

JAK2 Testing Platform and Reporting Changes

Date issued: June 28, 2021

Effective April 12, 2021, the JAK2 V617F mutation detection assay, previously performed using the Qiagen ipsogen JAK2 RGQ PCR kit was moved from the Cobas Z480 instrument to the Qiagen Rotor-Gene Q as the latter instrument has superior analytical sensitivity (0.042% vs 0.01%). Effective June 28, 2021, the JAK2 V617F mutation detection assay will be reported as follows:

Test result	Will be reported as
% Mutant Allele < 0.042% Copy Number = any	Qualitative Result; Negative % Mutant will NOT be provided Report Comments: Results should be correlated with clinical, morphological and other laboratory studies.
% Mutant Allele ≥ 0.042% Copy Number < 50	Qualitative Result; Positive % Mutant < 1 Report Comments: The allelic burden is less than 1%, and below the range of quantitation. Quantitative results of less than 1% Mutant allele are of undetermined clinical significance. Results should be correlated with clinical, morphological and other laboratory studies.
% Mutant Allele 1% > V617F % ≥ 0.042% Copy Number ≥ 50	Qualitative Result; Positive % Mutant; Test reported value will be provided Report Comments: Quantitative results of less than 1% Mutant allele are of undetermined clinical significance. Results should be correlated with clinical, morphological and other laboratory studies.
% Mutant Allele ≥ 1% Copy Number ≥ 50	Qualitative Result; Positive % Mutant; Test reported value will be provided Report Comments: Results should be correlated with clinical, morphological and other laboratory studies.

References/Resources:

JAK 2 RCQ PCR Kit Handbook, Ref 673613, Qiagen GmbH

The relevance of a low JAK2V617F allele burden in clinical practice: a monocentric study. *Oncotarget*, 2017, Vol. 8, (No. 23), pp: 37239-37249

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