



(EXTERNAL)

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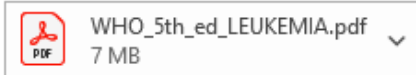
{EXTERNAL} RE: Concern regarding Acute Myelogenous Leukemia LCD



DAVID T YANG <dtyang@wisc.edu>

To NGS LCD Reconsideration-WELLPOINT (Shared Mailbox)

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Hi Virginia,

Thanks for your quick response! Please find attached a copy of the synopsis of the WHO 5th edition guidelines published in Leukemia.

I bring your attention to Table 8 in the WHO and Table 25 in the ICC.

Here, you can appreciate that mutations in any of the listed myeloid genes are diagnostic for AML myelodysplasia related. These mutations are not diagnostic for AML.

The vision of the WHO and ICC classification system is to emphasize that cytogenetics, FISH, and NGS mutational testing need to be performed.

This is very obvious to those of us who do hematopathology work every day, but difficult for anyone else to decipher. I stress that this is not a diagnostic test.

Trying to keep this brief, but there are many more reasons why requiring normal cytogenetics or core binding factor before approval of a test is a good idea. Your patients are suffering enough already and do not need this added insult.

Thank you for your attention,

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