NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

To: NHS Trusts ordering ctDNA tests within SE GLH region:
For your action – Notification of change in provider

10 November 2025

Dear Colleague,

We write with regards to the testing provision of circulating tumour DNA (ctDNA) testing for non-small cell lung cancer (NSCLC) and breast cancer. Following a successful Expression of Interest process, from 1st December 2025 ctDNA testing for patients living in the South East NHS Genomic Medicine Service (NHS GMS) geography will be carried out by South East NHS GMS rather than North Thames NHS GMS.

South East NHS GMS will become the third commissioned provider for ctDNA provision.

Frequently asked questions

1. **Which NHS Trusts need to route their samples to South East NHS GMS from 1st December 2025?**

   A full list of Trusts included in the South East NHS GMS geography is included in Annex A.

2. **Where should samples be sent to for the South East region?**

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

3. **What is the eligibility criteria for testing?**

   The eligibility criteria for ctDNA testing is outlined in the National Genomic Test Directory (NHS England » National genomic test directory). The criteria as at November 2025 is:

   NSCLC (M4.14) – Patients with radiologically suspected stage III/IV lung cancer, likely unsuitable for curative intent surgery or radical radiotherapy and an ECOG

Performance Status between 0-3. Additionally, patients with a confirmed new histological diagnosis of NSCLC, previously untreated for advanced disease where diagnostic molecular testing has failed, and an alternative option would be to re-biopsy.

Breast Cancer (M3.13) – AT PROGRESSION: ESR1- As per NICE recommendation (TA1036) to guide treatment decisions in patients with ER positive, HER2-negative advanced / metastatic breast cancer that are progressing on first line treatment with endocrine therapy plus CDK 4/6 inhibitors (NB. Patients must have received at least 12 months of treatment). PIK3CA/AKT1/PTEN - As per NICE recommendations (TA816, TA1063) to guide treatment decisions in patients with ER positive, HER2-negative advanced / metastatic breast cancer that are progressing on first line treatment with an aromatase inhibitor plus CDK 4/6 inhibitor.

Associated NICE guidelines can be found here: NICE guidance | NICE

4. Where is the referral form to access testing?

The referral form can be found on the SEGMS website at the following location:

ctDNA-Request-Form-Nov-2025.pdf

5. Who is funding the ctDNA testing?

ctDNA testing for NSCLC and breast cancer is a nationally commissioned service, listed on the National Genomic Test Directory, and therefore the genomic test is funded by NHS England for all eligible patients. The blood collection kits for genomic testing need to be procured and funded by referring Trusts in line with other genomic tests commissioned by NHS England.

6. What blood collection kits are needed, how are they procured and how are they funded?

Referrals for ctDNA testing require two tubes of blood be collected in Streck Cell-Free DNA BCT filled to the 10ml line indicated on the tube.

To support the ctDNA test lung cancer pilot which took place from 2022 - 2025, blood collection kits were procured centrally and distributed by ctDNA providers to individual Trusts. This has now stopped.

From April 2025 ctDNA testing has been routinely commissioned as a standard test on the National Genomic Test Directory. Therefore individual Trusts are required to purchase kits locally, as they would for other genomic

tests, via their own procurement and ordering processes.

Kits must be purchased from Alpha Labs; further details on how to order blood collection kits will be provided soon.

7. **What are the benefits of implementing ctDNA for non-small cell lung cancer and breast cancer?**

NSCLC:

- Enable patients to receive targeted treatments much sooner and avoid repeated invasive procedures than under the current diagnostic pathway;
- Cost savings from diagnostic procedures and from avoided mistreatment and consequences for patients with a failed genomic test;
- Improved quality of life due for patients accessing treatment sooner.

Breast cancer:

- Support targeted treatment plans;
- Cost savings from avoided mistreatment and consequences for patients;
- Compliance requirement for NICE Technology Appraisal for breast cancer

8. **Who to contact with any issues**

For any further enquiries, please contact us at seglhsomaticcancer@synnovis.co.uk

Yours sincerely

Genomics Unit

Appendix A – Trusts falling within SEGMS region:

Conquest Hospital
Frimley Park Hospital NHS Trust
Guy's Hospital (GSTT)
Lewisham and Greenwich NHS Trust
Maidstone and Tunbridge Wells NHS Trust
Medway NHS Trust
Princess Royal University Hospital (KCH)
Queen Elizabeth Hospital Woolwich
Royal Surrey County Hospital NHS Trust
Royal Sussex County Hospital
St George's Hospital NHS Trust
St Richard's Hospital
St Thomas' Hospital (GSTT)
Evelina London Children's Hospital (GSTT)
The Tunbridge Wells Hospital
Kent Oncology Centre
Wexham Park Hospital
Worthing Hospital
Kent & Canterbury Hospitals NHS Trust
Queen Elizabeth The Queen Mother Hospital
Eastbourne District General Hospital
St Peter's Hospital (Chertsey)
William Harvey Hospital
Darent Valley Hospital
Western Sussex Hospitals NHS Foundation Trust
East Surrey Hospital
King's College Hospital
Royal Brompton Hospital (GSTT)
University Hospitals Sussex NHS Foundation Trust