



HEALTH SERVICES  
LABORATORIES

# Advance Diagnostics

2024/25 Service User Guide



Advanced  
**Diagnostics**



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## Service Hours

Mon to Fri: Routine Hours (7:30am to 7:00pm)  
Sample Queries (9:30am to 6:00pm)

Sat / Sun: Closed

## HSL-AD Contact Details

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## General Information

### Introduction

HSL Advanced Diagnostics (HSL-AD) is wholly owned and managed by Health Services Laboratories (HSL). HSL-AD and its team of 39 scientific and administration staff provide a leading service for immunohistochemistry, in-situ hybridisation and molecular pathology services nationally and internationally. HSL-AD is also supported by a team of specialist Consultant Histopathologists.

In 2023, we performed 350,000 immunohistochemistry and 8,500 fluorescent in situ hybridisation tests for a whole spectrum of diseases. Full details of our service can be found at [www.hsl-ad.com](http://www.hsl-ad.com).

The service also offers referral testing for include special stains. The laboratory service has a comprehensive test repertoire. Most stains are carried out using the Agilent Artisan, with the remainder performed manually.

### Accreditation

HSL-AD is a UKAS Accredited Medical Laboratory (No. 9007) and our full scope of accreditation can be viewed at the UKAS website using the following link: [HSL-AD Scope of Accreditation](#).

Referral for specials stains are received and managed by the HSL-AD laboratory, and then stained at our sister histology laboratory at 60 Whitfield Street. Staining for these tests falls under the UKAS customer number 9706 and the scope of accreditation for that service can be viewed using the following link: [HSL Cell Path Scope of Accreditation](#).

## Test Repertoire

HSL-AD has a large repertoire of IHC and ISH tests. If there are any markers not currently listed on our website, please contact the laboratory to enquire. We monitor all requests received into the laboratory and ensure that we have the broadest repertoire of antibodies and probes to supplement your diagnostics workflow. All referring laboratories will be contacted directly if any requested tests are not currently stocked by HSL-AD.

Clinical antibodies: [www.hsl-ad.com/ihc/clinical\\_antibodies](http://www.hsl-ad.com/ihc/clinical_antibodies)

Research antibodies: [www.hsl-ad.com/ihc/research\\_antibodies](http://www.hsl-ad.com/ihc/research_antibodies)

Clinical ISH probes: [www.hsl-ad.com/ish/clinical\\_probes](http://www.hsl-ad.com/ish/clinical_probes)

Research ISH probes: [www.hsl-ad.com/ish/research\\_probes](http://www.hsl-ad.com/ish/research_probes)

## Immunohistochemistry, In-Situ Hybridisation & Special Stain Requests

Copies of request forms can be downloaded from:  
[www.hsl-ad.com/ihc/ihc\\_and\\_ish\\_request\\_forms](http://www.hsl-ad.com/ihc/ihc_and_ish_request_forms)

There are two request forms for all tests offered by the HSL-AD service, organized as Stain & Return and Reported Tests.

- Stain & Return: Test Request Form (IHC/ISH/Molecular/Special Stains for stain and return).
- Reported: Reported IHC/FISH/Molecular Profiling request form for staining/processing and specific report generation at HSL-AD.

Please complete all request forms in full. In particular, three points of patient identification are required. Ensure that the slide/block and request form information match. The patient identifications required:

1. Surname
2. Date of Birth
3. Referring hospital laboratory/surgical number and block ID

The referring hospital/laboratory accepts responsibility for errors caused due to insufficient patient identification provided for diagnostic tests. For all interpretation requests we use the specific reported IHC/FISH/Molecular request forms. Please select the appropriate form and complete all details. These can be found by using the link above.

### Sample Requirements & Transport

**IHC (stain and return only)** - For stain and return IHC requests, we require sections cut at 3-4µm placed on positively charged IHC slides. Please provide an appropriate number of unstained sections to cover the number of requests per case plus an additional 2-4 sections for repeat staining that may be required.

**Special Stain (stain and return)** - For special stains, the vast majority of sections can be cut at 3µm onto positively charged IHC slides. Please provide an appropriate number of unstained sections to cover the number of requests per case. See the tables on pages 6 and 7 for slide requirements for Reticulin stain.

**IHC and FISH for interpretation** - For all interpretative requests, we require an appropriate number of unstained sections plus an additional 2 unstained sections for repeat/reflex testing that may be required.



IHC/CISH	No of Slides Required	Section Thickness	Additional Material	Reflex Testing	Slide Type
<b>Stain &amp; Return IHC/ISH</b>	No of tests + 1 USS per 4 IHC (max 4 USS)	3µm	N/A	N/A	SuperFrost Plus, Leica Bond Plus  RECOMMENDED
<b>Breast Her-2 (4B5)</b>	4	3µm	Relevant IHC (p63, SMM)	HER2 FISH	
<b>Gastric Her-2 (4B5)</b>	4	3µm	H&E	HER2 FISH	
<b>NSCLC IHC Panel</b> (ALK, ROS1, PD-L1)	7	3µm	H&E	FISH (ALK/ROS1)	
<b>ALK (D5F3)</b>	3	3µm	N/A	ALK FISH	
<b>ROS1 (D4D6)</b>	3	3µm	N/A	ROS1 FISH	
<b>PD-L1 (22C3)</b>	3	3µm	N/A	NO	
<b>PD-L1 (28-8)</b>	3	3µm	N/A	NO	
<b>PD-L1 (SP142)</b>	3	3µm	N/A	NO	
<b>pan-TRK (EPR17341)</b>	5	3µm	N/A	Gene Fusion Panel - Idylla	
<b>Mismatch Repair</b> (MMR, HNPCC)	6	3µm	N/A	NO	
<b>p16 (E6H4)</b>	3	3µm	N/A	NO	

FISH	Test Type	No of Slides Required	Section Thickness	Additional Material	Slide Type	
<b>HER2 (ERBB2)</b>	Amplification	3	3-4µm	H&E, Her-2 IHC & any relevant IHC	SuperFrost Plus, Leica Bond Plus  ESSENTIAL	
<b>MYC</b>	Amplification	3	3-4µm	N/A		
<b>NSCLC FISH</b> ALK, RET, ROS1	Rearrangement	No of tests + 2	5µm	H&E, ALK & ROS1 IHC (if tested)		
<b>Lymphoma*</b> BCL2, BCL6, CCND1, IGH, IRF4, MALT1, MYC	Rearrangement	No of tests + 4	2-3µm	H&E & any relevant IHC		
<b>Lymphoma*</b> DLBCL / HG B-Cell Lymphoma	*All requests will automatically be processed for BCL2, BCL6, MYC, MYC::IGH FISH. Subsequent FISH testing for IGK, IGL, MYC::BCL6 and / or BCL2::IGH may be required to provide a complete diagnostic profile					
<b>Lymphoma</b> CCND1, CCND1::IGH	Rearrangement	4	2-3µm	H&E & any relevant IHC		
<b>Liposarcoma</b> CDK4, MDM2	Amplification	No of tests + 2	3-4µm	H&E		
<b>DDIT3, ETV6/NTRK3*, EWSR1, MAML2, MYB, NUTM, TFE3</b>	Rearrangement	No of tests + 2 *ETV6/NTRK3	5µm	H&E		
<b>FGFR1, FGFR2, MET, MYC</b>	Amplification	No of tests + 2	3-4µm	H&E		
<b>FGFR2</b>	Rearrangement	No of tests + 2	5µm	H&E		
<b>PDGFB</b>	Rearrangement	No of tests + 2	3µm	H&E		
<b>Melanoma</b>	Copy number alterations	No of tests + 3	3-4µm	H&E		

Stain and Return Special Stains	No of Slides Required	Section Thickness	Additional Material	Slide Type
<b>General Special Stains</b> All other silver stains except Retic	No of tests	3µm	3-4µm	SuperFrost Plus, Leica Bond Plus, Routine Non Adhesive slide
<b>Congo Red</b>	2	6-7µm	3-4µm	RECOMMENDED
<b>Silver stain: Retic</b>	2	5µm	5µm	SuperFrost Plus, Leica Bond Plus  ESSENTIAL

Molecular	No of Slides Required	Additional material required
<b>HPV Genotyping</b>	Tissue Block Only	H&E
<b>Veracyte Prosigna</b>	Tumour Resection Block Only	ESSENTIAL: Patient should be ER Positive & HER2 Negative, with accompanying full pathology report, to include biopsy, lymph node and excision specimens

## Slide Requirements for Staining Carried Out by HSL-AD

### Cutting of tissue sections to be referred to HSL-AD for IHC or FISH testing - see figure 1

All sections cut for IHC or FISH testing require special precautions for optimal performance and quality of staining procedures. Sections should be cut onto the recommended slide type.

#### Tissue Placement (All Routine Stain & Return IHC, MMR)

- Section placement should not be excessively high. HSL-AD primarily uses the Leica Bond III platform for IHC staining and the staining area does not cover the entire surface area of the slide.
- Sections from biopsies and small pieces of tissue should be placed in the area within the blue box.
- Sections from resections and larger / multiple pieces of tissue should be placed in the area covered by the red box.
- Placement of tissue in this way is applicable for all slide types.
- It is very important that the lesion of interest from mega blocks is placed on the test slides appropriately.

### Tissue Placement (Her-2, ER, ALK, ROS1, p16, pan-TRK, PD-L1 and FISH Tests)

- see figure 2

- These IHC tests are primarily performed on the Roche / Ventana and Agilent / Dako platforms.
- Section placement should be in the top third of the slide.
- Sections from resections and larger / multiple pieces of tissue should be placed as required, leaving some free space towards the bottom of the slide.

### Virology / Bacteriology IHC Requests

- see figure 3

- Cut a ribbon of 3 sections on each slide referred for the these tests e.g. CMV, H. pylori, T. pallidum [Syphilis] and VZV.



figure 1



figure 2



figure 3



## Slide Drying / Baking

- Once cut, all sections for IHC and FISH should be left to dry naturally or in a slide rack above a gentle heat source in an upright position for 30 minutes to 1 hour. Ensure that there is no remaining water underneath the section before baking. The use of slides recommended in this user guide are selected to optimize the drying process, reduce the time required and significantly reduce the number of repeat tests we perform.
- All sections for IHC or FISH should be placed in a temperature controlled oven at 60°C for one hour or at 37°C overnight.
- Sections should not be hot-plated using direct heat on the slide, as this may cause poor tissue adherence and unreliable IHC / FISH staining quality.
- The use of X-tra® Slides from any manufacturer is not suitable for FISH testing.
- If slide identification at the referring laboratory is done through printed labels, the maximum height of these labels must not exceed 22mm. If this is not possible, slides hand written with pencil are preferable.  
*(This is critical as HSL-AD primarily uses a range of staining platforms. IHC/CISH staining on these have been calibrated and validated for a specific slide surface area. Furthermore, labels extending down onto the slide staining area may exert a hydrophobic effect on the reagents applied).*
- Any deviations to these instructions may lead to compromised staining quality.

## Packaging and Sending of Slides / Blocks to HSL-AD

- All slides sent to us must be securely packaged in slide mailer boxes with lids taped down.
- Where possible, tape the slide boxes together to minimise movement inside the package.
- Blocks and slides must be thoroughly secured in protective material before sending i.e. blocks and slides should not be placed loose in any transport container (box) when accompanying other material.
- A new padded envelope should be used for all specimens. The reuse of envelopes is not advised as these may open during transport.
- Ensure all material (forms, slides and blocks) is in the package before sealing. (Confirm that three points of identification are present).
- Material receipt forms sent to HSL-AD must state the material sent i.e. block and slide numbers.
- Please ensure the correct address label is on the envelope.

## Packaging and Returning of Slides / Blocks to Equestor

- All slides (slide mailer boxes) and blocks (secured in protective material) are sent out in securely padded envelope via Royal Mail or courier.
- As standard, all cases are returned to referring laboratories using 1st class postage through the Royal Mail. Tissue blocks are tracked via the Royal Mail signed for service.
- If you would like to arrange a courier or want us to arrange one please contact us directly.

# Rejection Criteria

## Introduction

Requesting laboratories will be notified where samples are unsuitable for testing. Changes to the request form or new tissue section may be requested and testing will commence once the issue has been corrected. Patient material and requests will be returned to sites for correction if no communication to resolve is received.

The following issues will result in specimen rejection:

### Request Forms

- Illegible request (all request forms are designed as editable pdf documents, we recommend that requesting laboratories complete forms electronically).
- Test(s) required not stated.
- Requesting laboratory not stated.
- Requesting laboratory/surgical slide/block number not stated.

### Slides/Blocks

- Number mismatch between slide/block and request form
- Slides/blocks without information.
- Insufficient material received or slides broken in transit.

### Clinical Trials

- Inclusive of above, all requests for work coming through the laboratory as part of an organised clinical trial must have all information points completed and correct. All identifiable patient information must be anonymised (unless such information forms part of the trial process, e.g. DOB). Cases with incorrect or no information will be rejected. All corrections to request forms or data should be corrected with a single line through the incorrect information, be signed and dated. Where appropriate, an explanation of the nature of the correction should be stated.

# Results

## Results Interpretation

Any request with interpretation will be done by the appropriate specialist Consultant Histopathologist or Biomedical Scientist team depending on the test requested.

## Clinical & Scientific Advice

Customers are encouraged to contact the laboratory with any queries about the testing service we provide. All requests should be either telephoned directly or emailed to [ad@hslpathology.com](mailto:ad@hslpathology.com). The laboratory will liaise with our consultant colleagues where their clinical input is required.

## Results Availability

Reports are returned by email to the requesting hospitals only. HSL use encrypted email for the secure transmission of patient results and information as required. Where results are unexpected, require explanation or may require urgent intervention we will endeavour to contact the requestor.

## Downtime

Rarely there are times where instrument downtime may result in delay of slides being processed and returned. This occurrence is very rare and all major engineering tasks required for our IHC instruments and department are carried out during weekend periods. In the event of this, all customers will be contacted directly and will be informed of any situation with expected turn-around times.

## Complaints

HSL-AD 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 Head of Department, Quality Manager or a member of our Senior BMS team. Non-conformance reports are provided to affected customers upon request.

## Terms & Conditions

Each individual test request is considered as an agreement between HSL-AD and the referring laboratory to perform all available tests requested. Service level agreements are available for all referring laboratories/customers, please enquire for further information.

## Patient Confidentiality

Patient confidentiality is of the upmost importance to HSL-AD. All staff that come into contact with any confidential information are bound by the laws of the Data Protection Act 2018 (GDPR) and Human Rights Act 1998. The laboratory's privacy policy can be found at: [www.hsl-ad.com/privacy\\_statement](http://www.hsl-ad.com/privacy_statement).

The Laboratory also complies with Modern Slavery and Human Trafficking Statement under Section 54 of the UK Modern Slavery Act 2015.

## Turnaround Times & EQA

HSL-AD 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:

- Day of receipt of tissue block or pre-cut slides.
- Test with or without interpretation.
- Arrival time in laboratory (all FISH requests must arrive in the laboratory by 12:00 for TAT calculation to begin on that day, otherwise it will begin from the following working day).
- Courier or standard post (please send by at least 1st Class Royal Mail or Special Delivery).
- Stated TATs are based on receipt of sample in lab to sample/result leaving the HSL-AD Laboratory and do not include postal/courier delivery times to and from the lab. All requests involving interpretation are sent by encrypted email.



Test	TAT	EQA Scheme / Alternative QA	2023 EQA
<b>Routine IHC &amp; ISH (FFPE)</b>	24-48 hours	UKNEQAS ICC & ISH (General, Lymphoma, GIST, Breast, Neuropathology); NordiQC	Good
<b>Routine IHC (Cytology)</b>	24-48 hours	UKNEQAS ICC & ISH (Cytology)	Good
<b>HER2 IHC + Interpretation</b>	72 hours	UKNEQAS ICC & ISH (Breast & Gastric)	Good
<b>ALK IHC + Interpretation</b>	72 hours	UKNEQAS ICC & ISH (ALK)	Good
<b>ROS1 IHC + Interpretation</b>	72 hours	UKNEQAS ICC & ISH (ROS1)	Good
<b>PD-L1 22C3 + Interpretation</b>	5 days	UKNEQAS ICC & ISH (PD-L1); NordiQC	Good
<b>PD-L1 28-8 + Interpretation</b>	5 days	Alternative QA method	Good
<b>PD-L1 SP142 + Interpretation</b>	5 days	NordiQC	Good
<b>Mismatch repair (MMR) IHC + Interpretation</b>	7 days	UKNEQAS ICC & ISH (MMR)	Good
<b>p16 IHC + Interpretation</b>	72 hours	UKNEQAS ICC & ISH (General)	Good
<b>HPV Genotyping + Interpretation</b>	10 days	GENQA FFPE DNA Extraction Alternative QA method	Good
<b>HPV RNAscope (High &amp; Low Risk)</b>	10 days	UKNEQAS ICC & ISH (HPV Pilot)	Good
<b>HER2 FISH + Interpretation</b>	5 days	UKNEQAS ICC & ISH (Breast HER2 ISH)	Good
<b>ALK, ROS1, RET FISH + Interpretation</b>	10 days	UKNEQAS ICC & ISH, Alternative QA method	Good
<b>MDM2, CDK4 FISH + Interpretation</b>	10 days	GENQA Alternative QA method	Good
<b>Lymphoma FISH + Interpretation</b>	10 days	GENQA Alternative QA method	Good
<b>Melanoma FISH + Interpretation</b>	10 days	Alternative QA method	Good
<b>All other FISH (Amplification)</b> FGFR1, FGFR2, MET, MYC	10 days	Alternative QA method	Good
<b>All other FISH (Translocation)</b> DDIT3, ETV6, EWSR1, FGFR2, MAML2, B, NUTM, NTRK3, PDGFB, TFE3	10 days	Alternative QA method	Good
<b>Biocartis Idylla</b> (EGFR, Gene Fusion Panel)	72 hours	Alternative QA method	N/A
<b>Veracyte Prosigna</b>	10 days	Alternative QA Method	Good

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