

Attachment D

Salient Characteristics of equipment:

- A real-time cycler capable of deciphering the most difficult Class IV Single Nucleotide Polymorphisms (SNPs) by High Resolution Melt (HRM).
- Fast ramping and negligible equilibration times for short run-times
- Have high thermal and optical uniformity, with short equilibration times
- The following testing performed on the instrument must be fully automated and available at the time of bid: To include but not limited to JAK2 testing.
- General instrument characteristics include a simple, touch-screen user interface, with easy-to-use software with advanced security features.
- General instrument characteristics include, but are not limited to, a real-time nucleic acid amplification and detection system, which measures nucleic acid signals from amplified DNA using fluorescent detection.
- With a choice of up to 6 excitation sources and 6 detection filters, combined with a short, fixed optical path, and can be used for multiplex reactions, ensuring minimum fluorescence variability between samples and eliminating the need for calibration or compensation.
- Fixed optical path ensuring consistent excitation of every sample, which means that there is no need to use a passive internal reference dye such as ROX.
- Minimum maintenance capabilities
- Cost-effective and easy temperature-accuracy verification.
- Optical calibration not being required at installation, or when the instrument is moved.
- "Plug and play" connectivity between the computer and the instrument for ease of use.
- Physical characteristics: includes no more than 50 lbs., and the Dimensions (H x W X D) should be no more than 15" x 20" x 25" to accommodate our limited space. • Capable of detecting at least up to 14 patients simultaneously.
- The systems must improve overall productivity in the Molecular Diagnostics Lab, reducing the need for repeat testing thus reducing reagent waste. The system should not require monitoring during a run and should be 100% "walk-away" system.
- All in one compact, benchtop unit.

Functionality and Performance Specifications of the JAK2 Quantitative Reagents:

- Accurate quantitation of the JAK2 V617F/G1849T mutation.
- The kit is for real-time PCR on real-time PCR instruments.
- The kit provides reagents optimized for reliable and sensitive detection and quantitation of the JAK2 V617F/G1849T mutation in genomic DNA.
- The sensitivity should have a limit of detection (LOD) of 0.061%.

- This optimal sensitivity should be able to be obtained on specimens containing at least 10,000 copies of the JAK2 gene (wild-type and V617F mutation).
- The JAK2 Quant Kit should be a ready-to-use kit for the detection and quantification of the JAK2 V617F/G1849T somatic mutation due to a single nucleotide polymorphism.
- The JAK2 Quant Kit should provide 4 plasmid standard dilutions for mutant JAK2 V617F and 4 for the wild-type JAK2 allele. Use of the standards enables accurate quantification of transcripts.
- Results are expressed as a percent of JAK2 V617F in total JAK2.
- JAK2 Kit should include at least 24 reactions: V617F Positive Control, V617F Negative Control, 2 sets of standards plasmid dilutions JAK2 wild-type and JAK2 V617F, 2 Primers and Probe Mixes JAK2 wild-type and JAK2 V617F