Contents

GENERAL INFORMATION

1. INTRODUCTION

Lab 21 Ltd is a molecular diagnostics 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.lab21.com.

2. ACCREDITATION

Lab 21 Ltd is accredited to UKAS under the ISO15189:2012 standards.
Our current certificate and scope can be found on the UKAS website
For the latest accreditation status please contact Lab 21 customer services.

3. SERVICE AVAILABILITY

Routine working hours for the laboratory are:

Monday – Friday: 09.00 – 17.30

The laboratory is closed on Bank Holidays.

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

4. RESULTS INTERPRETATION

Due to the nature of the services provided only interpretation of the results produced by Lab 21 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

Lab 21 Ltd 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 upmost importance to Lab 21 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 http://lab21.com/privacy-policy/

10. CONTACT DETAILS

Lab 21 Ltd is based at the following address

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

Telephone 01223 395450 Email : info@lab21.com

SAMPLE REQUIREMENTS AND TRANSPORT

11. TEST REQUESTS

Copies of request forms can be obtained from the laboratory, either by email info@lab21.com 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 Lab 21s 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

<table>
<tr><th>TEST</th><th>RAS-RAF</th><th>EGFR</th><th>BRAF</th><th>cfDNA EGFR</th><th>ALK-FISH</th><th>ROS-1 FISH</th><th>HER2-FISH (ERBB2)</th><th>PD-L1 IHC (22C3)</th></tr>
<tr><td>Sample Origin</td><td>Multiple Origins</td><td>NSCLC</td><td>NSCLC & Melanoma</td><td>NSCLC</td><td>NSCLC</td><td>NSCLC</td><td>Breast & Gastric</td><td>NSCLC</td></tr>
<tr><td>Sample Type</td><td>10x Unstained slides at 5-10µm & 1x H&E</td><td colspan="2">3 Microcentrifuge tubes containing 3 x 5-10µm sections per tube</td><td>2 x cfDNA Roche Tubes only</td><td colspan="2">4x Unstained slides at 5µm & 1x H&E</td><td>4x Unstained slides at 3µm & 1x H&E</td><td>5x Unstained slides at 3-4µm</td></tr>
<tr><td rowspan="2">Additional requirement</td><td rowspan="2">Use SuperFrost Plus, Leica Bond Plus or TOMO Slides</td><td colspan="2">For small biopsy samples (2-3mm), more sections may be submitted</td><td rowspan="2">Tubes available from Lab 21 on request.</td><td colspan="4">Use SuperFrost Plus, Leica Bond Plus or TOMO Slides. "Xtra" slides from any manufacturer are not suitable.</td></tr>
<tr><td>tumour material (>10%).</td><td>tumour material (>15%).</td><td colspan="4">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.</td></tr>
</table>

For information and guidance on our BRCA service please contact Lab 21 Customer Services.

14. SAMPLE REQUIREMENTS FOR VIROLOGY

14.1. 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

14.2. Test Requirements

TEST	HIV-1 Viral Load	HIV-1 PR-RT Resistance	HIV-1 Integrase Resistance	Viral RNA HIV-1 V3 Tropism by Genotype	Proviral DNA HIV-1 V3 Tropism by Genotype	HLA B*57:01	HIV TDM
Sample Type	**EDTA PLASMA**	**EDTA PLASMA**	**EDTA PLASMA**	**EDTA PLASMA**	**EDTA WHOLE BLOOD**	**EDTA WHOLE BLOOD**	**EDTA or LI-HEP PLASMA**
Volume required	>2ml	>2ml	>2ml	>2ml	>2ml	>2ml	>2ml
Additional requirement	Prior to separation blood should be stored between 2-25°C for no longer than 24 hours. Plasma should be separated within 24 hours of collection by centrifugation.			Use for samples with HIV VL >500 copies/ml	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 14.3 below

For information and guidance on our HR HPV service please contact Lab 21 Customer Services.

14.3. 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.

15. 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 receipt of sample in lab to sample/result leaving the Lab 21 Laboratory and do not include postal/courier delivery times to and from the Lab.

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

Test	TAT	EQA Scheme
EGFR	5 days	UKNEQAS for Molecular Genetics Lung
BRAF	5 days	UKNEQAS for Molecular Genetics Melanoma
cfDNA EGFR	5 days	UKNEQAS for Molecular Genetics Pilot
PDL1 IHC*	10 days	UKNEQAS ICC PD-L1
HER2 FISH*	7 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
BRCA*		EMQN CAP
HR HPV	7 days	QCMD
HLA B*57:01 detection	5 days	UKNEQAS H&I Scheme 7
HIV VL	5 days	UKNEQAS
PR-RT	14 days	QCMD
V3 Tropism	14 days	NRL
Integrase Genotyping	14 days	QCMD
TDM*	14 days	Instand**

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