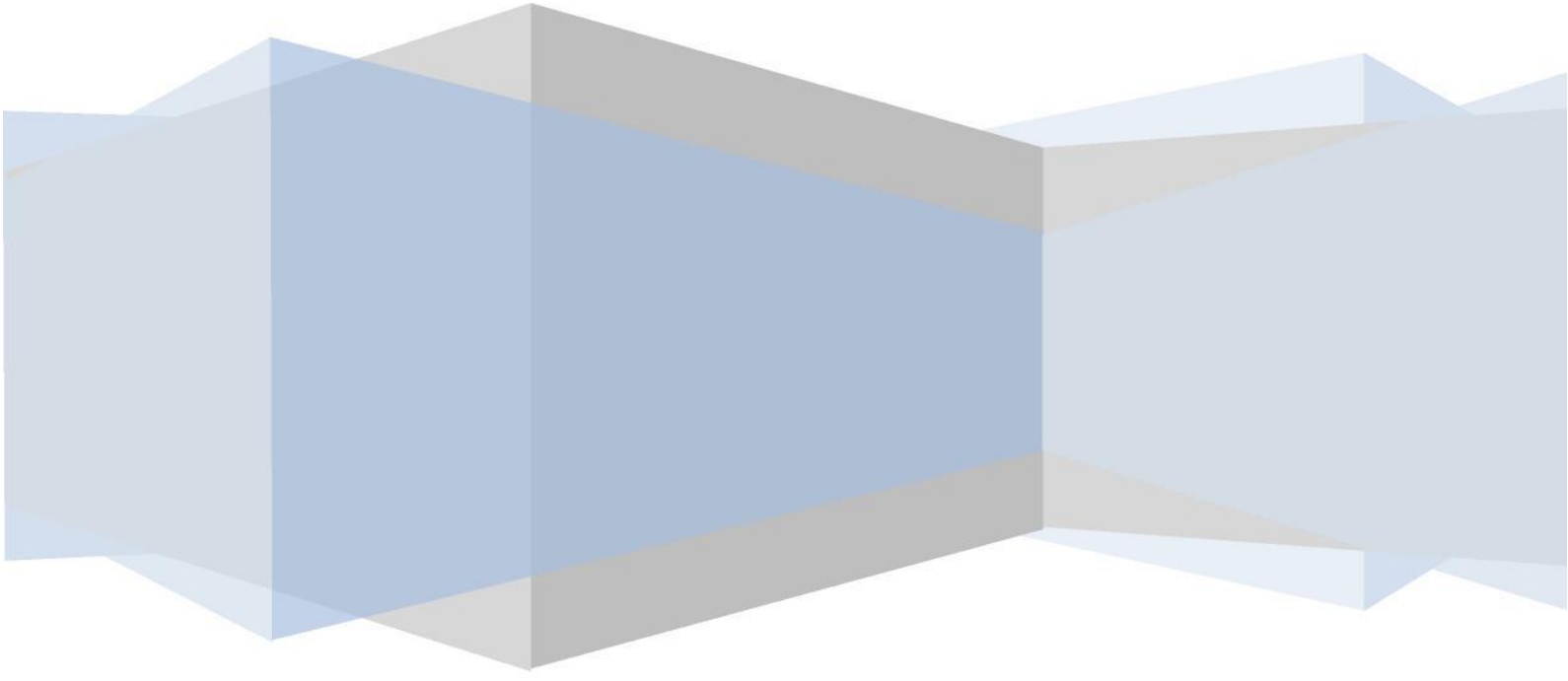
UCL-Advanced Diagnostics

2015/16 Service Update



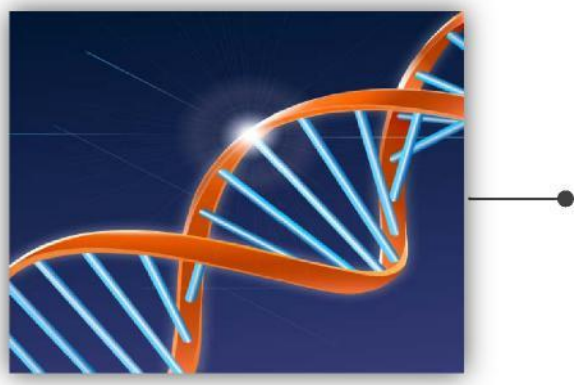
About UCL-Advanced Diagnostics

UCL Advanced Diagnostics (UCL-AD) is the immunohistochemistry, *in situ* and molecular diagnostics service arm of the UCL-Cancer Institute and a bridge between the Cancer Institute and University College Hospitals NHS Trust (UCLH). It is also the host laboratory for UKNEQAS ICC and ISH.

A 30 strong team of clinical, scientific and administrative staff provide accredited immunohistochemistry, *in situ* hybridization, molecular and digital pathology services throughout the UK and overseas. In 2014 we performed 135,000 immunohistochemistry, 3500 *in situ* and 2000 molecular diagnostic tests for a whole spectrum of diseases.

In order to ensure that we remain at the forefront of somatic mutation testing, UCL-AD, together with the Cancer Institute, has invested in a strategic personalized medicine program which has resulted in the translation of next generation sequencing technology into routine diagnostic practice.

We strongly believe that rapid, accurate and cost effective diagnostic testing; enabling assignment of targeted therapeutics should be available to all cancer patients, providing patients, pathologists, oncologists and clinicians alike with the best possible tools to aid in the diagnostic and therapeutic decision making process.



High quality mutation analysis for targeted therapies.

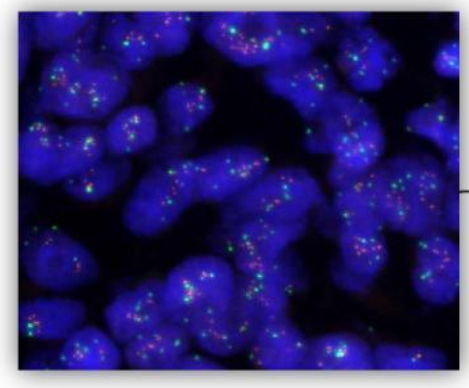
Overview of 2013/2014

UCL-AD continued to provide a high quality referral service to our patients and referring professionals.

The demand for targeted therapeutic biomarker testing continued to increase and expand. HER2 testing continues to increase each year and 2013/14 was no different, with Breast and Gastric cancer now routine requirements of the patient pathway. Additionally, in 2013 we introduced routine ALK testing of patients with NSCLC. This testing was funded by Pfizer and

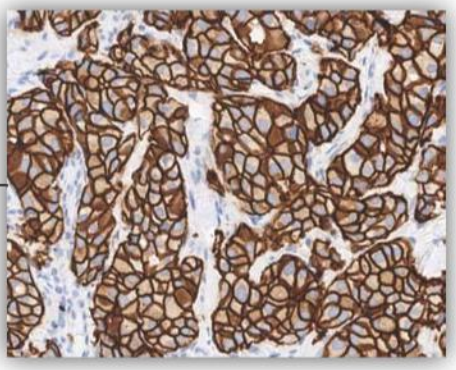
will continue to be until the end of March 2015. Please refer to enclosed letter outlining changes to ALK funding from 1st April onwards.

2013/14 witnessed a large expansion of our therapeutic biomarker testing capabilities with expanded ISH/FISH and Mutation testing portfolios. With this expansion, UCL-AD is now in a very strong position to meet the expanding demand for testing of novel and emerging treatment related biomarkers and works closely with leading oncologists to identify upcoming clinical trials which our patients may benefit from. This is reflected in our adoption of both emerging FISH targets, such as ROS1 and MET in NSCLC and FGFR1 & 2 in a variety of tumours, and Next Generation Sequencing (NGS) as our primary technology for tumour associated mutation analysis.



Accurate assessment of gene amplifications and translocations

Targeted prognostic and predictive biomarker testing



Our molecular pathology laboratory in Shropshire House has gone from strength to strength and in October 2014 moved to an entirely* NGS based service using the IonTorrent™ PGM platform with a 22 gene tumour panel (MGP-1) for mutation testing.

*We continue to offer BRAF V600 mutation only screening via a CE-IVD qPCR assay for any customers who require this.

NGS offers patients and referring professionals an expanded testing portfolio with increased diagnostic yield and improved clinical significance/utility than previously employed assays. It also opens up avenues for patients to gain access clinical trials exploring the usefulness of emerging treatments.

Update for 2015

Over the last year we have continued to see an increase in the use of tissue biomarkers and molecular targets to complement morphological diagnosis. Traditional biomarkers used to determine tumour lineage are now routinely complemented with biomarkers which provide information not only to the pathologist but also to the oncologist, playing a vital role in crucial therapeutic decisions.

2015 will see the continued expansion of UCL-AD's range of immunohistochemical, *in situ* and molecular tests, as new and novel antibodies, probes and molecular assays are translated from research, validated for clinical utility and offered to aid in diagnosis.

Continuous improvement in ***test quality, expanded menu, efficient turnaround time*** and ***cost effectiveness*** are our key drivers, and will continue to be in 2015. Detailed turnaround times will be available to all of our customers in 2015 and we would encourage referring laboratories to enquire about the availability of this information.

We continuously listen to and monitor customer requests and early 2015 will see the introduction of numerous new diagnostic, prognostic and therapeutic IHC & ISH assays, such as GATA-3, c-MYC, SOX-10 and Phospho-histone H3 (PHH3) for IHC and FGFR1, FGFR2 and RET FISH assays. Please refer to our website www.uclad.com/ihc or contact our IHC & ISH Clinical Services Manager, David Allen for availability or interest in new assays.

In 2014, we reluctantly had to pass on rising consumable costs to our customers, something which in light of challenging economic circumstances we had not increased since 2010. This was reflected in a small price increase on our routine IHC service, with the price of our therapeutic biomarker testing for IHC and ISH remaining unchanged.

We are pleased to confirm that there will be ***NO INCREASE IN COST PER TEST FOR 2015/16 (Routine IHC, Biomarker IHC & Mutation testing; April 2015-April 2016)*.***

*To ensure the sustainability of our clonality testing service we have to increase prices from April 1st 2015. Please refer to enclosed 2015/16 pricelist.

2015 will see further development of the ***UCL-AD Digital Pathology Service.*** Digital Pathology is entering a period of more widespread knowledge of the potential capabilities and technical improvements have these possibilities. In 2015 we will develop new relationships with companies who are at the forefront of this technology. This service facilitates both improved turnaround time for urgent and routine samples and improved efficiency for external case review.

We welcome your feedback and look forward to continuing to provide a rapid, high quality clinical service and working together, strengthening our relationship over the coming year.

Contact Details

Professor Adrienne Flanagan
Clinical Manager and Lead of UCL-AD
Professor of Research Pathology
EMAIL: a.flanagan@ucl.ac.uk

Mr. David Allen
Lead BMS
Clinical Services Manager IHC/ISH *(acting)*
Tel No: 020 7679 6912 (Rockefeller)
EMAIL: david.allen@ucl.ac.uk

Dr. Phil Bennett
Principal Clinical Scientist
Clinical Services Manager Mutation & Clonality
TEL: +44 (0)20 7679 9338 (Shropshire House)
EMAIL: p.bennett@ucl.ac.uk

Dr. Naomi Guppy
Research Services Manager
Tel No: 020 7679 6913
EMAIL: n.guppy@ucl.ac.uk

Payment Terms

Mr. Simon Mackie
UCL-Advanced Diagnostics
1st Floor, Rockefeller Building
21 University Street
London
WC1E 6JJ
Tel No: 020 7679 6039
EMAIL: simon.mackie@ucl.ac.uk

An indication of charge is returned with all stained slides. Payment will be due 30 days from the date of our invoice.

For private healthcare requests which are to be billed via personal patient insurance, requests MUST be accompanied with complete details of the patient **Insurance Policy Provider** and **Insurance Policy Number**.

UCL-Advanced Diagnostics
Rockefeller Building
21 University Street
London
WC1E 6JJ
Tel: 02076796039
Fax: 02076796275
EMAIL: info@uclad.com
Web: www.uclad.com