ABOUT OXFORD DIAGNOSTIC LABORATORIES

Run by Oxford Immunotec, Oxford Diagnostic Laboratories are the UK's largest referral laboratory for analyses based on the T-SPOT technology using a standardised ELISPOT platform.

OUR QUALITY STANDARDS

Oxford Diagnostic Laboratories operate under Oxford Immunotec's quality management system under International Standards: ISO 17025:2017, ISO 13485:2016 and MDSAP requirements. UKAS accredited No. 4066.

T-SPOT.*COVID*

T-SPOT.*COVID* is a CE marked test for detecting a T cell-mediated response to SARS-CoV-2 infection. The T-SPOT.COVID antigen panels are designed as overlapping peptides spanning sequences of the Spike (COV-A) and Nucleocapsid (COV-B) proteins. This peptide design offers maximum epitope coverage for enhanced detection of T cell reactivity and no HLA restrictions. Antigenic formulations of 253 peptides covering the most immunogenic regions of the virus genome allows measurement of the breadth of immunity and ensures the impact of point mutations is minimised.

The T-SPOT.*COVID* test is proven to detect evidence of a T cell-mediated immune response to SARS-CoV-2 infection in PCR positive patients with negative serology test results[4]. The T-SPOT.*COVID* test, complemented by serology results, gives a comprehensive view of an individuals' immune response to SARS-CoV-2

A Public Health England study during the UKs first wave of the COVID-19 pandemic tested 2,826 key workers for anti-spike IgG and SARS-CoV-2 reactive T cells using a research use only version of the T-SPOT.*COVID* test[5]. The results showed that in an unselected group of 2,672 workers, 26 % (696) were positive for T cells. Of these 26 % only 53 % (367/696) were positive by serology. The study concluded that a high peripheral blood SARS-CoV-2 specific T cell response may be associated with risk of developing COVID-19

T-SPOT.*TB*

Used for diagnosing Tuberculosis, the world's largest cause of death from infectious disease. The T-SPOT.*TB* test has been approved for sale in over 50 countries. It offers the benefits of simple phlebotomy and T cell count normalisation, helping to deliver accurate clinical results in all patients, no matter their immune status.

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Document: ODL-UK-FLY-NA-0001

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2. Diel R, Wrighton-Smith P, Zellweger JP. Cost-effectiveness of interferon-gamma release assay testing for the treatment of latent tuberculosis. Eur Respir J 2007; 30: 321-332.
3. Banaei N, Gaur RL, Pai M. 2016. Interferon gamma release assays for latent tuberculosis: what are the sources of variability? J Clin Microbiol 54:845–850.
4. Oxford Immunotec Ltd, 2021; T-SPOT.*COVID* Package Insert EU: T-SPOT.COVID-PI-UK-0001
5. Wyllie D, Mulchandani R, Jones HE et al. SARS-CoV-2 Reactive T cell numbers are associated with protection from COVID-19: A prospective cohort study. medRxiv. doi: 10.11012020.11.02.20222778

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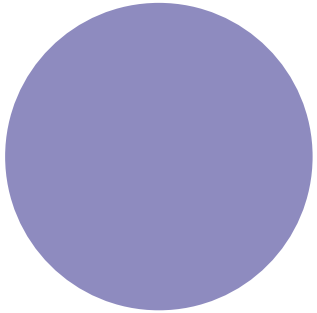
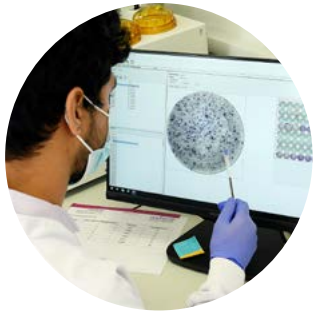
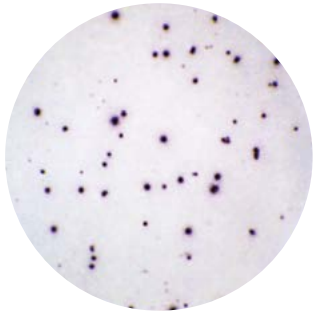






T-SPOT.® *TB*
T-SPOT.® *COVID*
SENDING SAMPLES

USING THE **T-SPOT** TESTING SERVICE

INTRODUCTION

The T-SPOT technology is a simplified ELISPOT technique allowing us to visualise the T cell reactivity to specific infections[1-2]. Firstly peripheral blood mononuclear cells (PBMCs) are isolated from a standard whole blood sample. We then prepare a normalised cell suspension which is used in the test. The PBMCs are stimulated by infection-specific antigens which release interferon-gamma. The number of reactive T cells are counted by direct visualisation of spots, with each spot representing a single reactive T cell.

SAMPLE REQUIREMENTS	
Sample type	Whole blood. Lithium heparin, sodium heparin and sodium citrate are all acceptable.
Sample volume	Adults: 6 ml Children ≥2 to <10 years: 4 ml Infants <2 years: 2 ml
Immunocompromised patients	Please provide an additional tube to ensure we obtain sufficient PBMCs
Sample storage prior to despatch	Room temperature – and **never** refrigerated
Age of samples on arrival at ODL	We should receive samples within 32 hours of blood draw.
Address for samples	Oxford Diagnostic Laboratories, 143 Park Drive, Abingdon, OX14 4SE
DX Delivery Number	DX 654 1400 Abingdon 94OX
Customer Services	Tel: 01235 433164 Email: csuk@oxfordimmunotec.com
Website	www.oxforddiagnosticlaboratories.eu

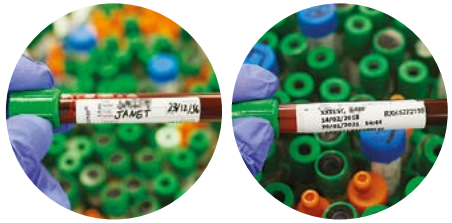
PHLEBOTOMY TECHNIQUE

Tests using T-SPOT technology are functional assays and can be susceptible to introduction of skin and environmental microorganisms during phlebotomy[3]. It is important that puncture site preparation includes the same skin disinfection procedures that you adopt for blood culture samples.

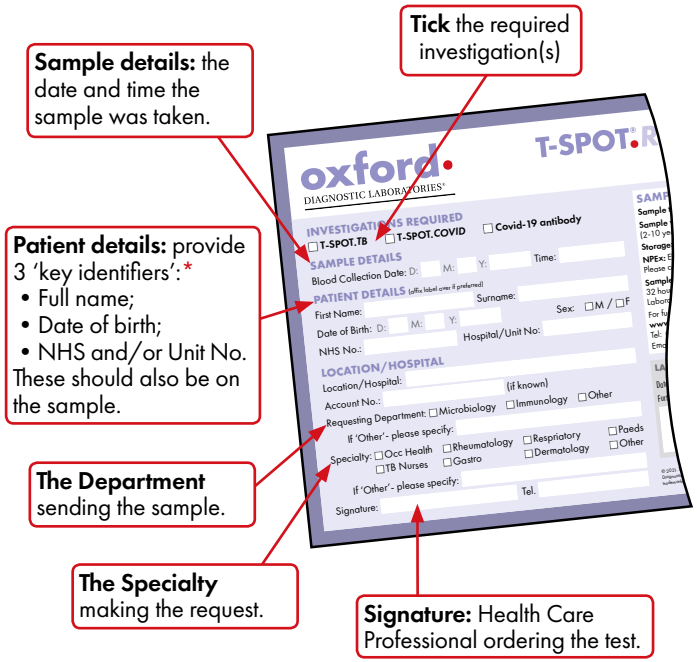
LABELLING THE SAMPLE

Provide 3 key identifiers:*
- Full name
- Date of birth
- NHS/Unit No.

Plus the date and time of the sample.



COMPLETING THE FORM



*We work to the national guideline: 'Patient sample and request form identification criteria', produced by the Institute of Biomedical Science and available at: www.ibms.org/resources

SENDING SAMPLES TO THE LABORATORY

Samples and request forms should preferably be sent for morning delivery 'by 09:00'. They should be packed to be compliant with postal guidelines for sending diagnostic samples (UN3373, P650). For assistance with cost effective sample transport solutions please contact Customer Services.

The laboratory is open to receive samples Monday to Saturday 08:00 – 14:30. To arrange a delivery outside these times and to check holiday closures please contact Customer Services.

NPEx ELECTRONIC REQUESTING AND REPORTING

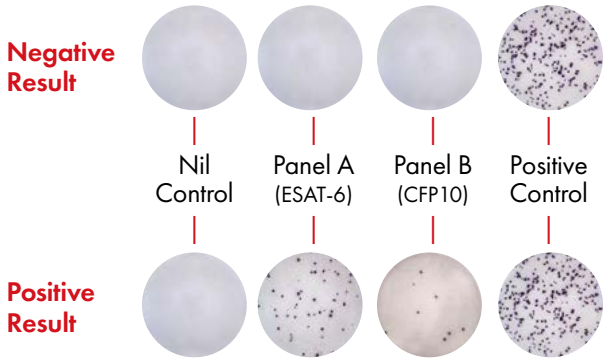
We use NPEx (National Pathology Exchange) to connect with pathology laboratories across the UK. Electronic requesting offers efficient booking in. NPEx enables electronic result return into your laboratory information management system, ready to send back to the clinical team. Please contact Customer Services to discuss being set up on NPEx.

RESULT INTERPRETATION FOR T-SPOT.*TB*

The T-SPOT.*TB* test is a functional assessment of the number of reactive PBMCs to two antigen panels assessed against negative and positive controls. So for each sample there are four ELISPOT wells.

Negative result
Both antigen panels: Spot count ≤ 5.
A negative test indicates that Tuberculosis infection is unlikely.

Positive result
One or both panels: Spot count ≥ 6.
A positive spot count indicates that Tuberculosis infection is likely.



Borderline (equivocal) result
Spot count 5 – 7.
For such results a retest is recommended.

Indeterminate result
Here the Nil control is high (> 10 spot count) or the positive control count is low (< 20 spot count).