

SAMPLE FLOW CYTOMETRY / MOLECULAR (FISH) REPORT

DIAGNOSIS:

ABC Hospital #B05-1234

Bone marrow aspirate: Mantle cell lymphoma (see comments).

COMMENT

Flow cytometry identifies a neoplastic B cell population (colored red in histograms below) expressing lambda-restricted cytoplasmic light chains, intermediate CD19 and FMC7, bright CD20, low CD5 and CD38, and no significant CD10, CD23 or ZAP-70. This immunophenotype, in conjunction with the concurrent identification of the t(11;14) by FISH (see below), is diagnostic for mantle cell lymphoma. The neoplastic B cells represent about 58% of the total leukocytes by flow cytometry.

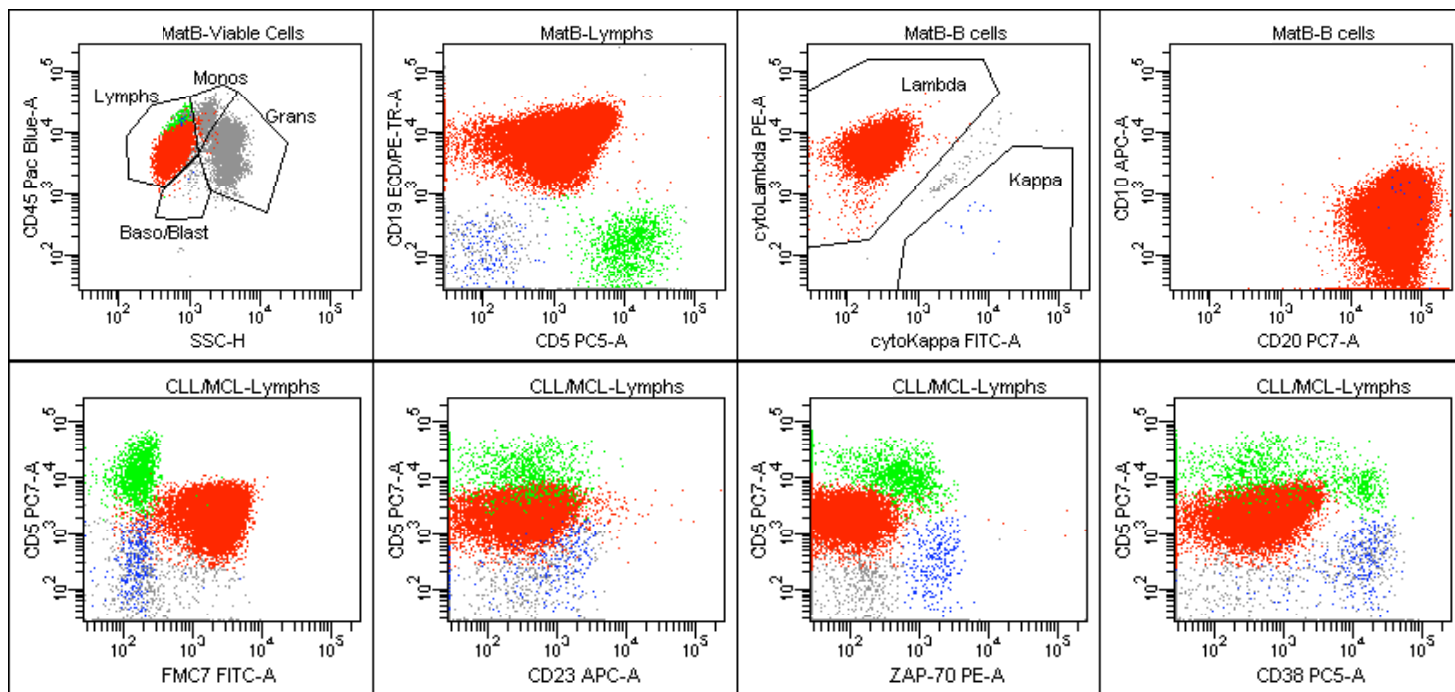
SPECIMEN INFORMATION:

A1 =B05-1234 bone marrow aspirate

RECEIVED FOR THE FOLLOWING:

Flow cytometry; t(11;14)(q13;q32) by FISH

RESULTS:



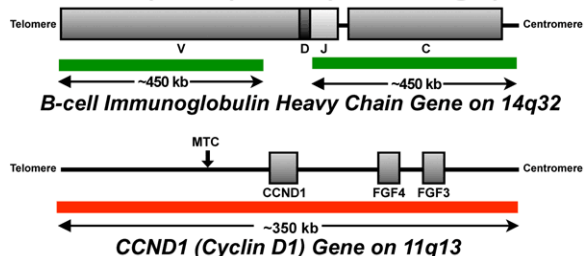
Immunophenotyping by flow cytometry after lysis of the erythroid cells reveals that the white blood cells consist of 62.5% lymphocytes, 0.5% monocytes, 31.5% maturing granulocytes, and 0.5% blasts. The lymphocytes consist of 92% B cells (CD19+), 3.8% T cells (CD3+), and < 1% NK cells (CD3-, CD7+).

ANTIBODIES USED: CD5, CD10, CD19, CD20, CD23, CD38, CD45, CD56, FMC7, kappa, lambda, and ZAP-70

FLUORESCENCE IN SITU HYBRIDIZATION FINDINGS:

Bone marrow is fixed in methanol-acetic acid. Cytospin cell preparations are made and cells are incubated, along with appropriate positive/negative controls, with a Vysis detection system, an analyte specific reagent containing 2 separate probes (see probe map below): the first to the IgH gene on 14q32 (SpectrumGreen), and the second to the cyclin D1 (CCND1) gene on 11q13 (SpectrumOrange). Quantitative analysis of t(11;14) FISH is performed using the MetaSystems™ Metafer scanning system on at least 200 cells. The threshold for positivity is established from a group of reactive and neoplastic cases which do not contain the translocation of interest. A positive case is defined as a case in which the mean number of dual fusion signals detected is 3 standard deviations above the mean of this negative control group. The threshold established for the (t11;14(q13;q32) FISH assay is 2.4% {3 standard deviations above the mean of a t(11;14) negative control group of cases; mean of t(11;14) negative cases is 0.7%}.

Map of Dual Color, Dual Fusion Probes for t(11;14) FISH (CCND1/IgH)



| Dual Color/Dual Fusion Probe Set | Result (% of cells positive) |
|----------------------------------|------------------------------|
| t(11;14)(q13;q32) | POSITIVE (10.0%) |

ELECTRONICALLY SIGNED

Todd S. Barry, M.D., Ph.D.
 Hematopathologist

In compliance with CMS regulations, the pathologist's signature on this report indicates that the case has been personally reviewed, and the diagnosis made or confirmed by the Pathologist.

NOTE: Some of the tests reported here may have been developed and performance characteristics determined by PhenoPath Laboratories. They have not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, the FDA has determined that such clearance or approval is not necessary. Pursuant to the requirements of CLIA, this laboratory has established and verified the accuracy and precision of all tests, and additional information about these tests is available upon request. PhenoPath Laboratories is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.