

# **TruSight Tumor 170 Local App**

## **Customer Release Notes**

**v1.0.1**

***For TruSight Tumor 170 Reagents***

## Introduction

These Release Notes detail the key features and known limitations for this version of the TruSight Tumor 170 local analysis application.

## I. TruSight Tumor 170 Local App Version 1.0.1

### NEW FEATURES:

- No new features.

### DEFECT REPAIRS:

- This repair addresses two defects detailed in the April 2018 [Product Quality Notification](#).
  - An issue that could cause the app to skip samples or lanes within samples during analysis if certain problematic sample names were used.
  - An issue that could cause the app to swap or merge results from different samples if certain problematic sample names were used.

### KNOWN ISSUES:

During final testing, multiple lots of TruSight Tumor 170 reagents resulted in an analytical sensitivity of 98.3% with previously characterized samples harboring fusions and splice variants and an analytical specificity of 95% with previously characterized samples of normal karyotypes.

1. Splice variant coordinates may differ from standard VCF format recommendations. Exon and intron annotations should not be affected.
2. Fusions in the following cases will be called, but may not pass fusions score cutoff:
  - Breakpoints near repetitive genomic regions
  - Fusions of two genes located in close proximity
  - Contig being misaligned as an intragenic sequence
3. Fusions in the following cases will have a decreased chance of being called:
  - Loci with a high volume of sequencing errors
  - Loci enriched for short fragments
  - Loci with unique reads marked as duplicates
4. Fusions in the following cases may be called incorrectly:
  - Fusions of two genes from the same family
  - Fusions of two genes highly homologous to sequences in unassigned chromosomes