
 CAMBRIDGE CLINICAL LABORATORIES	Type:	Standard Operating Procedure		
	Title:	CCL User handbook		
	Document No.:	CLM-030	Version No.:	09

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GENERAL INFORMATION

1. INTRODUCTION

Cambridge Clinical Laboratories is a molecular diagnostic testing laboratory, specialising in the areas of oncology and virology. We are a strong team personnel including biomedical scientists, laboratory scientists, 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.

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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 Laboratory Services 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 utmost 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.

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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 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 completed 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)

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13. SAMPLE REQUIREMENTS FOR ONCOLOGY

13.1. General Oncology Instruction

Safeguards should be undertaken to prevent sample-to-sample DNA contamination.

- Cleaning of the microtome and any equipment used in the sectioning area should be completed between the sampling of each block.
- Disposable blades provide the best means to eliminate block-to-block contamination.
- 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	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)
<i>Sample Origin</i>	Multiple Origins	NSCLC	NSCLC & Melanoma	NSCLC	NSCLC	Breast & Gastric	NSCLC, HNSCC Gastric & Urothelial	NSCLC, Breast & Urothelial
<i>Sample Type</i>	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	
<i>Additional requirement</i>	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.

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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. Select MDx ® for Prostate Cancer


- Urine (first catch) must be collected immediately following a modified digital rectal exam (DRE) procedure.
- Urine volume required > 2ml
- Additional requirement: mandatory patient information (urine collection date, PSA value, date tested and prostate volume)
- Urine sample stored and transported at room temperature needs to reach CCL laboratory within 4 days of sampling to be accepted for testing.

14.3. 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.

14.4. 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.

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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
<i>Sample Type</i>	EDTA PLASMA	EDTA PLASMA	EDTA PLASMA	EDTA WHOLE BLOOD	EDTA or LI-HEP PLASMA
<i>Volume required</i>	>2ml	>2ml	>2ml	>2ml	>2ml
<i>Additional requirement</i>			Use for samples with HIV VL >500 copies/ml		Centrifuge within 4 hours of collection and send plasma. If submitting more than one sample for the same patient please complete separate test request forms for each time point. 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.

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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
Select MDx® Prostate	Post DRE Urine <4 days old
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

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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-QulP 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
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**
SelectMDx® Prostate	10 days	N/A
Free and Total PSA	5 days	RIQAS IMMUNOASSAY PROGRAMME
<u>Oncimmune®</u> Early CDT Lung Cancer	5 days	N/A
Proclarix® Prostate	6 days	N/A
FIT	5 days	WEQAS Quantitative Faecal Hb

**Current drugs included in EQA:

Atazanavir, Darunavir, Dolutegravir, Efavirenz, Elvitegravir, Etravavirine, Lopinavir, Maraviroc, Nevirapine, Raltegravir, Rilpivirin, Ritonavir, Tenofovir