



- Test name** : SSTP Liquid
Specimen receipt : Only Monday – Friday; 8.45am – 4pm (excluding public holidays)
Test Set-up : Every Wednesday (Thursday if Wednesday falls on a public holiday)
Turnaround time : 10 working days from day of test set up

The SSTP Liquid assay is an amplicon-based next generation sequencing (NGS) assay incorporated with molecular tagging that allows sensitive detection of circulating cell-free tumour nucleic acids in the peripheral blood (liquid biopsy). Only SNVs and short delins are validated for this assay. This assay can be used to determine the presence of genomic alterations in circulating tumour nucleic acids in patients that would predict response of a cancer to targeted therapy (predictive testing).

Indications for testing

To determine the presence of somatic variants in plasma circulating cell-free tumour nucleic acids that would predict response of a cancer to targeted therapy (predictive testing).

Limitations

1. Only single nucleotide variants (SNVs) and small insertions / deletions (delins) are validated in this assay. Gene amplifications and fusions are tested but the sensitivity and specificity of the assay for these findings have not been validated. This assay also does not detect large insertions and deletions.
2. The absence of detectable variants in cell-free DNA/RNA may be due to tumour biology or a variant allele frequency that is below the limit of detection of this assay. It does not exclude the presence of a genomic alterations in the patient's tumour. Further evaluation with a tissue biopsy should be considered for negative cases.
3. Genomic findings may be derived from other alterations such as clonal haematopoiesis (CH).
4. This assay is not designed to assess for germline changes and the results are not definitive for the presence or absence of a germline variant.

Specimen requirements

20 mls of blood collected in K₂EDTA blood collection tubes (for example 4 tubes of blood will be required if 6 ml tubes are used). Gently invert the blood tubes multiple (8-10) times upon blood collection to prevent coagulation. The tubes should then be labelled with patient's details, placed into a specimen zip-lock bag (individual case per bag), and accompanied by a hard copy test request form with relevant clinical information or an electronic test request

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Reg No 198703907Z

order in the Computerised Physician Order Entry system (CPOE) (for relevant SingHealth institutions). The date and time of blood draw should be indicated in the hard copy request form or CPOE order.

Specimens should be sent to 20 College Road, Academia building, Diagnostic Tower, Level 8, Client and Specimen Management (CSM) where it will then be internally transferred immediately to Anatomical Molecular Laboratory (ATOM) for testing. Specimens should reach ATOM within 2 hours from the time of blood draw, after which the specimen may be rejected. Specimens are received by ATOM only on Monday – Friday; 8.45am – 4pm (excluding public holidays).

Any other queries can be directed to the Anatomical Molecular Laboratory (ATOM) at (65) 6576 7191.

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Table 1. List of 44 genes and their corresponding exons covered by the SSTP Liquid assay for detecting single nucleotide variants (SNVs) and small insertions / deletions (delins)

Gene	RefSeq ID	Exon
<i>AKT1</i>	NM_005163.2	Exon 3
<i>ALK</i>	NM_004304.4	Exon 21 Exon 22 Exon 23 Exon 24 Exon 25
<i>APC</i>	NM_000038.5	Exon 16
<i>AR</i>	NM_000044.3	Exon 6 Exon 8
<i>ARAF</i>	NM_001654.4	Exon 7
<i>BRAF</i>	NM_004333.4	Exon 11 Exon 15
<i>CHEK2</i>	NM_007194.3	Exon 11
<i>CTNNB1</i>	NM_001904.3	Exon 3
<i>DDR2</i>	NM_006182.2	Exon 8 Exon 15 Exon 17
<i>EGFR</i>	NM_005228.3	Exon 3 Exon 7 Exon 8 Exon 10 Exon 11 Exon 12 Exon 18 Exon 19 Exon 20 Exon 21 Exon 22 Exon 24 Exon 26
<i>ERBB2</i>	NM_004448.3	Exon 2 Exon 3 Exon 4 Exon 5 Exon 7 Exon 8 Exon 17 Exon 19 Exon 20 Exon 21 Exon 22 Exon 24

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<i>ERBB3</i>	NM_001982.3	Exon 3 Exon 7 Exon 8 Exon 9 Exon 23
<i>ESR1</i>	NM_000125.3	Exon 5 Exon 7 Exon 8
<i>FBXW7</i>	NM_018315.4	Exon 8 Exon 9 Exon 10 Exon 11
<i>FGFR1</i>	NM_015850.3	Exon 4 Exon 5 Exon 7 Exon 9 Exon 10 Exon 13 Exon 14 Exon 15 Exon 16 Exon 18
<i>FGFR2</i>	NM_000141.4	Exon 2 Exon 5 Exon 6 Exon 7 Exon 9 Exon 10 Exon 11 Exon 12 Exon 13 Exon 14 Exon 15 Exon 16
<i>FGFR3</i>	NM_000142.4	Exon 4 Exon 7 Exon 8 Exon 9 Exon 13 Exon 14 Exon 16
<i>FGFR4</i>	NM_002011.4	Exon 13
<i>FLT3</i>	NM_004119.2	Exon 20
<i>GNAI1</i>	NM_002067.4	Exon 5
<i>GNAQ</i>	NM_002072.4	Exon 5
<i>GNAS</i>	NM_000516.5	Exon 8

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		Exon 9
<i>HRAS</i>	NM_005343.3	Exon 2 Exon 3
<i>IDH1</i>	NM_005896.3	Exon 4
<i>IDH2</i>	NM_002168.3	Exon 4
<i>KIT</i>	NM_000222.2	Exon 8 Exon 9 Exon 10 Exon 11 Exon 13 Exon 14 Exon 17 Exon 18
<i>KRAS</i>	NM_004985.4	Exon 2 Exon 3 Exon 4
<i>MAP2K1</i>	NM_002755.3	Exon 2 Exon 3 Exon 6
<i>MAP2K2</i>	NM_030662.3	Exon 2 Exon 6
<i>MET</i>	NM_000245.3	Exon 2 Exon 3 Exon 4 Exon 11 Exon 14 Exon 16 Exon 17 Exon 18 Exon 19 Exon 20
<i>MTOR</i>	NM_004958.3	Exon 30 Exon 39 Exon 40 Exon 43 Exon 44 Exon 45 Exon 47 Exon 48 Exon 50
<i>NRAS</i>	NM_002524.4	Exon 2 Exon 3 Exon 4
<i>NTRK1</i>	NM_002529.3	Exon 14 Exon 15
<i>NTRK3</i>	NM_002530.3	Exon 16

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<i>PDGFRA</i>	NM_006206.4	Exon 7 Exon 10 Exon 11 Exon 12 Exon 14 Exon 14 Exon 16 Exon 18
<i>PIK3CA</i>	NM_006218.3	Exon 2 Exon 3 Exon 5 Exon 8 Exon 10 Exon 14 Exon 21
<i>PTEN</i>	NM_000314.6	Exon 1 Exon 2 Exon 5 Exon 6 Exon 7 Exon 8 Exon 9
<i>RAF1</i>	NM_002880.3	Exon 7
<i>RET</i>	NM_020630.4	Exon 10 Exon 11 Exon 13 Exon 14 Exon 15 Exon 16
<i>ROS1</i>	NM_002944.2	Exon 36 Exon 37 Exon 38 Exon 39 Exon 42
<i>SF3B1</i>	NM_012433.3	Exon 15
<i>SMAD4</i>	NM_005359.5	Exon 3 Exon 9 Exon 10 Exon 12
<i>SMO</i>	NM_005631.4	Exon 3 Exon 5 Exon 6 Exon 8 Exon 9 Exon 11
<i>TP53</i>	NM_000546.5	Exon 2

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		Exon 3
		Exon 4
		Exon 5
		Exon 6
		Exon 7
		Exon 8
		Exon 9
		Exon 10
		Exon 11

In addition, the genes below are tested for gene amplifications and fusions but the sensitivity and specificity of the assay for gene amplification and fusion have not been validated. Any gene amplification / fusion found is recommended to have orthogonal confirmation with another assay or correlation with findings from molecular profiling of tumour tissue:

- Gene amplification: *CCND1, CCND2, CCND3, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, MET, MYC*

- Gene fusion: *ALK, BRAF, ERG, ETV1, FGFR1, FGFR2, FGFR3, MET, NTRK1, NTRK3, RET, ROS1*