**NW GLH ctDNA lung Pathway - Pilot Phase 3 SOP**

This SOP outlines the basic steps to follow for NHS Trusts to access ctDNA testing kits for phase 3 of the lung ctDNA pilot pathway.

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| **Step** | **Activity** | **Responsibility** |
| 1 | **Required materials**  North West Genomic Laboratory Hub (NWGLH) will provide blood collection kits (BCK) to NHS Trusts that will consist of: -   * 1 Foundation medicine Liquid biopsy kit containing 2 blood collection tubes and UN3373 compliant rigid sample transport packaging, including absorbent tube pouches and biohazard bag * Pre-paid postage, for return of samples to NW GLH Manchester laboratory. * Please note one BCK per patient   Please contact [mft.northwest.ctdna@nhs.net](mailto:mft.northwest.ctdna@nhs.net) to obtain;   * Blood collection kits (BCK) - To access, NHS Trusts will need to complete a BCK Order Form, detailing the number of kits required and where the kits need to be sent, including a contact name. Please allow 3 working days for the kits to arrive. **A minimum of 10 kits per order and a maximum of 50.**      * Electronic test requisition form (TRF) * Instructions for use (IFU) leaflet * Patient information sheet | NW GLH  Local clinical team |
| 2 | **Eligibility Criteria for patients**  Eligibility:   * Radiologically suspected stage III/IV Lung cancer, likely unsuitable for curative treatment * ECOG PS 0-3 * Histological diagnosis of NSCLC where molecular testing has failed and alternative option would be re-biopsy   Provide the patient with a patient information sheet- signed consent **not** required. | Doctor/CNS |
| 3 | **Blood collection**  Please contact [mft.northwest.ctdna@nhs.net](mailto:mft.northwest.ctdna@nhs.net)should you have any queries about any of the documents below: -   * Blood Collection Kit Order Form * Test requisition form * Instructions for use (IFU) leaflet * Patient information sheet   Please follow the instructions outlined in the IFU for sending samples to NW GLH    **Please avoid sending samples on a Friday if possible as the laboratory cannot process samples over the weekend and therefore the sample may be delayed.** | Local clinical team |
| 4 | **NW GLH test request form**  Please complete all sections of the test requisition form    Please note mandatory fields are:  DOB  Sex  Has the patient had any type of transplant  If yes please state type(s)  Sample collection date (dd/mm/yyyy)  Suspected lung cancer  Stage |  |
| 5 | **Shipping**  Ensure blood bottles **and** completed NW GLH ctDNA testing for Suspected Lung Cancer form are placed in the BCK as per the instructions in the IFU and securely seal the box.  Record the Royal Mail Tracking number on the postage label to enable tracking during transit.  Return the BCK to NW GLH via your Trust post room;  NWGLH ctDNA service,  5th Floor, St Mary’s Hospital,  Manchester University Foundation Trust  Oxford Road, Manchester  M13 9WL  The BCK should arrive at the NWGLH within 48 hours of venepuncture. | Local clinical team |
| 6 | **Results**  Results will be sent securely to the emails provided on the test request form via NHS.net or hospital email (.nhs.uk). Please include: -   * The referring clinician/department * The regional GLH hub * Lead oncologist   Results usually available within 14 calendar days. | NW GLH laboratory |