**Marsden360 ctDNA 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.  This document is a guide and can be updated regionally with any specifics you wish to add locally.

|  |  |  |
| --- | --- | --- |
| **Step** | **Activity** | **Responsibility** |
| 1 | **Required materials**  RMH will provide blood collection kits (BCK) to NHS Trusts that will consist of: -   * 2 Blood collection tubes (Streck tubes) per patient * UN3373 compliant rigid sample transport packaging, including absorbent tube pouches and biohazard bag and pre-paid postage, for return of samples to The Royal Marsden NHSFT, Clinical Genomics laboratory * Please note one BCK per patient   Please contact [Marsden360@rmh.nhs.uk](mailto:Marsden360@rmh.nhs.uk) 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 * Blood tube label template * Patient information sheet | RMH  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 [**Marsden360@rmh.nhs.uk**](mailto:Marsden360@rmh.nhs.uk)should you have any queries about any of the documents below: -   * Blood Collection Kit Order Form * Test requisition form * Instructions for use (IFU) leaflet * Tube template labels * Patient information sheet   Please follow the instructions outlined in the IFU for sending samples to Clinical Genomics at The Royal Marsden | Local clinical team |
| 4 | **Marsden360 test requisition form**  Please complete all sections of the test requisition form    Section 1:  Patient information  Section 2:  Specimen collection information  Record Royal Mail tracking number from postage address label  Section 3:  Advanced cancer stage and therapy  Section 4:  Ordering Physician. Medical consent can be signed by CNS  Section 5:  Additional recipients for the report  Section 6:  Diagnosis  Section 7: - not essential for pilot  Relevant Clinical History  Photocopy the Marsden360 test requisition form for your own records. | Local clinical team |
| 5 | **Shipping**  Ensure blood bottles **and** completed Marsden360 test requisition 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 Clinical Genomics at The Royal Marsden via your Trust post room;  Clinical Genomics  The Centre for Molecular Pathology  The Royal Marsden NHS Foundation Trust  Cotswold Road  Sutton  Surrey  SM2 5PT  The BCK should arrive at the Royal Marsden 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. | RMH laboratory |