



Roche

Push the Boundaries of Sensitivity

Unleash the true power of digital PCR

Digital 
LightCycler®

Enhanced ability to detect minimal DNA or RNA molecules

The Digital LightCycler® System from Roche is an IVD system with a unique set of features to bring about the latest advancements in digital PCR technology. The high-sensitivity capabilities of the Digital LightCycler® System can identify the ultra-rare mutations that were previously out of reach; encouraging you to take the leap to seek out and answer harder questions.

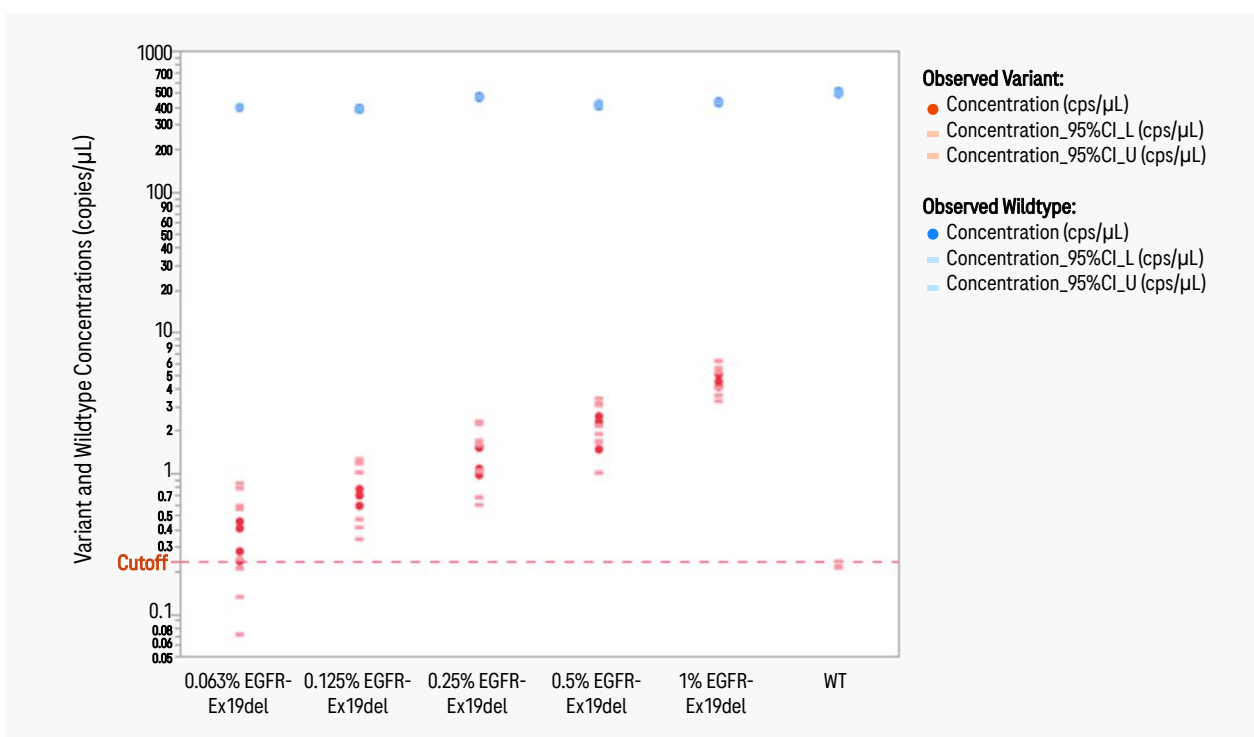


*Applications are not licensed for sale in Canada

CASE IN POINT

Detecting indels down to 0.2% allele fraction with the 20,000 high sensitivity plate

An EGFR-Ex19del (exon 19 deletion) indel assay was tested using cell-line genomic DNA, with 66 nanograms per reaction. A titration of the EGFR-Ex19del mutant was performed from 1% to 0.063% with constant wild-type DNA background at 430 cps/ μ L.






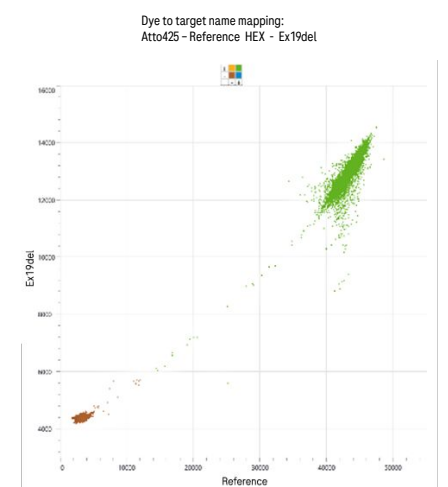
Across the entire titration scheme, the wild-type DNA background was comparable. The negative control (100% wild-type) displayed an observed false positive of 0 cps/ μ L, with 95% CI upper limit at 0.23 cps/ μ L. Accordingly, this upper CI limit for the negative control was used to set the cut-off, meaning that anything above the cut-off is above noise and therefore is indicative of the presence of the EGFR-Ex19del mutant.



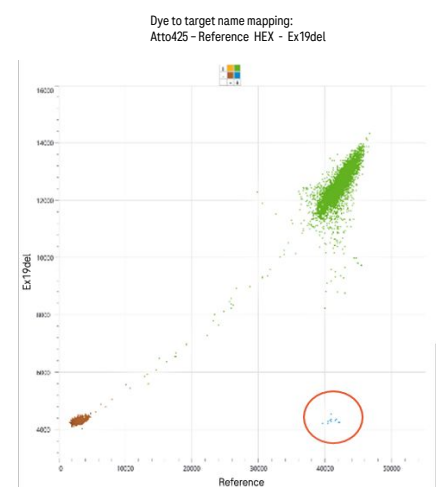
Both technical replicates of the 0.125% EGFR-Ex19del samples were called significantly over the noise, with 95% CI lower limit above the cutoff, indicating that the system is capable of detecting a rare mutation at $<0.2\%$ allele fraction.

From the same experiment, 2D scatter plots of samples with 0%, 0.125%, and 0.25% of the EGFR-Ex19del variant are depicted below. In each plot:

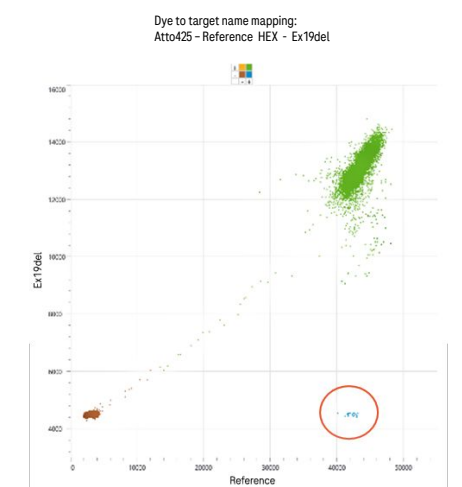
-  Brown cluster is composed of partitions without the template
-  Green cluster is composed of partitions of the wild-type and wild-type plus variant templates
-  Blue cluster is composed of partitions with only variant templates



0% EGFR-Ex19del



0.125% EGFR-Ex19del



0.25% EGFR-Ex19del

There are a few blue partitions in the 0.125% and 0.25% scatter plots, but none in the 0% scatter plot. Quantification of the variant based on blue partitions confirmed that the 0.125% sample was called significantly higher over the noise, indicating that the system is capable of detecting an indel mutation at <0.2% allele frequency.



Contact your Roche representative today to find out how you can unleash the true power of digital PCR