



San Francisco, Sep 16, 2021

Subject: Customer notification - Invitae's commitment towards IVDR compliance

Dear customer,

We would like to inform you on the efforts we are taking in view of the new EU In Vitro Diagnostics Regulation (IVDR), coming into effect as of May 2022. We are developing a new solid tumor IVD solution, the assay will be designed to detect multiple classes of genomic alterations across a range of genes implicated in solid malignant neoplasms, and will be compatible with both formalin-fixed paraffin-embedded (FFPE) tissue samples and plasma specimen types. Invitae's IVD tests will be based on our diagnostic platform, which combines the patented Anchored Multiplex PCR (AMP™) technology with Illumina's MiSeqDx and NextSeq 550Dx sequencing systems and Invitae Solid Tumor IVD software.

Our goal is to broaden patient access to next-generation sequencing (NGS)-based oncology testing and comprehensive genomic profiling, and aid in identifying appropriate treatment options.

The first products in scope of our trajectory towards IVDR compliance will be

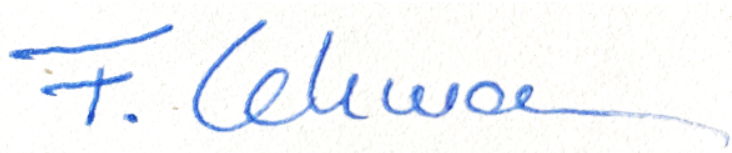
- Invitae Solid Tumor IVD RNA - providing genomic profiling of carefully curated biomarker content including ALK, ROS1, RET and NTRK1/2/3 fusions as well as MET Exon 14 skipping
- Invitae Solid Tumor IVD ctDNA - identifying variations including substitutions and insertion-deletion mutations in cell-free circulating tumor DNA including EGFR, KRAS, BRAF as well as MET Exon 14 skipping.

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Like many IVD manufacturers, we are focused on taking the steps necessary to achieve IVDR compliance for our products in as timely a manner as possible, and will also continue exploring all compliant options to support our customers during this regulatory transition.

For more information please contact us by emailing: [ivd\\_kits@invitae.com](mailto:ivd_kits@invitae.com)

Yours sincerely,



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