Fun with control charts: Monitoring neoplastic mutation frequencies over time

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INTRODUCTION

In order to ensure a laboratory assay is performing optimally and accurately results must be monitored over time. Per the College of American Pathologists (CAP) in general, for quality assurance purposes, results of any given assay must be reviewed monthly to assess for trends, outliers, and other possible problems to ensure timely investigation and/or remedy if needed. For molecular testing, choosing an appropriate method for monitoring can be difficult as the results of testing are not quantitative and the frequency of a positive finding may vary based of a patients clinical diagnosis and other demographic information.

METHODS

All result data collected on multiple single gene assays to evaluate various neoplastic processes from January 2014 (as the earliest possible date) to January of 2020 were reviewed. Using Excel 2010, the proportion of positive tests per month were examined utilizing control charts looking for trends, outliers, or other significant findings with control limits set to 2 standard deviations. The number of total tests per month was also plotted over time. Separate charts were made to evaluate recent data (January 2018-January 2020). The assays examined included: BRAF, CALR, CEBPA, EGFR, FLT-3, KIT, KRAS, MGMT, MPL, and NPM1.

RESULTS

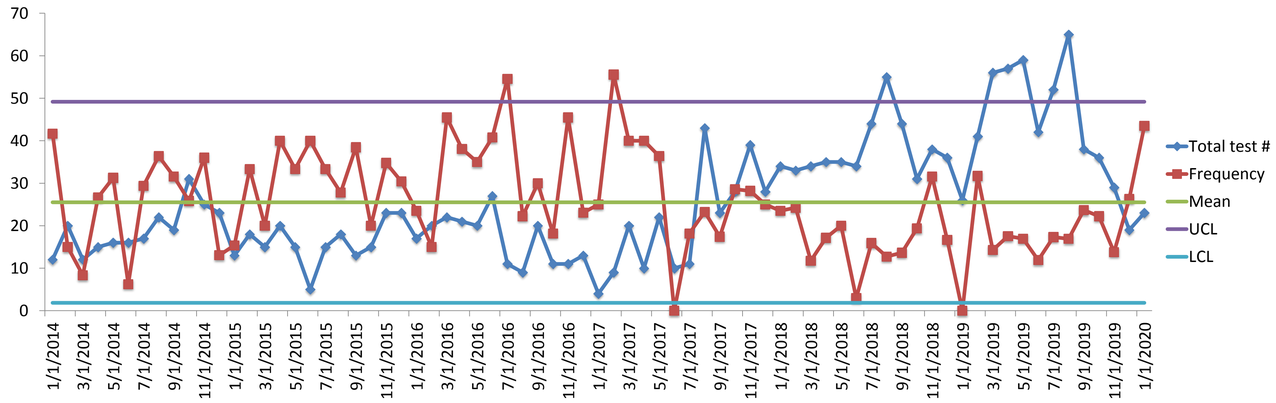

Figure 1: *BRAF* mutation frequencies starting in 2014

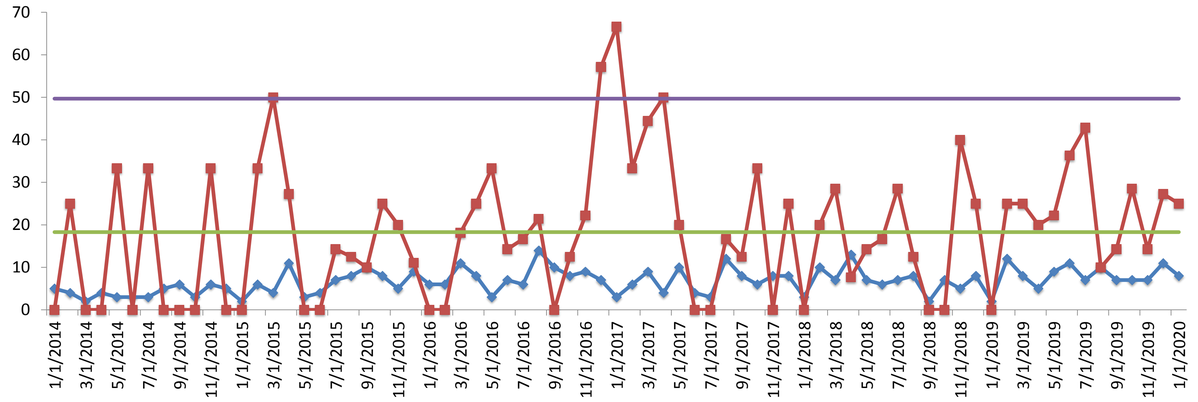

Figure 2: *KIT* mutation frequencies starting in 2014

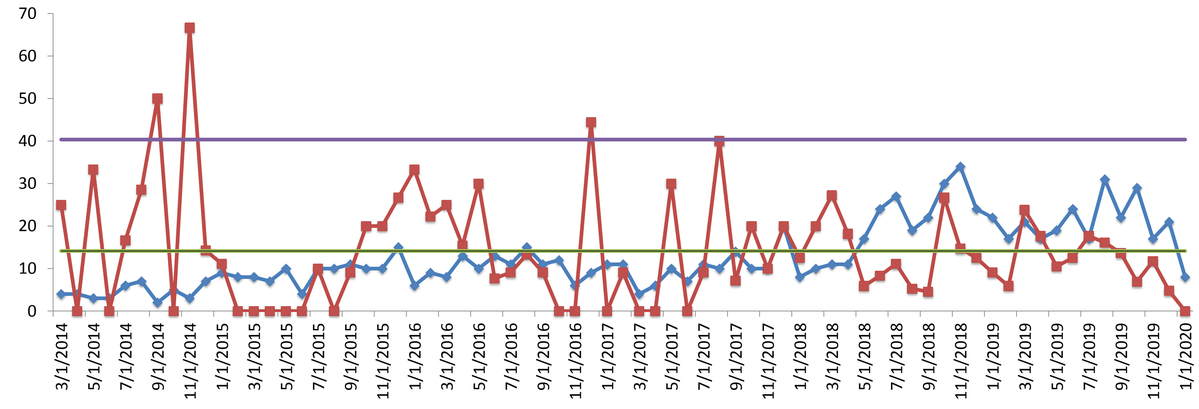

Figure 3: *FLT-3* internal tandem duplication mutation frequencies starting in 2014

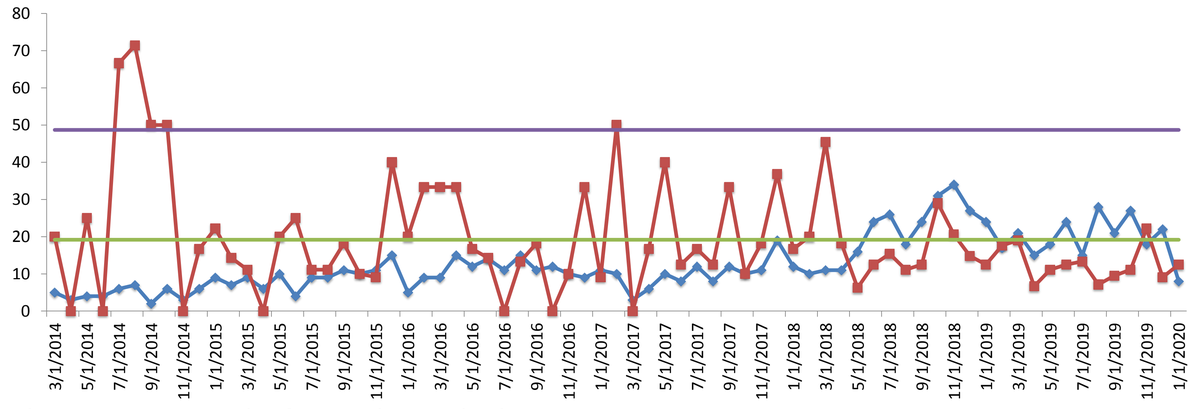

Figure 4: *NPM1* mutation frequencies starting in 2014

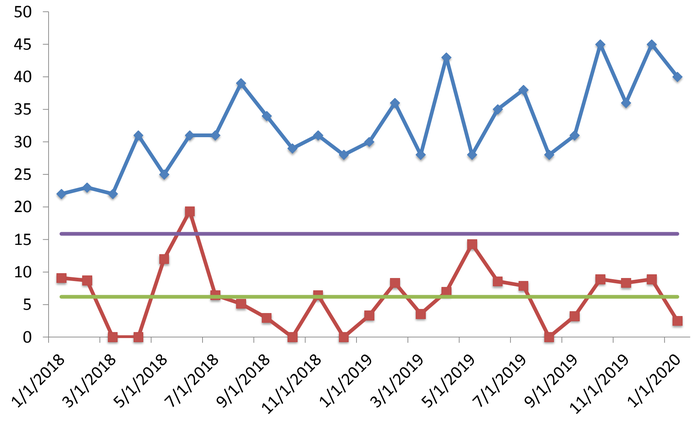

Figure 5: *CALR* mutation frequencies starting in 2018

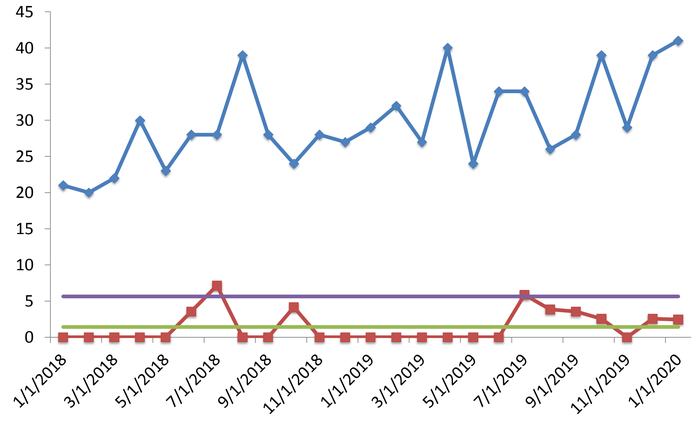

Figure 6: *MPL* mutation frequencies starting in 2018

CONCLUSIONS

Utilizing control charts for monitoring molecular assays can be very useful for test monitoring and quality assurance. Outliers and trends can be easily recognized allowing for rapid investigation and remedy if needed. Finally, review of this data gave us an opportunity to better understand the frequency of finding mutations, in the examined genes, in our local population.