

March 6th 2026

Dear Colleagues,

Following the recent NHS England communication, this letter provides full details of the transition of circulating tumour DNA (ctDNA) testing for:

- **M3.13 – Breast Cancer**
- **M4.14 – Non-Small Cell Lung Cancer (NSCLC)**

This applies to all Central and South referring organisations.

1. What Is Changing?

Current Arrangement

ctDNA testing is currently provided by the North West Genomic Medicine Service (NWGMS) using the Roche Foundation Medicine assay.

From 1 April 2026

Testing will transfer to the South East Genomic Medicine Service (SEGMS) based at Guy's Hospital, London.

Testing will be performed using MSK-ACCESS® powered by SOPHiA DDM™ and analysis and reporting will follow the national test directory requirements. This validated next-generation sequencing (NGS) assay is capable of:

- Detecting small nucleotide variants in **147 genes** (including TERT promoter and MET exon 14 skipping)
- Detecting copy number variants in **71 genes**
- Detecting **10 gene fusions** (DNA-based testing)
- Analysing all targets required under the National Genomic Test Directory for M3.13 and M4.14

2. Reporting

- Reports will be issued from: **seglhsomaticcancer@synnovis.co.uk**
- Follow National Genomic Test Directory standards
- Include details of any additional oncogenic variants identified.

If detailed interpretation of additional variants is required, referrals can be made to the **SE GMS Solid Tumour Genomics Tumour Advisory Board (GTAB)** via gstt.gtabsoutheastglh@nhs.net
GTAB referral form: <https://southeastgenomics.nhs.uk/wp-content/uploads/2024/09/Blank-GTAB-referral-form.pdf>

Please note: report format will differ from current NWGMS reports.

3. Transition Period

There will be a short overlap period until June 1st 2026:

- NWGMS will continue testing residual samples sent in **Roche tubes** until June 1st
- NWGMS cannot process samples sent in **SEGMS Streck tubes**

- Streck samples incorrectly sent to NWGMS will be forwarded to Guy's Hospital, which may delay results
- Roche tubes mistakenly sent to South East GMS will be forwarded to NWGMS which may delay results.

After June 1st, all samples should be sent in Streck tubes to South East GMS.

Please ensure samples are sent to the correct laboratory using the correct collection kits.

4. Turnaround Time

Expected turnaround time under the new service: **10–14 calendar days**

5. Referral Process

Please use the **SEGMS ctDNA referral form** [ctDNA-Request-Form-Nov-2025-1.pdf](#)

- Forms should be completed electronically where possible
 - A printed copy **must accompany every sample**
 - Handwritten forms are acceptable but must be clearly legible. Incomplete or unclear forms may delay testing.
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6. Key Changes to Note

Please ensure the following changes are implemented from 1 April 2026:

- **The address for sending samples has changed** – samples must now be sent to Guy's Hospital (see Section 7).
- **Referrals must be sent using two Streck Cell-Free DNA BCT tubes.**
- **Blood collection kits must be procured via your local hospital** in line with other genomic tests. Individual Trusts are responsible for ordering and funding their kits.

Failure to follow these requirements may result in delays to testing.

7. Sample Requirements (Critical)

ctDNA sampling differs significantly from other genomic tests.

Please follow these instructions carefully:

- **Do NOT use EDTA (purple top) tubes** — these will be rejected
 - Use **two Streck Cell-Free DNA BCT tubes**
 - Each tube must be filled to the **10 mL line**
 - Samples must be kept at **room temperature**
 - Do **not** refrigerate
 - Package carefully using the absorbent pouches and transport box supplied
 - Streck tubes are glass and prone to breakage if not properly protected.
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8. Where to Send Samples

Cancer Genetics, Synnovis Genetics Laboratories

4th Floor, Southwark Wing

Guy's Hospital, London SE1 9RT

9. Blood Collection Kits

Kits must be procured and funded by individual referring Trusts.

Supplier: Alpha Laboratories Ltd

Order code: VBC-KIT-GH-01

Email: Please contact Alpha Laboratories directly for pricing and ordering.

solutions@alphalabs.co.uk

Using Existing Roche Stock

During the transition period:

- Existing Roche tubes may continue to be used and sent to NWGMS.
- Roche tubes must not be used for samples intended for SEGMS.

Please ensure samples are sent to the correct laboratory to avoid delays.

Packaging and Transport

Streck tubes are glass and must be packaged carefully.

- Use the absorbent pouches supplied in the kit.
- Use the transport box provided.
- Ensure tubes are secured to prevent breakage in transit.

Improper packaging may result in sample rejection.

10. Test Eligibility (this is unchanged)

Eligibility criteria remain the same.

NSCLC (M4.14)

Eligible patients include:

- Radiologically suspected Stage III/IV lung cancer
- Unsuitable for curative surgery or radical radiotherapy
- ECOG Performance Status 0–3

Or:

- Newly confirmed advanced NSCLC
- Untreated for advanced disease
- Where diagnostic molecular testing has failed
- Where re-biopsy would otherwise be required

Breast Cancer (M3.13)

At progression:

ESR1 – As per NICE TA1036

For ER-positive, HER2-negative advanced/metastatic breast cancer progressing after at least 12 months of first-line endocrine therapy plus CDK4/6 inhibitor.

PIK3CA / AKT1 / PTEN – As per NICE TA816 and TA1063

For ER-positive, HER2-negative advanced/metastatic breast cancer progressing on first-line aromatase inhibitor plus CDK4/6 inhibitor.

Please refer to the National Genomic Test Directory for full criteria.

11. Education and Support

Further information is available on the South East Genomics [ctDNA webpage](#).

We are also offering educational sessions with our expert ctDNA team. You have a choice of dates to sign up for:

- **Thursday 19th March 12-1pm**. Register [here](#)
- **Tuesday 31st March 12 – 1pm** Register [here](#)

Please share with colleagues.

12. Contact

We recognise there will be questions during this transition.

For queries, please contact seglhsomaticcancer@synnovis.co.uk

Kind regards,
Nicola Foot
Head of Service, Cancer Genetics

Tony Williams
Clinical Director, Central & South GMS

Glossary

SE GMS : South East Genomic Medicine Service (Cancer Genetics laboratory based at Guy's Hospital)

NW GMS : North West Genomic Medicine Service

cfDNA (ccfDNA)

Circulating cell-free DNA — fragments of DNA shed into the bloodstream that can be analysed from a blood sample.

ctDNA : Circulating tumour DNA — the tumour-derived fraction of circulating cell-free DNA.

MSK-ACCESS[®] : A validated ctDNA next-generation sequencing assay originally developed by Memorial Sloan Kettering Cancer Center and commercialised by SOPHiA GENETICS.

Streck Cell-Free DNA BCT : A blood collection tube designed to preserve circulating cell-free DNA for molecular testing.
