

Dear Colleagues,

Further to the NHS England letter issued on 10/11/2025, we would like to provide you with additional information regarding the new ctDNA service that will be provided by the South East Genomic Medicine Service (SEGMS). This letter includes:

- 1) Specific detail about the NGS panel that we use for testing
- 2) The strategy for reporting genomic variants
- 3) Sample requirements and test order forms
- 4) Interim information for procurement of blood collection kits
- 5) Details of planned educational sessions

1) NGS Panel details

The SEGMS panel of choice is MSK-ACCESS® powered with SOPHiA DDM™

This NGS panel has been fully validated and can detect small nucleotide variants in 147 genes, including the TERT promoter region and MET exon 14 skipping, copy number variants in 71 genes and 10 gene fusions detected by DNA based testing. Please see the <u>factsheet</u> for full details of the genes covered by the panel. Further information can be found here: <u>MSK Access - SOPHIA GENETICS</u>

2) Reporting Strategy

Reporting and full interpretation on the front page of the report will be in line with the requirements of the <u>National Genomic Test Directory for Cancer</u> with inclusion of a list of additionally detected oncogenic/likely oncogenic variants on page 2.

If full interpretation of any additional variants is required, a referral to our solid tumour GTAB can be made by completing the <u>GTAB referral form</u> and submitting it by email to <u>gst-tr.gtabsoutheastglh@nhs.net</u>

3) Sample requirements and test order forms

Please complete the ctDNA request form, which is designed to be completed electronically and printed; a paper copy **MUST** be included with all referrals. Handwritten forms are acceptable, but any handwritten text **MUST** be written clearly and legibly to avoid delays to testing.

Sample requirements for ctDNA are very different to other tests. Please follow these key steps:

- EDTA (purple top) tubes are **NOT** appropriate for ctDNA testing and will be immediately rejected upon receipt.
- 2. Two Streck Cell-Free DNA BCT tubes **MUST** be filled to the 10ml line as indicated on the tube.
- 3. Specific blood draw instructions are included in the collection kits and will be available on the SEGMS website.
- 4. Samples must be kept at room temperature and not refrigerated.
- 5. Pack the glass Streck tubes very carefully for transport using the transport box and packaging supplied as part of the blood collection kit*.

^{*}The blood collection kits are no longer funded centrally by NHSE; kits must be procured and funded by individual referring Trusts.



4) Blood collection kits

i. Ordering new stock

As an interim measure Streck tubes can be ordered from Alpha Labs using the Royal Marsden product code: VBC-KIT-RM-01. These kits include instructions for use and a pre-paid Royal Mail tracked 24h delivery address label.

Once you have placed the order, you **MUST** contact Alpha Labs on <u>solutions@alphalabs.co.uk</u> with the number of kits ordered and they will provide the correct Royal Mail tracked 24h address label which you will need to print and affix over the existing Royal Marsden label.

This is a TEMPORARY and short-term fix while we transition to the new pathway.

ii. Using up existing stock

If you have existing stock of Streck tubes with the old Royal Marsden address labels, please contact Alpha Labs at solutions@alphalabs.co.uk stating the number of kits remaining, and they will provide updated address labels as a PDF at no additional cost. Please print these new labels and affix over the existing Royal Marsden shipping labels.

iii. New SEGMS collection kits

Kits with the correct address labels will be available to order in around 4 weeks.

A new product code will be required to order these kits; we will communicate the details as soon as it's finalised.

iv. Collection kit and general queries

Please contact the Cancer Genetics laboratory via seglhsomaticcancer@synnovis.co.uk if you have any questions.

v. Laboratory address

Samples should be sent to:

Cancer Genetics
Synnovis Genetics Laboratories
4th Floor Southwark Wing
Guy's Hospital
SE1 9RT

5) Educational and live drop-in sessions:

Please join us on 2nd December to find out about the new testing pathway for ctDNA testing for lung and breast cancer patients in the southeast.

If you order ctDNA testing, or plan to in the future, this is an essential education session.

We will guide you through the pathway from sample acquisition to issuing of reports and our team will be on hand to answer any questions you may have.



If you are unable to join us on December 2nd we are holding a second session on December 11th.



In addition, we will be holding live drop-in sessions via MS Teams – further details will be circulated by email after go-live.

Kind regards,

Nicola Foot Richard Hall

Head of Service, Cancer Genetics Director of Operations

Glossary

SEGMS: South East Genomic Medicine Service. The Cancer Genetic service is part of the SEGMS and is based at Guy's Hospital

ctDNA: circulating tumour DNA; a subset of cfDNA derived from tumour cells.

cfDNA (or ccfDNA): circulating cell free DNA; short-lived fragments of genetic material, shed into the bloodstream, which can be analysed from a blood sample with specialist genomic techniques; blood must be collected with cfDNA blood tube.

MSK-ACCESS® powered with SOPHiA DDM™: ctDNA NGS assay developed by the Memorial Sloan Kettering centre in the US, and now commercialised and distributed by Sophia Genetics, and validated for clinical diagnostic use by the SE GLH

Streck Cell-Free DNA BCT: cfDNA preserving blood collection tube