Infection Division

Toxoplasma Reference Unit

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Toxoplasma Reference Unit
User Handbook

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1 Introduction

The Toxoplasma Reference Unit (TRU) is located within the Public Health Wales Microbiology laboratories based in Singelton Hospital, Swansea. The Unit provides specialist diagnostic and clinical advice services to hospitals across England and Wales to support the investigation, diagnosis and management of infection caused by *Toxoplasma gondii.*

Reference serological and molecular investigations are performed for a wide range of at-risk clinical groups including pregnant women, neonates/infants and immunocompromised individuals such as transplant recipients, people living with HIV and cancer patients.

Expert interpretation of laboratory results and advice on appropriate investigations, treatment options, patient management and infection prevention are available during operating hours via telephone and e-mail.

Research and development interests focus on diagnosis, management and epidemiology of toxoplasma infection. Work includes evaluation and enhancement of assays, development of international standards, support of UK NEQAS quality assessment schemes, contribution to clinical guidelines and reporting of enhanced epidemiology data. In addition, the TRU supports training and education of healthcare professionals via presentations and published educational resources.

2 Contact details

Toxoplasma Reference Unit

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3 Key staff

Acting Head of Unit, Consultant Clinical Scientist – **Dr Stephen Hadfield**

Operational Manager, Serodiagnostic Services – **Heather Alderson**

Senior Healthcare Scientist – **Sayeed (Rafi) Ali**

Senior Biomedical Scientist – **Alis Twigg**

4 Opening hours

The full services of the TRU are available 08:45 to 17:00 Monday to Friday. The TRU is closed on public holidays.

Note: For urgent requests during normal laboratory hours, please telephone the laboratory to ensure priority processing.

Where urgent samples are sent by courier outside normal working hours, arrangements must be agreed with the laboratory before the sample is sent.

5 Clinical Services

Laboratory Investigation of Toxoplasma Infection

- **Immunocompetent patients (Referred specimens)**
  Confirmatory testing is offered where this will result in more timely and appropriate patient management through exclusion of other aetiologies.

- **Vulnerable clinical groups (Reference specimens)**
  Specialist testing is offered in a range of clinical scenarios including pregnancy/infants, HIV/AIDS, organ transplantation/other immunosuppressed and suspected ocular disease in order to both

achieve a definitive diagnosis and facilitate timely and appropriate patient management.

Clinical advice

Clinical advice on specific management strategies based on results of reference testing or general advice, including further investigation, anti-toxoplasma therapies and other management options.

Public Health advice on risk and risk-reduction

Both general information and information on an individual case basis can be provided.

6 Examinations offered

6.1 Assays and appropriate sample types

TRU offers the following tests for examination of toxoplasma infection:

- Sabin-Feldman dye test (DT; reference serology test -IgG & IgM)
- IgM EIA
- Platelia lgM EIA (BioRad)
- IgG avidity
- Molecular diagnosis (PCR)

See Table 1 for appropriate sample types and assays for different clinical scenarios. See Section 10 for sample volumes.

Table 1: Appropriate specimen types and assays for investigation of toxoplasma infection.

Clinical scenario	Helpful specimens	Assay
Immunocompetent		
Acute toxoplasmosis	Blood (clotted or serum)	DT and IgM EIA
Pregnancy/Congenital toxoplasmosis		
Mother	Blood (clotted or serum)	DT and IgM EIA, other assays as required
	Amniotic fluid (>1ml)	PCR
Neonate/infant	Neonatal blood (clotted/serum)	DT, IgM, EIA, Platelia lgM[2]
	EDTA blood	PCR[3]
Stillbirth	Foetal blood (clotted/serum)	DT, IgM, EIA, Platelia IgM[2]
	Foetal CNS/cardiac tissues/EDTA blood	PCR[3]
HIV/AIDS		
HIV/AIDS	Blood (clotted or serum)	DT and IgM EIA, Platelia IgM[2]
	CSF (if CNS involvement)/EDTA blood	PCR[3]
	CNS tissue[1]	PCR
Organ transplant		
Pre-transplant donor and recipient screen	Blood (clotted or serum)	DT and IgM EIA
	CSF (if CNS involvement)/EDTA blood	PCR[3]
Post-transplant	Blood (clotted or serum)	DT and IgM EIA
	EDTA blood	PCR[3]
	CNS tissue[1]	PCR
	BAL (if respiratory signs)	PCR
Ocular toxoplasmosis		
Ocular toxoplasmosis	Blood (clotted or serum)	DT and IgM EIA
	Aqueous/vitreous fluid	PCR

[1]PCR cannot differentiate active from latent infection.
[2]Not currently within scope of UKAS accreditation.
[3]Additional serology will be performed, if serum not also received.

6.2 Charges

Reference specimens (free of charge)

All reference testing is carried out free of charge for all National Health Service laboratories in England and Wales.

Reference specimens are:

Dye Test/IgM – All immunosuppressed/immunodeficient patients (e.g. HIV/AIDS, tissue transplant recipients, cancer therapy recipients/patients) and neonates.

PCR – EDTA blood requested by TRU, and any other appropriate specimen-types (CSF, ocular fluids, BALs, amniotic fluid, products of conception).

Referred specimens (charged)

Referred serum samples from NHS laboratories will be subject to charge; prices are reviewed annually and available on request.

Referred specimens are:

Dye Test/IgM EIA – Serum/plasma (immunocompetent patients)

PCR – EDTA blood where PCR was not requested by TRU (unless indicated to be IgM-positive by referring laboratory).

Non-NHS specimens (charged).

Samples received from private laboratories and from outside the UK will be subject to charge; prices are reviewed annually and available on request.

6.3 Urgent samples

The reference laboratory will endeavour to process samples urgently in acute or severe cases where findings will inform clinical management decisions. Urgent samples are usually received during normal working hours. Please telephone to inform the laboratory of urgent requests prior to despatch. Mark "urgent" clearly on the request form.

Where urgent samples are sent by courier outside normal working hours, arrangements must be agreed with the laboratory before the sample is sent.

6.4 Turnaround times

The TRU aims to complete testing within the times indicated in Table 2. Results are returned by Royal Mail to the address on the request form. Please contact the laboratory if results are required urgently.

Table 2: Turnaround times (from receipt of sample to issue of report)

Testing	Turnaround time (working days)
Primary reference serology (Dye Test & IgM EIA)	7
Primary reference serology + Additional serology testing (IgG avidity assay, Platelia IgM)	10
Molecular Diagnostics (PCR)	3-10 (N.B emergency PCR 1 day, where clinically indicated and agreed in advance with TRU)

7 UKAS accreditation and examinations outside the scope of our accreditation

Public Health Wales Microbiology Division is a UKAS accredited medical laboratory No. 9510 (ISO 15189:2022).

The following tests in the TRU are currently outside of our accredited scope:

- Platelia™ Toxo IgM

The test has been fully verified and ongoing assurance of quality in the meantime is maintained by internal and external quality assurance, quality control and training.

Please refer to the Public Health Wales Schedule of Accreditation for the full scope.

8 Instructions for Completion of Request Forms

Both the request form and sample container must be labelled with at least two patient identifiers, such as:

- Patient name & date of birth
- Sending laboratory's reference number

Minimum information required on the request form:

- Full name of patient or patient identity number
- Date of birth
- Sex
- Sending laboratory's reference number
- Date sample was collected
- Tests or investigations required
- Laboratory findings
- Address of requester (including postcode)
- Telephone number
- Relevant clinical details
- Date of onset and duration of illness

Other helpful information

- Travel history
- Occupation/pets/animal contact

Any required information on the sample or request form that is missing could result in a delay in sample processing.

Please provide full details of where to send the result and who to contact if we need to report an urgent, significant result.

9 Requirements for patient consent

It is the responsibility of the referring clinician or laboratory to ensure that appropriate consent has been obtained in accordance with local policies before specimens are submitted.

10 Criteria for acceptance and rejection of samples received by TRU

10.1 Criteria for acceptance of samples received

The following samples will be accepted:

- Serum/plasma - 1ml (neonates 200µl; serum preferred)
- Whole (unseparated) EDTA blood - 2.5-5ml (neonates 0.5-1ml)
- CSF – 300µl
- Ocular fluid – 300µl
- Amniotic Fluid >1ml
- Bronchioalveolar lavage >1ml

Please contact the laboratory if testing of a sample type outside of this list is required (e.g. DNA extracts).

10.2 Criteria for rejection of samples received

Unless agreed prior to sending, samples other than those listed above will be rejected, including:

- Urine samples
- Faeces samples
- Swabs
- Samples with insufficient volume

The user will be contacted if the sample is urgent or if it may be difficult to collect a second sample. A hard copy report will be issued stating that the sample has been rejected, reason and suggested repeat samples that will be accepted or contact details for further information.

11 Results & Reporting

The TRU aims to complete testing and issue reports within the turnaround times stated above. Turnaround times are calculated from receipt of the specimen in the laboratory to issue of the report.

- Reports are issued to the referring laboratory using the postal address provided on the request form. The laboratory does not currently issue reports electronically.
- Results required urgently should be clearly indicated on the request form and the laboratory should be contacted prior to dispatch of the specimen.

- Results of urgent requests and results that may aid immediate patient management will be telephoned by the laboratory.
- If a delay occurs that is expected to significantly exceed the published turnaround time and may adversely affect patient management, the laboratory will endeavour to notify the referring laboratory where appropriate.

12 Protection of personal information

The laboratory acts in compliance with the Caldicott and Data Protection Act Principles in respect of personal identifiable information and the protection of other sensitive material where disclosure may be inappropriate. This requires all organisations handling personal information to comply with a number of important principles regarding privacy and disclosure.

The Data Protection Act states that anyone who processes personal information must comply with eight principles. These state that information must be:

- Fairly and lawfully processed.
- Processed for limited purposes.
- Adequate, relevant and not excessive.
- Accurate and up to date.
- Not kept for longer than is necessary.
- Processed in line with individuals' rights.
- Secure.
- Not transferred to other countries without adequate protection.

The Act also allows people to find out what personal information is held about them. This could be on computer or on paper records.

Confidentiality of information requires that all persons working within the NHS who record, handle, store or in any capacity deal with confidential or person-identifiable information have a duty to maintain that confidence. That duty of confidence continues even after the death of the patient or after an employee or contractor has left the Organisation.

All employees have a recognised confidentiality agreement as part of their working contract. It is the responsibility of all staff to adhere to this agreement when dealing with any confidential information, in any format.

All staff are required to undertake mandatory information governance training every two years and are bound by the NHS Wales Information Governance Policy and Public Health Wales policies and procedures that

require that staff and contractors also adhere to the requirements of the Data Protection Act 1998 and to Caldicott principles.

Patient information is only accessible to authorised staff and will only be shared outside of the organisation when strictly necessary for patient care and with trusted organisations.

13 Feedback and Complaints

The Toxoplasma Reference Unit is committed to providing a high-quality, responsive, and reliable reference service. We welcome feedback from our service users as it helps us to continually improve the quality and effectiveness of our service.

A user satisfaction survey is distributed biennially to all referring laboratories and service users. The survey invites feedback on key aspects of the service, including turnaround times, quality of advice and clinical support, accessibility, communication, and overall efficiency. The results are reviewed by the laboratory management team and used to identify opportunities for service improvement and to inform future developments.

Please note: the TRU user satisfaction survey is designed to be completed by healthcare personnel and not patients or members of the public. Please do not share these links with members of the public.

If a particular member of staff or department deserve recognition, please leave them a compliment.

Voicing a concern or complaint allows us to investigate and learn from your experiences and improve the services we offer here in Public Health Wales. If the laboratory team cannot help to resolve your concern, details of how to make a complaint can be found here: https://phw.nhs.wales/feedback-and-complaints/.

14 Guidance documents

Management of toxoplasma in infants:

https://discovery.ucl.ac.uk/id/eprint/10112357/1/262.full.pdf

Food and other risk factors:

https://webarchive.nationalarchives.gov.uk/ukgwa/20171011173726/https://acmsf.food.gov.uk/sites/default/files/multimedia/pdfs/committee/acmsfrtaxopasm.pdf