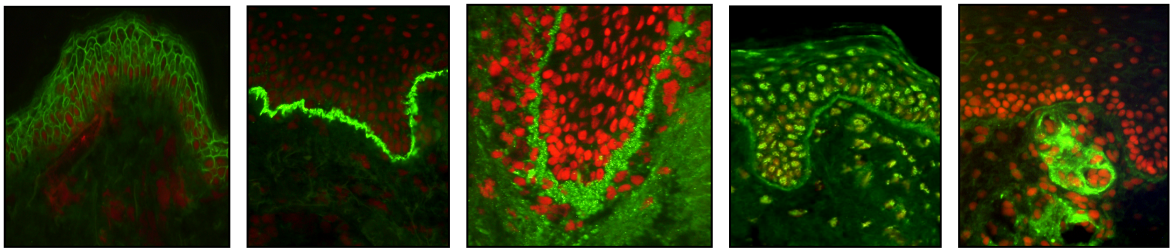
DIAGNOSTIC IMMUNODERMATOLOGY SERVICES:

USER GUIDE



The Synnovis Immunodermatology Laboratory is the only dedicated skin immunofluorescence referral laboratory in the UK. We receive approximately 8,500 samples per year from over 100 centres around the UK.

Conditions assessed

The laboratory specialises in contributing to the diagnosis and management of the following diseases using immunofluorescence and ELISA techniques:

Condition	No. of biopsies requested	Biopsy site(s) for DIF studies
Pemphigus (all forms)	1	Peri-lesional uninvolved
Pemphigoid (all forms)	1	Peri-lesional uninvolved
Pemphigoid gestationis	1	Peri-lesional uninvolved
Epidermolysis bullosa acquisita (EBA)	1	Peri-lesional uninvolved
Linear IgA bullous dermatosis (LABD & CBDC)	1	Peri-lesional uninvolved
Dermatitis herpetiformis (DH)	1	Peri-lesional uninvolved
Discoid lupus erythematosus (DLE)	1	Lesional
Systemic lupus erythematosus (SLE)	**2**	Lesional **and** uninvolved (non-sun exposed)
Lichen planus (LP)	1	Lesional
Porphyria	1	Lesional
Vasculitis	1	Lesional
Amyloidosis	1	Lesional

NB *For accurate direct immunofluorescence diagnosis of the immunobullous diseases in bold above, biopsy of* ***normal perilesional*** *skin or mucosa is essential. Lesional and/or heavily inflamed biopsies are sub-optimal for this technique and are unlikely to yield diagnostically useful results.*

Specimen Requirements

Immunofluorescence can be performed on either epithelial biopsies (direct) or serum (indirect). Enzyme-linked immunosorbent assays (ELISAs) can only be performed on serum.

NB The laboratory does not accept blister fluid specimens for analysis.

Direct immunofluorescence (DIF)

This is a one-step procedure for detecting *in vivo* deposition of immunoglobulins, complement component C3 and fibrinogen in epithelial tissues including skin, buccal mucosa and conjunctiva.

Sample required	Tissue biopsy/biopsies from appropriate site *(see table on page 1)*
Biopsy preparation	• Whenever possible, separate biopsies should be taken for histology and DIF. • Bisecting biopsies for DIF analysis should be avoided, to preserve epithelial integrity. • For uninvolved perilesional or lesional skin, a 3- or 4-mm punch biopsy is sufficient. • Biopsies should be placed in a specimen pot containing at least 3 ml Michel's medium, which can be provided on request. **Biopsies are stable in this medium for up to 6 months at room temperature**. • Containers must be labelled with patient name and date of birth.
Request form	Request forms are provided with the Michel's medium specimen pots or can be downloaded from https://www.synnovis.co.uk/departments-and-laboratories/immunodermatology-laboratory-at-st-thomas. These should be fully completed to include: • Patient name (forename and surname) • Date of birth • Requesting clinician name • Sender details • Report destination • Biopsy site • Clinical information *(including question(s) to be answered and differential diagnoses)*
Transport	• The specimen container must be placed in a sealed plastic bag, with the request form outside the plastic bag. • The bagged specimen should be placed into a primary container, with adequate absorbent material, in case of leakage. • Securely seal the primary container, then place it in a secondary shipping container. • Specimens should be sent by either courier service or registered post to the below address and shipped at ambient temperature.

Rejection criteria for samples	• Tissue not transported in Michel's medium • Tissue contaminated with formalin • Request form inadequately filled out or absent • Specimen pot details fail to match those on the request form
Factors known to significantly impact performance of DIF and/or interpretation of results	• Heavily inflamed biopsies • Lesional biopsies (exceptions noted in table on page 1) • Biopsies with partially split, fully separated or missing epithelium • Failure to immerse specimen in Michel's medium for transit. • Formalin contamination
Procedure for handling sub-optimal biopsy specimens	• In the event of a query around specimen or request form identification, requesting centres will be contacted within 24 hours of receipt of specimen, if contact information is available. • Biopsies with sub-optimal morphology revealed during microscopy will be reported as sub-optimal and corrective action provided in the report. • Given their clinical importance, the laboratory will only reject a biopsy specimen as a last resort and, in most cases, will attempt to return the biopsy to the client, under such circumstances.
Turnaround time	**5 working days** from receipt in laboratory to verification of report.

Indirect immunofluorescence (IIF)

This is a two-step procedure for demonstrating circulating auto-antibodies in a patient's serum, utilising a number of epithelial substrates.

Sample required	5 ml coagulated venous blood or 0.5 ml serum, sent to laboratory within 48 hours of collection (1 month for separated serum, following storage at 4°C). ***NB Please use a gold coloured, serum separator blood tube for collection of sample*** Serum samples must be labelled with patient name and date of birth.
Request form	All samples should be accompanied by a fully completed request form *(see DIF table for further details)*
Transport	Serum specimens can be shipped at ambient temperature and should **not** be frozen. *(see DIF table for further details)*
Rejection criteria	• Non-coagulated blood or plasma received • Specimens showing extensive haemolysis or lipaemia • Request form inadequately filled out or absent • Blood tube details do not match request form

Factors known to significantly impact performance of IIF and/or interpretation of results	• Plasma processed, rather than serum • Specimens showing extensive haemolysis or lipaemia • Specimens frozen prior to analysis • Specimens stored at room temperature for over 2 weeks prior to analysis.
Procedure for handling sub-optimal serum specimens	• In the event of a query around specimen or request form identification, requesting centres will be contacted within 24 hours of receipt of specimen, if contact information is available. • Submitted plasma specimens will be rejected and the requesting centre informed within 24 hours of receipt of specimen. • Sub-optimal serum specimens *will* normally be processed but a comment may be added to the report, to guide interpretation, if (e.g.) haemolysis or lipaemia is considered sufficiently extensive to influence the results.
Turnaround time	**8 working day**s from receipt in laboratory to verification of report.

ELISA

The laboratory performs the following 5 assays for quantification and monitoring of specific circulating antibodies:

Antibody	Disease	Positivity threshold
Desmoglein 1	Pemphigus	>30 U/ml
Desmoglein 3	Pemphigus	>30 U/ml
BP180/collagen XVII	Pemphigoid	>20 U/ml
BP230/dystonin	Pemphigoid	>10 U/ml
Collagen VII*	Epidermolysis bullosa acquisita	>20 U/ml

Each ELISA can be performed on 10 µl of serum and results are reported in (arbitrary) U/ml. ELISAs are normally performed in combination with IIF studies, hence sample requirements are identical to those for IIF. Relevant ELISA testing will be determined by lab staff, dependent on immunofluorescence results and information provided on the request form.

Factors known to significantly impact performance of ELISA are the same as those for IIF listed above.

**Please note that the collagen VII ELISA is not currently within the laboratory's UKAS scope of accreditation (see below)*

[Internal users only]

All tests to be performed in the Immunodermatology Laboratory should be requested using the appropriate test codes ("Direct immunofluorescence", "Indirect immunofluorescence plus relevant ELISAs", "DSG1/3 ELISA", "BP180/230 ELISA" or "COLVII ELISA") on Epic LIMS. Appropriate barcode labels will be printed for specimen pots but no hard copy request form is required. Use standard internal transport pathways to send specimens to the lab. In the event of Epic failure, paper request forms will be accepted, using the external request form available for download (see page 2). Please note that the laboratory is located on the St Thomas' site.

Laboratory operating hours:

09:00 – 17:00, Monday to Friday

Contact information:

Tel: 020 7188 6364

Email: immunodermatology@gstt.nhs.uk
synnovis.imf@nhs.net

Address: Immunodermatology Laboratory
St John's Institute of Dermatology
St Thomas' Hospital
Westminster Bridge Road
LONDON
SE1 7EH

Results are available to clinicians by telephone or email.

No information will be given to patients or their relatives, in accordance with data protection legislation.

Any complaints (or compliments) regarding the laboratory diagnostic service should be directed to the Clinical Lead and/or Laboratory Manager, in the first instance, as detailed below.

Senior staff:

- **Dr Richard Groves**, *Consultant Dermatologist/Clinical Lead*
- **Dr John Mee**, *Principal Clinical Scientist/Lab Manager*
- **Dr Catherine Stefanato**, *Consultant Dermatopathologist*
- **Asif Khan**, *Senior Biomedical Scientist*
- **Laura Taylor**, *Senior Biomedical Scientist*

For clinical advice, including patient management issues, please contact Dr Groves on **020 7188 6279** or richard.groves@gstt.nhs.uk.

For results interpretation or any other lab-related queries, please contact Dr Mee on **020 7188 3057** or john.mee@nhs.net.

The Synnovis Analytics Immunodermatology laboratory is a UKAS (United Kingdom Accreditation Service) accredited medical laboratory (No. **8126**); accredited to ISO15189:2012 for the scope described in the UKAS Schedule of Accreditation which can be found on the UKAS website: https://www.ukas.com/find-an-organisation.