# TERMS AND CONDITIONS OF SERVICE

**1. DEFINITIONS**

"Conditions means the terms and conditions of Service contained herein;
"Contract" means the contract between us and you for the provision of the routine testing service, comprising these Conditions, the Service Description, the Request Form and, if applicable, Customer Registration Form, a valid quotation or Service Agreement signed and accepted by You;
"Request Form" means the form filled in by you to request the Service;
"Customer Registration Form" means the form we require to be completed by all new customers;
"Service" means the Oxford Diagnostic Laboratories testing service as described in the Service Description from time to time;
"Service Description" means the information detailing the Service contained herein and other related information;
"ODL®", "We" or "us" means Oxford Diagnostic Laboratories, a trading division of Oxford Immunotec Ltd (Registered Company no. 4516079);
"You" means the organisation identified on the Request Form to whom we will provide the Service.

**2. APPLICATION OF CONDITIONS**

**2.1** The Contract will be the only term and conditions upon which we will supply the Service. All other terms and conditions (including any contained on your purchase order) or representations are excluded, unless expressly agreed to in writing by one of our authorised representatives. For the avoidance of doubt, the Company's sales representatives and Territory Managers are not authorised representatives, except Territory Managers are authorised to sign quotes.
**2.2** The Contract constitutes the entire agreement between us. We each acknowledge that we have not entered into the Contract on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in the Contract.

**3. DUTIES**

We will provide the Service in accordance with the Service Description so long as you comply with the requirements set out in the Service Description. We will comply with applicable provisions of the General Data Protection Regulations 2016/679 and all applicable rules and implementing legislation promulgated in relation thereto. Submission of blood samples to ODL for testing implies consent for ODL to process the personal data provided with the sample. ODL will process the data only in order to provide the service as described in this document. ODL will retain the data only for a period appropriate to deliver the service and in line with any regulatory requirements. Assay results will only be reported in a secure manner and as agreed with the sample provider. This may require patient data to be transferred to a third country and appropriate steps will be taken to ensure the protection of any exported personal information through implementation of Standard Contractual Clauses.

**4. NON-PERFORMANCE OF ASSAY**

If we are unable or unwilling to perform the Service we will let you know as soon as possible.

**5. PAYMENT**

**5.1** Invoices must be settled in full by cash or in cleared funds to the bank account detailed on the invoice, within 30 days of invoice date.
**5.2** All prices are quoted exclusive of VAT unless otherwise stated.
**5.3** You will be invoiced at list price unless you hold a valid quotation with us.
**5.4** If you are late in settling our invoice, we reserve the right to claim interest under the Late Payment of Commercial Debts (Interest) Act 1998 at the rate of 8% above the Bank of England Base Rate. We also reserve the right to add claimant claims compensation arising from late payment under section 5A of the Late Payment of Commercial Debts (Interest) Act 1998.
**5.5** Despite the payment terms set out in the Service Description, we may require payment from you before we provide the Service and/or refuse to provide the Service if you owe us money.
**5.6** You will have a credit limit of £5,000 unless otherwise agreed.
**5.7** You will be billed for tests that produce a reportable result, as described below, and you will not be charged for indeterminate or non-reportable results.

**6. QUALITY**
Our provision of the Service is subject to the disclaimers set out in the Service Description.

**7. LIMITATION OF LIABILITY**
**7.1** Nothing in these conditions will operate to exclude or limit our liability for death or personal injury arising out of our negligence or for our fraud in any way whatsoever.
**7.2** Subject to condition 7.1, under no circumstance will we have any liability (whether in contract, tort (including negligence) or otherwise) under or in connection with the Contract for:
(a) indirect, special or consequential losses of any nature; (b) wasted or lost management time or time of other employees, loss of profits, contracts or business, loss of goodwill or loss of anticipated savings; or (c) any increased costs or expenses.
**7.3** Subject to condition 7.1, our maximum total liability (whether in contract, tort (including negligence) or otherwise) under or in connection with the Service, will not exceed the total price of the Service.
**7.4** The express terms of the Contract are in place of all warranties, conditions, terms, representations, undertakings and obligations implied by statute, common law, custom, trade usage, course of dealing or otherwise, all of which are excluded to the fullest extent permitted by law.

**8. YOUR DUTY TO TAKE CARE**
You shall indemnify us against any claims, proceedings, costs, loss, damages or liabilities resulting from, (i) your acts or omissions, and (ii) any failure by you or any other person in control of assay results from the Service (other than us), to ensure patient confidentiality and compliance with applicable provisions of the General Data Protection Regulations.

**9. DELAY**
We reserve the right to defer the date of delivery or cancel the Service or reduce the usage of the Service ordered by you (without liability to us) if we are prevented from or delayed in carrying on our business due to circumstances beyond our reasonable control.

**10. GENERAL**
**10.1** You will comply with all relevant regulatory requirements in connection with the Service.
**10.2** No person who is not a party to the Contract has any right to prevent the variation or cancellation of any provision of the Contract or its termination. No person who is not a party to the Contract may enforce any benefit conferred upon them by the Contract, unless the Contract expressly provides otherwise.
**10.3** The Contract will be governed by English law and any dispute arising out of or in connection with the Contract must be dealt with in the English Courts.
**10.4** It is your responsibility to retain the original results of the Service that are sent to you.
**10.5** We may (but will not be obliged to) retain copies of results from the Service, and use such results for our own marketing or internal business purposes.
**10.6** ODL may use a third party laboratory to process samples. Where this may be applicable, please refer to Form SOP10-0030.0002 for additional terms and conditions.

**SERVICE DESCRIPTION**

ODL offers a national testing service to laboratories and clinicians using the T-SPOT®.*TB*, T-SPOT.*COVID* and T-SPOT.*CMV* tests ("Service"). Further information on the T-SPOT *assay*, including its limitations, is set out in our published documentation.

**Specimen Acceptance Criteria**

T-SPOT.*TB* – we require 6ml of blood
T-SPOT.*COVID* – we require 6ml of blood
T-SPOT.*CMV* – we require 12ml of blood

The blood is required to be collected in standard heparin (green-topped) vacutainer tubes. Paediatric samples may require less blood (please call the laboratory to seek advice, as blood volumes depend on age). Samples must be accompanied with a completed ODL test Request Form and must reach ODL within 32 hours of venepuncture. Blood samples should be stored at 18-25°C; do not refrigerate samples. Please ensure that you include your Customer Account Number on all test requests, and that you indicate clearly on the form which test you are requesting by using the tick boxes. Specimens must arrive by 2.00pm Monday to

Saturday, unless previously arranged with the laboratory. ODL is closed on public holidays and over the Christmas and New Year period each year (please call us, or consult our website, to find out the exact dates for this year).

We place no restriction on the numbers of samples that can be sent at one time, however, if sending more than 20 samples we would appreciate advance notification to help us better plan our workflow.

**What will Oxford Diagnostic Laboratories do?**
1. We will carry out the Service, as described here and in the Terms and Conditions of Service, and following the instructions given on the test Request Form.
2. The test results for the T-SPOT.*TB*, T-SPOT.*COVID* and T-SPOT.*CMV* tests will be sent by email (and post if requested) to the requesting laboratory within two working days of receipt of sample and all required documentation. Test results will not be released until all required specimen and billing information is provided.
3. For large T-SPOT.*TB* screenings, as described in the quotation, results are reported within three working days of receipt of sample and all required documentation. Test results will not be released until all required specimen and billing information is provided.
4. You will be invoiced as per the agreed schedule stated in your original quotation, either by post or by email.
5. ODL will be responsible for disposal of any samples provided.

**Results Interpretation and Quality Control – T-SPOT.*TB***

A typical result would be expected to have few or no spots in the Nil Control and ≥20 spots in the Positive Control. Each spot represents the footprint of an individual cytokine-secreting T cell, and evaluating the number of spots obtained provides a measurement of the abundance of *M. tuberculosis* complex sensitive effector T cells in the peripheral blood.

A Nil Control spot count in excess of 10 spots should be considered as 'Indeterminate'. Refer to the T-SPOT.*TB* Technical Handbook for possible causes (download from www.oxfordimmunotec.com). If this occurs, another sample should be collected from the individual and sent to ODL for testing.

Typically, the cell functionality Positive Control spot count should be ≥ 20 or show saturation (where spots are too numerous to count). A small proportion of patients may have T cells which show only a limited response to PHA. Where the Positive Control spot count is
< 20 spots, it should be considered as 'Indeterminate', unless either Panel A or Panel B is 'Positive' as described below, in which case the result is valid.

The T-SPOT.*TB* test results are interpreted by subtracting the spot count in the Nil Control well from the spot count in each of the Panel wells, according to the following algorithm:

- The test result is 'Positive' if (Panel A minus Nil Control) and / or (Panel B minus Nil Control) ≥ 6 spots.
- The test result is 'Negative' if both (Panel A minus Nil Control) and (Panel B minus Nil Control) ≤ 5 spots. This includes values less than zero.

Due to potential biological and systematic variations, where the higher of (Panel A minus Nil Control) and (Panel B minus Nil Control) is 5, 6 or 7 spots, the result may be considered as Borderline (equivocal). Borderline (equivocal) results, although valid, are less reliable than results where the spot count is further from the cut-off. Retesting of the patient, using a new sample, is therefore recommended.

**A 'Positive' result indicates that Tuberculosis infection is likely.**

**A 'Negative' result indicates that Tuberculosis infection is unlikely.**

The results should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to or infection with *M. tuberculosis.*

**Results Interpretation and Quality Control – T-SPOT.*COVID***

The T-SPOT.*COVID* test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, specifically the T cell response. The test could be used alongside serology tests to support clinical assessment of individuals, for example who present with suspected COVID-19 but are PCR negative and is complementary to serology

**A 'Reactive' test indicates that the sample contains effector T cells sensitized to SARS-CoV-2**

**A 'Non-Reactive' test indicates that no effector T cells sensitized to SARS-CoV-2 were detected**

**Results Interpretation and Quality Control – T-SPOT.*CMV***

The T-SPOT.*CMV* assay is an *in vitro* diagnostic test intended to be used to assess a patient's level of anti-CMV cell-mediated immunity.

The T-SPOT.*CMV* test is not intended for use in determining CMV infection and should not be used to include or exclude CMV infection.

Spot count reported per 250,000 peripheral blood mononuclear cells.

**The number of spots is indicative of the strength of the cellular immune response to CMV.**

A Nil Control spot count in excess of 10 spots should be considered as 'Indeterminate'. If this occurs, another sample should be collected from the individual and sent to ODL for testing.