work-up
- Tissue sample preferred for initial testing
- Peripheral blood when insufficient tissue

FDA/NCCN approved*

- EGFR gene mutations
- ALK
- ROS1
- BRAF/ BRAF V600E
- KRAS / KRAS G12C
- NTRK 1/2/3**
- MET Exon 14 skipping
- c-MET/MET (IHC)
- RET
- PD-L1 via IHC
- HER 2 IHC
- TMB
- dMMR
- NRG1
- FGFR alterations

Emerging

- High-level MET amplification
- FGFR alterations

*Prior to finalizing plans for treatment, it is essential to follow approved testing recommendations and await test results

***When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Advanced/Metastatic Disease at Time of Disease Progression (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C or IV
- Test at initial work-up
- Tissue biopsy preferred
- Peripheral blood when insufficient tissue

FDA/NCCN approved

- If not completed initially, complete comprehensive NGS panel via tissue biopsy and/or liquid biopsy*
- If patient was on a first-generation targeted therapy and progresses, consider testing again

Emerging

- n/a

*All NGS panels should include FDA-approved and clinically supported biomarkers including, but not limited to, EGFR (T790, exon 19-21), ALK, ROS1, PD-L1, TMB, dMMR, BRAF, KRAS G12C, RET, MET, NTRK, and HER2 mutation. When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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Personalized Medicine testing recommendations for:

NSCLC - Adenocarcinoma, Large Cell, NOS

Advanced/Metastatic Disease at Time of Disease Progression after Prior Therapy (somatic)

When and what should be tested?

- Treatment eligible
- Stage IV
- After failure of prior therapies
- Tissue biopsy preferred
- Peripheral blood when insufficient tissue

FDA/NCCN approved

- If patient was on a first-generation targeted therapy and progresses, consider testing again
  - EGFR T790M, exon 19-21
  - MET
  - BRAF
  - KRAS G12C
  - HER2 mutation

Emerging

- Comprehensive NGS panel via tissue
- C797S
- Cell cycle gene amplifications
- PIK3CA

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Personalized Medicine testing recommendations for:

NSCLC - Squamous

Newly Diagnosed, Non-Metastatic (somatic)

When and what should be tested?

- Treatment eligible
- Stage IB-IIIA
- Newly diagnosed or upon local recurrence
- Tissue sample preferred
- Liquid biopsy if tissue sample is inadequate for further testing

FDA/NCCN approved*

- Stage IB- IIIA
  - EGFR (exon 19 or L858R)
  - PD-L1
  - ALK rearrangement

Emerging

- Consider genomic testing
- NGS panel including PIK3CA, dMMR, and MSI
- MRD

*When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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Personalized Medicine testing recommendations for:

NSCLC - Squamous

Advanced/Metastatic Disease (somatic)

When and what should be tested?

- Treatment eligible
- Stage IIIB/C non-curative intent or Stage IV
- Newly diagnosed or upon progression to at least stage IIIB
- Tissue sample preferred
- Liquid biopsy if tissue sample insufficient for further testing

FDA/NCCN approved*

- EGFR
- ALK
- KRAS
- ROS1
- BRAF / BRAF V600E
- NTRK 1/2/3
- MET exon 14
- RET
- PD-L1
- HER 2 IHC
- dMMR
- MSI
- TMB
- NRG1
- FGFR alterations

Emerging

- PIK3CA

*When sufficient tissue is available (or even liquid biopsy is an option), comprehensive genomic profiling is appropriate to identify driver mutations

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