Service User Agreement for Diagnostic Laboratory Services (Online Account Application)

Purpose of this document

This document sets out the agreement that every clinic, practice, pharmacy, practitioner or other organisation must accept when applying online for an account with Kernel Diagnostic Laboratories LTD (KDL). It establishes that account holders send samples to KDL as **independent requesters**, under their own legal and regulatory arrangements, and not under KDL's registration or clinical governance. It also forms the written agreement between KDL and each requester for the purposes of ISO 17025:2017 (pre-examination processes and agreements with users).

1. About this Agreement

1.1 This Service User Agreement (the "**Agreement**") is between Kernel Diagnostic Laboratories LTD ("**KDL**", "**we**", "**us**") and the organisation or individual practitioner named in the account application (the "**Account Holder**", "**you**").

1.2 You accept this Agreement by ticking the acceptance box and submitting the online account application. Acceptance in this way is a binding agreement, as if signed. KDL will not open an account until this Agreement has been accepted.

1.3 The person accepting this Agreement confirms that they are authorised to do so on behalf of the Account Holder and to bind the Account Holder to it.

1.4 This Agreement is for business and professional users only. Accounts are not available to members of the public acting for their own personal purposes.

1.5 This Agreement applies together with the KDL Terms of Use (POL-043) and KDL's published user handbook and collection instructions. If there is any conflict, this Agreement takes precedence for Account Holders.

2. Definitions

2.1 **Services** means the laboratory testing, analysis and reporting services provided by KDL, together with any consumables, request forms, labels or transport materials KDL supplies.

2.2 **Collection Activities** means everything done before a sample is received at KDL, including patient selection and assessment, consent, venepuncture or other sample collection, labelling, storage, packaging and transport.

2.3 **Personnel** means any employee, contractor, agent or practitioner of the Account Holder who carries out Collection Activities or requests Services.

2.4 **Responsible Clinician** means the appropriately qualified healthcare professional named by the Account Holder under clause 5.

2.5 **Applicable Law** means all laws, regulations and regulatory requirements that apply to the Account Holder and its Collection Activities in the place where those activities take place, in the United Kingdom or elsewhere.

3. Independent Status of the Account Holder

3.1 The Account Holder is an independent requester of the Services. It is not a sub-contractor, employee, agent or partner of KDL, and nothing in this Agreement creates any such relationship.

3.2 The Account Holder carries out all Collection Activities under its own registration, licences, authorisations, insurance and clinical governance, and not under KDL's registration, governance framework or policies.

3.3 KDL does not direct, supervise, manage or control the Account Holder's Collection Activities, Personnel or patients. The supply of consumables, request forms, labels, transport materials, or collection and transport instructions is provided so that samples arrive in a condition suitable for testing. It does not mean KDL takes responsibility for, or control of, any Collection Activity.

3.4 The Account Holder must not describe itself or its services as being provided on behalf of, or under the registration of, KDL.

4. Account Holder's Legal and Regulatory Compliance

4.1 The Account Holder warrants and undertakes, on acceptance of this Agreement and continuously for as long as it holds an account, that:

(a) it holds, and will maintain, every registration, licence, authorisation, permission or exemption required by Applicable Law to carry out its Collection Activities and to request and receive the Services. In England this includes any registration with the Care Quality Commission that is required. Elsewhere it includes the requirements of the relevant regulator in that country or jurisdiction;

(b) all Personnel are competent, appropriately trained and, where required by Applicable Law or professional standards, registered with the relevant professional regulator;

(c) it holds, and will maintain, professional indemnity and public liability insurance (or equivalent indemnity arrangements) adequate for its Collection Activities;

(d) it obtains and records valid patient consent for collection and testing, and for sharing patient information and samples with KDL;

(e) it complies with Applicable Law and professional standards on infection prevention and control, health and safety, safeguarding, clinical waste and the safe transport of diagnostic specimens; and

(f) every test it requests is lawful, appropriate and requested for a legitimate purpose.

4.2 The Account Holder is solely responsible for its compliance with Applicable Law and for its Collection Activities and Personnel.

4.3 KDL is entitled to rely on the warranties in clause 4.1 without enquiry. KDL has no obligation to check, verify or monitor the Account Holder's registrations, licences, insurance, Personnel or compliance. KDL may, but is not obliged to, ask for evidence of any of these matters at any time, and the Account Holder must provide it promptly.

4.4 The Account Holder must tell KDL in writing within 5 working days if any warranty in clause 4.1 stops being true, including if any registration or insurance is suspended, cancelled, restricted or lapses. It must stop sending samples to KDL until the matter is resolved.

5. Responsible Clinician

5.1 The Account Holder must name in its account application a Responsible Clinician: an appropriately qualified healthcare professional who will receive results, interpret them and take clinical responsibility for acting on them, including any urgent or critical result.

5.2 The Account Holder must make sure the Responsible Clinician's contact details held by KDL are accurate and that the Responsible Clinician (or a named deputy of equivalent standing) can be reached during KDL's reporting hours.

5.3 The Account Holder must update the Responsible Clinician's details through its account, or by written notice to KDL, before any change takes effect.

6. Requests, Sample Collection and Transport

6.1 Each request must be fully and accurately completed, including at least two patient identifiers, the tests required, relevant clinical details, and the date and time of collection.

6.2 Samples must be collected, labelled, stored, packaged and transported in accordance with KDL's current collection and transport instructions and Applicable Law.

6.3 KDL may reject, or report with a qualifying comment, any sample that is unlabelled, mislabelled, unsuitable, damaged, delayed, or otherwise does not meet KDL's acceptance criteria.

6.4 Results apply to the sample as received by KDL. KDL is not responsible for the effect on results of any Collection Activity or of anything that happens to a sample before KDL receives it.

7. Results and Clinical Responsibility

7.1 KDL will release results to the Account Holder through its laboratory information system or another agreed secure method.

7.2 The Account Holder and its Responsible Clinician are solely responsible for interpreting results, communicating them to patients, and making and acting on any diagnosis, treatment or other clinical decision. KDL does not provide clinical management of the Account Holder's patients.

7.3 Where a result meets KDL's criteria for urgent or critical reporting, KDL will follow its critical results procedure. This includes reasonable attempts to contact the Responsible Clinician using the details provided. The Account Holder is responsible for making sure those details are accurate and that someone is available to receive and act on the result.

7.4 The Account Holder must not alter results, or present them as anything other than KDL's report, when passing them to patients or third parties.

8. KDL's Responsibilities

8.1 KDL will:

(a) maintain the registrations required for the laboratory services it carries out;

(b) carry out examinations in accordance with its quality management system and with reasonable skill and care;

(c) report results accurately and within its published turnaround times, which are targets and not guarantees;

(d) make its current collection and transport instructions and sample acceptance criteria available to the Account Holder; and

(e) tell the Account Holder of any significant disruption to the Services that is likely to affect results or turnaround.

8.2 KDL's responsibility begins when a sample is received at the laboratory.

9. Data Protection and Confidentiality

9.1 Each party is an independent controller of the personal data it processes. The Account Holder is controller for its patients' data in connection with its own services and Collection Activities. KDL is controller for the data it processes to provide, record and report the Services.

9.2 Each party must comply with the UK GDPR and the Data Protection Act 2018, or other data protection law that applies to it.

9.3 The Account Holder must have a lawful basis for sharing patient data with KDL and must give its patients appropriate privacy information, including that their samples and information will be sent to KDL for testing.

9.4 Each party must keep the other's confidential information confidential, use appropriate security measures, and tell the other party without undue delay of any personal data breach affecting data shared under this Agreement.

10. Fees and Payment

10.1 The Account Holder must pay KDL's fees for the Services in accordance with KDL's current price list and payment terms.

10.2 KDL may require payment in advance, or on receipt of invoice, as it specifies. KDL may suspend Services while any invoice is overdue.

11. Liability and Indemnity

11.1 KDL has no liability for any loss, damage, claim, fine, penalty or cost arising from:

(a) the Account Holder's Collection Activities, Personnel or patients;

(b) the Account Holder's failure to hold any registration, licence, authorisation or insurance, or otherwise to comply with Applicable Law;

(c) any inaccurate or incomplete request or patient information supplied by the Account Holder;

(d) anything that happens to a sample before KDL receives it; or

(e) the interpretation of, or any clinical action taken or not taken on, a result.

11.2 The Account Holder will indemnify KDL against all losses, liabilities, claims, fines, penalties, costs and expenses (including reasonable legal fees) that KDL suffers or incurs because of any breach by the Account Holder of clause 3, 4, 5, 6.1, 6.2 or 9, or because any warranty in clause 4.1 is untrue.

11.3 KDL is not liable for any loss of profit, revenue, business, goodwill or data, or for any indirect or consequential loss.

11.4 Subject to clause 11.5, KDL's total liability under or in connection with this Agreement, whether in contract, tort (including negligence) or otherwise, is limited to the fees paid by the Account Holder to KDL in the 12 months before the event giving rise to the claim.

11.5 Nothing in this Agreement limits or excludes either party's liability for death or personal injury caused by its negligence, for fraud or fraudulent misrepresentation, or for any other liability that cannot be limited or excluded by law.

12. Suspension and Termination

12.1 KDL may refuse any application, or refuse any request or sample, at its discretion.

12.2 KDL may suspend or close an account immediately by notice if KDL reasonably believes that any warranty in clause 4.1 is untrue, that the Account Holder has breached this Agreement, or that continuing to provide the Services would put patients, KDL or its staff at risk.

12.3 Either party may end this Agreement for any reason by giving the other 30 days' written notice.

12.4 Ending this Agreement does not affect samples already received, which KDL will process and report unless it is unsafe or unlawful to do so. Clauses 4, 7.2, 9, 10, 11 and 15 continue to apply after this Agreement ends.

13. Intellectual Property

13.1 All intellectual property in KDL's services, systems, reports, documentation, logos, trademarks and methods belongs to KDL or its licensors. The Account Holder receives a limited licence to use KDL reports for the care of the patients concerned.

14. Changes to this Agreement

14.1 KDL may update this Agreement. Each version carries a version number and date.

14.2 KDL will give at least 14 days' notice of any material change by email or through the Account Holder's account, and may ask the Account Holder to accept the updated version before submitting further requests. If the Account Holder continues to submit requests after the notice period, it accepts the updated version.

15. Record of Acceptance

15.1 When this Agreement is accepted, KDL will create and keep a record of the acceptance. This includes the Agreement version number, a cryptographic hash (SHA-256) of the exact text accepted, the date and time, the account and user identity, the information entered in the application, and the technical details of the submission (such as IP address and browser).

15.2 The parties agree that this record is evidence of the Account Holder's acceptance of the version of this Agreement it identifies.

16. General

16.1 This Agreement, together with the documents referred to in clause 1.5, is the entire agreement between the parties about its subject matter.

16.2 If any provision of this Agreement is found to be invalid or unenforceable, the rest of the Agreement continues in force.

16.3 The Account Holder may not assign or transfer this Agreement without KDL's written consent.

16.4 No one other than KDL and the Account Holder has any right to enforce any term of this Agreement under the Contracts (Rights of Third Parties) Act 1999.

16.5 KDL is not liable for any delay or failure caused by events beyond its reasonable control.

17. Governing Law and Jurisdiction

17.1 This Agreement and any dispute arising from it are governed by the law of England and Wales, and the courts of England and Wales have exclusive jurisdiction.

18. Contact

18.1 Questions about this Agreement should be sent to info@kdlabs.co.uk. Notices under this Agreement must be sent in writing to that address, or to the address held for the Account Holder in its account.

Annex A – Information Captured at Application and Acceptance Statement

A1. Required application fields

KDL does not verify these details. They are recorded as the Account Holder's declaration.

(a) **Organisation / practice details:** legal name, trading name (if different), registered or business address, country, company number (if applicable), main contact name, email and telephone.

(b) **Responsible Clinician:** full name, profession or role, contact telephone and email for result notification, and professional registration body and number (optional, not verified).

(c) **Deputy contact** for urgent results (recommended).

(d) **Name and role** of the person accepting the Agreement.

A2. Acceptance statement (checkbox wording)

☐ I confirm that I am authorised to accept this Agreement on behalf of the organisation named above. I confirm that it holds all registrations, licences, insurance and authorisations required by law for its sample collection activities, and that the Responsible Clinician named above will receive and act on results. I have read and agree to the KDL Service User Agreement, version 1.

A3. Acceptance record

The acceptance record described in clause 15 is stored in the KDL LIMS against the account. The record must not be editable after creation. The published text of each version of this Agreement must be kept unchanged so that its hash can be checked later.

Date of last update: 22 October 2026