## Contents

## GENERAL INFORMATION

### 1. INTRODUCTION

Cambridge Clinical Laboratories is a molecular diagnostic testing laboratory, specialising in the areas of oncology and virology. We have a strong team of personnel including biomedical scientists, laboratory scientists, QA/RA, administration and commercial staff. Full details of our services can be found at www.CamClinLabs.co.uk

### 2. ACCREDITATION

Cambridge Clinical Laboratories is a UKAS accredited medical laboratory No. 9325 to the ISO15189:2012 standard.
Our current certificate and scope can be found on the UKAS website.

### 3. SERVICE AVAILABILITY

Please see our website at www.CamClinLabs.co.uk for current opening times.
Our core working hours for the laboratory are:

Monday – Friday: 09.00 – 17.30

Royal Mail, other couriers or other methods of sample delivery are generally not accepted on a Saturday.

### 4. RESULTS INTERPRETATION

Due to the nature of the services provided only interpretation of the results produced by Cambridge Clinical Laboratories can be provided as the full clinical picture cannot be considered.

### 5. RESULTS AVAILABILITY

Reports are emailed out to the contact email given on the test request form, or a set of emails set up as part of the account.

Where results are unexpected, require explanation or may require urgent intervention we will endeavor to contact the requestor.

### 6. DOWNTIME

Rarely there are times where instrument downtime may result in delay of samples being processed and returned. This occurrence is very rare and all major engineering tasks required for our instruments are carried out as swiftly as possible as part of our service agreements. In the event of this, all customers will be contacted directly and will be informed of any situation with expected turnaround times.

## 7. COMPLAINTS

Cambridge Clinical Laboratories makes every effort to provide the best service to users and to maintain a high standard of quality at all times. However, mistakes do occur and we are happy to receive any comments and to try to resolve any complaints. If you feel that the service we have provided is not up to an excellent standard then please contact our Clinical Laboratory Manager or a member of our Senior BMS team. Non-conformance reports and root cause analysis are provided to affected customers upon request once complete.

## 8. TERMS AND CONDITIONS

Service level agreements are available for all referring laboratories/customers, please enquire for further information.

Service level agreements for medical services will cover, but are not limited to the following details.

- Agreements to provide medical laboratory services shall take into account the request, the examination and the report.
- The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.
- The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used, shall be defined, documented and understood.
- The laboratory shall have the capability and resources to meet the requirements.
- Laboratory personnel shall have the skills and expertise necessary for the performance of the intended examinations.
- Examination procedures selected shall be appropriate and able to meet the customers' needs.
- Customers and users shall be informed of deviations from the agreement that impact upon the examination results.
- Reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.
- SLAs will have a defined length and expiry.

For all requests not covered by SLA, our standard terms and conditions will apply.

## 9. PATIENT CONFIDENTIALITY

Patient confidentiality is of the upmost importance to Cambridge Clinical Laboratories Ltd. All staff that come into contact with any confidential information are bound by the laws of General Data Protection Regulation (GDPR), Human Rights Act 1998, as well as the Caldicott Guidelines, common law and such obligations undertaken in contracts with third parties.

Our Privacy Policy is available on our website.

## 10. CONTACT DETAILS

Cambridge Clinical Laboratories is based at the following address:

Park House, Winship Road, Cambridge, CB24 6BQ
For all enquiries, please contact:

Telephone 01223 395450 Email: info@CamClinLabs.co.uk

### SAMPLE REQUIREMENTS AND TRANSPORT

## 11. TEST REQUESTS

Copies of request forms can be obtained from our website www.CamClinLabs.co.uk and the laboratory, either by email info@CamClinLabs.co.uk or call the office on 01223 395450.

Please indicate the tests required when requesting a test request form.

Test request forms need to be completed in full. In particular **three points** of patient identification are required. Ensure that the sample and request form information match.

The referring hospital/laboratory accepts responsibility for errors caused due to insufficient patient identification provided for diagnostic tests.
Submission of a test request constitutes an order for work under Cambridge Clinical Laboratories standard terms and conditions unless a Service Level Agreement is in place.

Verbal requests for tests must be confirmed by submission of a competed test request form or a written request for further testing (email) within 24 hours of the verbal request.

## 12. TRANSPORT

Avoid transit over the weekend.
Send using DX courier service between Monday -Thursday.
Send using First Class Post between Monday - Thursday.
Ensure that any packaging used meet requirements for transporting diagnostic specimens (UN3373)

# 13. SAMPLE REQUIREMENTS FOR ONCOLOGY

## 13.1. General Oncology Instruction

Safeguards should be undertaken to prevent sample-to-sample DNA contamination.
a) Cleaning of the microtome and any equipment used in the sectioning area should be completed between the sampling of each block.
b) Disposable blades provide the best means to eliminate block-to-block contamination.
c) Change gloves between the cleaning of the microtome and the sectioning of each new block.

Samples stained with dyes containing heavy metals, sections on slides with coverslip, tissue not in cassettes and Megablocks cannot be accepted.

Failure to send the correct sample type will result in an untested report.

## 13.2. Test Requirements

| TEST | 30 GENE LUNG PANEL | RAS-RAF PIK3CA RET Analysis KRAS G12C | EGFR | BRAF | ALK-FISH | ROS-1 FISH | HER2-FISH (ERBB2) | PD-L1 IHC (22C3) | PD-L1 IHC (SP142) |
|---|---|---|---|---|---|---|---|---|---|
| *Sample Origin* | NSCLC | Multiple Origins | NSCLC | NSCLC & Melanoma | NSCLC | NSCLC | Breast & Gastric | NSCLC, HNSCC Gastric & Urothelial | NSCLC, Breast & Urothelial |
| *Sample Type* | 10x Unstained slides at 5-10µm & 1x H&E | | 3 Microcentrifuge tubes containing 3 x 5-10µm sections per tube | | 4x Unstained slides at 5µm & 1x H&E | | 4x Unstained slides at 3µm & 1x H&E | 5x Unstained slides at 3-4µm | |
| *Additional requirement* | Use SuperFrost Plus, Leica Bond Plus or TOMO Slides | | For small biopsy samples (2-3mm), more sections may be submitted | | Use SuperFrost Plus, Leica Bond Plus or TOMO Slides. "Xtra" slides from any manufacturer are not suitable. | | | | |
| | | | tumour material (>10%). | tumour material (>15%). | Tissue sections should be from specimens fixed in 10% neutral buffered formalin. These slides should be air dried for 30-60 mins then heated in an oven at 56-60 degrees for at least 60 mins. | | | | |

*For information and guidance on our BRCA service please contact Customer Services.*

## 14. SAMPLE REQUIREMENTS FOR SCREENING SERVICES

### 14.1. Total & free PSA + Proclarix® Prostate

- Clotted blood sample (e.g., collected in serum separating tube) need to arrive to CCL within 24 h of collection for laboratory to centrifuge sample and collect serum.
- Alternatively prepare serum sample within 24h of blood collection, freeze and send frozen sample.
- Serum volume required > 2ml

### 14.2. Faecal Immunochemical Testing (FIT)

- Home kit for sample collection containing flat stool FIT sample tube with transport buffer is dispatched from CCL to customer.
- Sample requires testing as soon as possible, stored and transported at room temperature needs to reach CCL laboratory within 5 days of sampling.
- Only samples collected in CCL provided FIT collection tube will be accepted for testing.

### 14.3. Oncimmune® Early CDT Lung Cancer

- Sample requirements for home kit:
  EDTA fingerprick blood microtube filled up to 600µL with blood stored and transported at room temperature needs to reach CCL laboratory within 4 days of sampling.
- Samples requirement for professional services:
  - Serum sample stored and transported at room temperature needs to reach CCL laboratory within 12 days of sampling. Serum volume requirement is up to > 1ml.
  - Whole blood collected in EDTA sample tube stored and transported at room temperature needs to reach CCL laboratory within 4 days of sampling.
  - EDTA fingerprick blood microtube filled up to 600µL with blood stored and transported at room temperature needs to reach CCL laboratory within 4 days of sampling.

### 14.4. Stockholm3

- Whole blood collected in 2 EDTA sample tubes stored and transported at room temperature needs to reach CCL laboratory within 36 hours of sampling.
- If that is not possible first sample tube needs to be centrifuged at 2000G for 10 mins and plasma removed into sterile secondary tube. The tubes can then be stored up to 3 days in refrigerator (2-8°C) upright or frozen.
- Frozen samples can be shipped to CCL but have to remain frozen during transit.

### 14.5. Bladder EpiCheck®

- Urine sample with minimal volume of 10mL is required to be collected from the start of urination.
- Once collected sample can be stored at room temperature for up to 1 day and in the refrigerator (2-8°C) for up to 5 days.
- Sample need to reach CCL within 5 days of collection and can't spend longer than 24h in transport.

# 15. SAMPLE REQUIREMENTS FOR VIROLOGY

## 15.1. General Virology Instructions

Spun plasma should be transferred to polypropylene screw cap tubes (1.5-2ml capacity).
Failure to send the correct sample type will result in an untested report

## 15.2. Test Requirements

| TEST | HIV-1 PR-RT Resistance | HIV-1 Integrase Resistance | Viral RNA HIV-1 V3 Tropism by Genotype | HLA B*57:01 | HIV TDM |
|---|---|---|---|---|---|
| *Sample Type* | **EDTA PLASMA** | **EDTA PLASMA** | **EDTA PLASMA** | **EDTA WHOLE BLOOD** | **EDTA or LI-HEP PLASMA** |
| *Volume required* | >2ml | >2ml | >2ml | >2ml | >2ml |
| *Additional requirement* | | | Use for samples with HIV VL >500 copies/ml | | Centrifuge within 4 hours of collection and send plasma.<br><br>If submitting more than one sample for the same patient, please complete separate test request forms for each time point.<br><br>See Section 15.3 below |

## 15.3. TDM Trough Sample Guidance

Trough levels are used to determine whether the drug is within the desired target range (i.e. to check for efficacy) and we will usually provide an interpretation of the trough level. Peak samples may be useful in certain situations; for example, if the patient is experiencing toxicity on a particular drug.
Trough samples are collected at the end of the dosing interval, just before the next dose is due. The actual time depends on how often the patient is taking the drug. For a twice daily regimen it is 12 h post dose (we can use samples taken between 10-14 hours); for a once daily regimen it is 24 h post dose (we can use samples taken between 20-28 hours).
For most antiretroviral drugs there is no defined toxicity level.
We can provide information on where a patient's level falls compared to population PK data for a limited number of drugs.

It can be difficult to collect trough samples. For Efavirenz, Etravirine, Nevirapine and Rilpivirine, we can project trough concentrations using mean population half-life data on samples collected >4h post-dose.
For the following Protease inhibitors, population PK (percentile) data for samples taken >4 h post-dose can be used to predict whether the trough is likely to be above or below the target value :Atazanavir, Darunavir, Fosamprenavir, Lopinavir, Saquinavir

Note that this is not 100% accurate and a true trough sample is recommended.
For drugs not listed above, a true trough sample is required.

## 16. ACCEPTANCE & REJECTION CRITERIA

### 16.1. We will accept a sample if:

- The site has an active account with Cambridge Clinical Laboratories or appropriate funding is stated. If no funding stated, submitting site or account will be invoiced.
- 3 Points of ID required matching sample to request form.
- The correct sample type as listed below.

| Test Requested | Sample Types Accepted |
|---|---|
| HIV-1 PR-RT Genotyping | EDTA Plasma |
| HIV-1 INT Genotyping | EDTA Plasma |
| HIV-1 viral V3 tropism | EDTA Plasma |
| TDM | EDTA or LI-Hep Plasma. <4hrs spin to plasma |
| HLA B*5701 Genotyping | EDTA Whole Blood |
| ALK Fish/ROS1 Fish/PDL1 IHC/HER2 Fish/RET/PIK3CA/RAS-RAF/KRAS G12C | FFPET - Block or USS (see below). |
| EGFR/BRAF | FFPET - Block, USS or sections in tubes |
| Total and free PSA + Proclarix® Prostate | Serum |
| Faecal Immunochemical Testing (FIT) | Stool sample in CCL provided FIT collection tube |

### 16.2. Rejection criteria

| | |
|---|---|
| Non-charged slides or corner cut slides for ISH/IHC | Reject - incompatible slides for staining |
| sections in tubes for ALK/ROS1/PDL1/HER2 | Reject - incompatible sample for staining |
| Unmounted FFPE Material | Reject - incompatible sample for sectioning |
| Plasma/Serum for HLA | Reject - incompatible sample for testing |
| EDTA whole blood submitted for TDM | Reject - incompatible sample for testing |
| Serum submitted for TDM | Reject - incompatible sample for testing |
| Plasma for Proviral tropism | Viral V3 may be suitable. |
| sections in tubes for RAS-RAF/PIKC3A/RET analysis | Reject – not suitable for macrodissection |
| Plasma submitted for total and free PSA | Reject - incompatible sample for testing |
| Plasma submitted for Proclarix® Prostate | Reject - incompatible sample for testing |

## 17. TURNAROUND TIME & EQA

The laboratory is always looking at ways to improve the TAT without compromising diagnostic accuracy and patient safety. TATs are closely monitored by the laboratory management on a regular basis and this information is available to service users upon request.

Please note stated turnaround times are in working days and are dependent on the following factors

- Test with or without interpretation
- Courier or standard post
- Stated TATs are based on sample being accepted by the laboratory for testing to result leaving the Cambridge Clinical Laboratories.

Tests marked with * are supplied by our approved partner laboratories.

| Test | TAT | EQA Scheme |
|---|---|---|
| EGFR | 5 days | ESPQA-QuIP EQA Lung Scheme Mutations |
| BRAF | 5 days | Gen QA Melanoma |
| PDL1 IHC* | 10 days | UKNEQAS ICC PD-L1 |
| HER2 FISH* | 10 days | Breast HER2 ISH Module of UKNEQAS ICC & ISH |
| ALK FISH* | 10 days | ALK Module of UKNEQAS for Molecular Genetics |
| ROS1 FISH* | 10 days | N/A |
| RAS – RAF NGS* | 12 days | EMQN |
| KRAS G12C* | 12 days | CAP |
| BRCA* | 20 days | CAP |
| PIK3CA* | 14 days | CAP |
| RET Fusions* | 14 days | GenQa 2021 Lung Cancer Comprehensive Scheme |
| RET Mutations* | 14 days | GenQa 2021 Lung Cancer Comprehensive Scheme |
| 30 Gene Lung Panel | 14 days | EMQN, GenQA and NordiQC |
| HLA B*57:01 detection | 5 days | UKNEQAS H&I Scheme 7 |
| PR-RT | 14 days | QCMD |
| V3 Tropism | 14 days | Instand |
| Integrase Genotyping | 14 days | QCMD and Instand |
| TDM* | 14 days | Instand** |
| Free and Total PSA | 5 days | RIQAS IMMUNOASSAY PROGRAMME |
| Oncimmune® Early CDT Lung Cancer | 5 days | ILC scheme |
| Proclarix® Prostate | 6 days | N/A |
| FIT | 5 days | WEQAS Quantitative Faecal Hb |
| Stockholm3 | 14 days | N/A |
| Bladder EpiCheck® | 7 days | N/A |

**Current drugs included in EQA:
Atazanavir, Darunavir, Dolutegravir, Efavirenz, Elvitegravir, Etravarine, Lopinavir, Maraviroc, Nevirapine, Rilpivirin, Ritonavir, Tenofovir