Product Schedule – Reference Laboratory Services

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Ordering

1.1 Our “Healthcare Customer Services Contact” means our customer services representatives available by telephone on +44 (0)115 973 9015.

1.2 To place your Order:

1.2.1 submit the Sample together with a completed Request Form relevant to the Services to be performed (which can be downloaded from our website or can be obtained by request from our Healthcare Customer Services Contact) to Source BioScience Healthcare, 1 Orchard Place, Nottingham Business Park, Nottingham NG8 6PX; or

1.2.2 where you require us to collect the Sample, submit a completed Request Form applicable to the Services to, Source BioScience Healthcare, 1 Orchard Place, Nottingham Business Park, Nottingham NG8 6PX together with your letter of authorisation for collection of the Sample including all relevant Sample identifier and collection address information.

1.3 For CTC Testing and CEC Testing you must also:

1.3.1 request a test kit from our Healthcare Customer Services Contact;

1.3.2 ensure your Sample submission is addressed for the attention of: "CTC Processing team" and is clearly marked as "Urgent Blood Sample for CTC Testing".

2 Mutation Analysis

2.1 “Mutation Analysis” means laboratory testing for the purpose of the identification of specific activating mutations in a specific gene, including but not limited to, KRAS, BRAF, NRAS, EGFR and PIK3CA involving a histopathology review of a Sample to ensure tumour tissue is present, analysis of data and the communication of all results related to Mutation Analysis to the referring clinician.

2.2 “Favourable Test Outcome” means for Mutation Analysis undertaken by us, either of the following outcomes:

2.2.1 activating mutation detected for the specific gene being analysed (KRAS, BRAF, NRAS, EGFR or PIK3CA as applicable to your Order); or

2.2.2 no activating mutation detected for the specific gene being analysed (KRAS, BRAF, NRAS, EGFR or PIK3CA as applicable to your Order).
2.3 “Unfavourable Test Outcome” means the following outcome of the Mutation Analysis undertaken by us: No Result for this Sample

2.4 You acknowledge that a Favourable Test Outcome is dependent upon us receiving Samples which are not Defective Samples and you acknowledge that there is an inherent risk that a fraction of the Services performed by us under this Contract may deliver an Unfavourable Test Outcome.

2.5 We shall not be liable for any Unfavourable Test Outcome unless such Unfavourable Test Outcome is caused by our negligent acts or omissions or our breach of any of our warranties under the Contract. Except as expressly provided in the Contract, you shall be liable for fees for the Services even in the case of an Unfavourable Test Outcome.

2.6 Where a Sample gives rise to an Unfavourable Test Outcome, we will notify you. We will undertake a further test on a new Sample at your request and expense. All additional testing will be charged at the standard fee.

3 FFPE Blocks

3.1 If the Sample is a formalin fixed paraffin embedded block you acknowledge that the number of sections cut and used by us for testing shall be dependent on the size and morphology of the Sample embedded in the block.
Product Schedule – Supply of Clones

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Definitions

In this Product Schedule:

“MTA” means the Materials Transfer Agreement(s) which you and your Researchers are subject to in respect of use of the clones supplied by us to you and which you have accepted; and

“Researcher” a person employed by you who carries out research on your behalf and who utilises the clones in that research.

2 Your Use of Clones

2.1 All clones supplied by us are for research purposes only and are supplied subject always to the terms of the relevant MTA.

2.2 You shall not make the clones available to, or allow the use of the clones by (or for the benefit of), any person other than a Researcher carrying out an investigation (as defined in the relevant MTA) and/or legitimate research.

2.3 You shall not use the clones for diagnostic purposes.

2.4 You shall not offer the clones for resale or distribution, or permit anyone else to.

2.5 You shall ensure that each Researcher complies at all times with the restrictions on use of the clones set out in the Contract. You shall immediately notify us in the event that you become aware of any breach of those restrictions in connection with the Contract.

2.6 You shall ensure that any publication of information generated using the clones contains the following acknowledgement: “Genomic products were provided by Source BioScience UK Limited (www.sourcebioscience.com)”.

3 Inherent Risks

3.1 You acknowledge that:

3.1.1 all clones are replicated from an original parent clone;

3.1.2 the original parent clone is developed and manufactured by a third party academic organisation and then supplied to us by that third party under licence;
3.1.3 we are only entitled to replicate the original parent clone and engage in the onward supply and distribution of the resultant clones pursuant to the terms and conditions of such licence;

3.1.4 we have no control over the content of any original parent clone supplied to us;

3.1.5 any original parent clone and any clones replicated from that original parent clone are pieces of DNA from a known organism and may, given their nature, self-mutate, deteriorate, die, become contaminated or otherwise be subject to unavoidable and/or uncontrollable change for any reason; and

3.1.6 our genomic reagent scientists will, when any CLONE(S) is/are ordered, necessarily have to take the relevant original parent clone(s) out of frozen storage and perform the necessary laboratory process to replicate it/them.

3.2 You acknowledge that the circumstances outlined above means there is an inherent risk beyond our control that any or all of the clones supplied by us to you may not conform to the description provided by us to you (if any), may not be of satisfactory quality, and may not be fit for any particular purpose. We shall have no liability for any such non-conformity, lack of quality, or unfitness for purpose caused by such inherent risk.

3.3 We shall have no liability for any breach of our warranties in relation to a clone if you do not notify us of the breach within three calendar months after receipt of the clone.

4 Libraries of Clones

4.1 Where we are supplying whole libraries of clones, we warrant that we shall (following replication) undertake a quality control check entailing our genomic reagent scientists checking for phage contamination, scoring each plate by matching it as closely as reasonably possible to the relevant original parent clone(s), and then sending a random number and selection of clones (around 5%) to our sequencing laboratory in order to sequence the DNA.

5 Indemnity

5.1 You shall indemnify us against all liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal and other professional costs and expenses) suffered or incurred by us arising out of or in connection with:

5.1.1 your (or your Researcher(s)') breach or negligent performance or non-performance of the Contract;

5.1.2 any claim made against us by a third party arising out of or in connection with the supply of the clones, to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of the Contract by you or your Researchers; and
5.1.3 any claim made against us by a third party for death, personal injury or damage to property arising out of or in connection with defective clones, to the extent that the defect in the clones is attributable to the acts or omissions of you or your Researchers.

5.2 The indemnity in this Product Schedule shall apply whether or not we have been negligent or at fault.
Product Schedule – Laboratory Supplies

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 LBC Products

1.1 “LBC Products” are any batch of products branded, presented or characterised by us as Liquid Based Cytology products.

1.2 We warrant that for a period of six (6) months after the date of dispatch, all LBC Products sold by us to you shall, under normal use, materially conform with our published specifications or, where none, normal industry standards for such LBC Products. We will replace any LBC Products that fail to conform with this warranty during that period, at our cost.

1.3 The warranty in paragraph 1.2 above is subject to your compliance with clause 9.2 of the Conditions.

2 Life Sciences Products and Serology Products

2.1 "Life Sciences Products" means any batch of products branded, presented or characterised by us as Life Sciences products.

2.2 "Serology Products" means any batch of blood group serology fluid reagents and diagnostic kits, including (by way of example and without limitation) phosphate buffered saline, a variety of red cell support solutions including diagnostic kits, lectins and lectin extracts and a number of products used for the storage and preservation of tissues, and/or any other products branded, presented or characterised by us as Serology Products.

2.3 Unless otherwise expressly specified in the relevant Data Sheet(s) (if any) or in the specific product information set out on our website, all Life Sciences Products or Serology Products supplied by us for research purposes only.

2.4 You shall not, unless otherwise expressly specified in the relevant Data Sheet(s) (if any) or in the specific product information set out on our website, use the Life Sciences Products or Serology Products for clinical or diagnostic purposes.

2.5 You shall use the Life Sciences Products and Serology Products only for in vitro laboratory purposes. In particular, you shall not use them or permit anyone else to use them for in vitro diagnostic purposes, ex vivo or in vivo therapeutic purposes, in foods, drugs or cosmetics of any kind, for consumption by or use in connection with or administration or application to humans or animals or for any other unauthorised purposes.

2.6 You shall not make the Life Sciences Products or Serology Products available to any person, firm or company for any purpose other than scientific investigation and legitimate research.
2.7 We warrant that all Serology Products have been developed specifically for blood group serology laboratories, are manufactured to BS EN ISO 9001:2008 standards and are CEmarked and that (subject always to the other provisions of these Conditions) on delivery the Serology Products shall comply with the applicable standards set out by the British Blood Transfusion Society, the Council of Europe and the Red Book (Guidelines for the Blood Transfusion Services of the UK).
Product Schedule - Histopathology Services

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Additional Work

1.1 You authorise us to undertake such extra levels and/or immunohistochemistry testing and/or special stains in relation to a Sample that the reporting consultant histopathologist acting reasonably and in accordance with normal industry standards on pathology reporting practice, determines as being necessary for the provision of a definitive histopathology report on the Sample (the “Additional Work”).

1.2 We shall be entitled to charge you for any such Additional Work in accordance with our standard price list, as updated from time to time, which is available from us on request.

1.3 You shall disclose to us at the time of placing your Order if the Sample is on in relation to which a pathologist has previously reported and failed to arrive at a diagnosis (a “Second Opinion Case”). We shall be entitled to charge for Second Opinion Cases at the Second Opinion Case rates set out in our standard price list, as updated from time to time, which is available from us on request.

2 Sample Preparation and Delivery

2.1 You shall comply with all of the requirements set out below in relation to any histopathology Services.

2.2 Unless otherwise arranged, where you are submitting pre-prepared GI cases one of the following levels of preparation is required:

   2.2.1 three sections stained respectively with (1) H & E, (2) Alcian blue combined with PAS or PAS and (3) Helicobacter stain such as ToIuidine blue or modified Giemsa;

   2.2.2 one H & E stained slide plus two unstained slides; or

   2.2.3 one H & E stained slide plus the associated block.

2.3 If you provide only one stained slide we shall be entitled to charge you for the cost of us processing any additional stains indicated where applicable to a given case.

2.4 Where you propose to submit wet specimen Samples:

   2.4.1 you shall discuss any high risk samples with us prior to dispatch;

   2.4.2 you shall complete the "Cases submitted to SBS form" and include it in the package;
2.4.3 you shall complete the "Authorisation to dispose of residual clinical tissues form" and return it to us to confirm your consent for us to dispose of residual tissue in accordance with our UKAS approved procedures;

2.4.4 where you are submitting breast samples you shall include specimen x-rays (where available) and advise us if any of the following prognostic indicators are to be undertaken and reported: i) ER; ii) PR; iii) Her 2; iv) Her 2 and FISH.

2.4.5 you shall ensure that your specimen pots are labelled appropriately as per Sample acceptance criteria.

2.4.6 we shall dispose of wet specimens as per human tissue retention guidelines. If you are requesting the return of wet tissue this must be confirmed this with us prior to commencement of any work.

2.4.7 we shall dispose of all empty tissue pots 7 calendar days after dissection.

2.4.8 it is essential that you ensure that the Samples are well fixed and submitted as per the instructions in our guide to service document. Poor fixation or inappropriate containers may result in deterioration or distortion of the sample.

2.5 You shall provide as much clinical information as possible in relation to Samples whether sent as wet or pre-prepared. You acknowledge that a lack of clinical information, macroscopic descriptions or endoscopy reports (where applicable) can make examination and diagnosis of the sample difficult or impossible.

2.6 Where possible, you shall submit paraffin block(s) with accompanying section stained with Haematoxin and Eosin.

2.7 You shall provide any Corneal or Colposcopic biopsies with three levels of H & E.

2.8 You shall include the original Sample Submission Form or a high quality copy with each Sample.

2.9 You acknowledge that a proportion of cases will require second opinion or double reporting to concur with industry standards of best reporting practice for example, without limitation, GI tract dysplasia.

2.10 Malignant or skin cancers are all reported to current minimum data set standards and the reports of inflammatory dermatoses are more detailed and complex as this type of case requires a greater degree of interpretation. In relation to any case, which may appear straightforward (on the basis of the information available on the original Sample Submission Form) but transpire to be more complex upon diagnosis, we reserve the right to up band the case in accordance with the considered advice of the relevant specialist. Similarly, cases whose clinical history suggests a diagnosis of a malignancy but upon review prove to be benign will be down-banded in line with the final diagnosis.

2.11 We shall conduct Duty of Care and Audit Services in confidence and in accordance with
General Medical Council and Royal College of Pathologists guidelines.

Product Schedule – Genomic Services

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Ordering

1.1 You shall submit your Order in accordance with the procedure below applicable to the given type of service you require:

1.1.1 for Contract Research Services and Custom Sequencing Projects in the following manner:

(a) you shall submit the requirements and specifications of the services which you are requesting from us, including a description of what services are to be performed, dates by which each service is requested to be performed and any other information as we may request to allow us to prepare a Quotation;

(b) we shall, as soon as reasonably practicable, provide you with a Quotation; and

(c) you shall submit an Order which constitutes an offer by you to purchase the Services.

1.1.2 for Routine Sequencing Services in the following manner:

(a) by placing an order through the Website using our online ordering facility; or

(b) by submitting Samples to us accompanied by a completed Request Form which can be obtained from us on request.

1.1.3 Where you place an order through the Website for Routine Sequencing Services, after placing an order, you will receive an e-mail from us acknowledging that we have received your order. This does not mean that your order has been accepted.

1.2 "Contract Research Services and Custom Sequencing Projects" means those services ordered by you that have been the subject of express discussion and negotiation between you and us leading to the preparation of a Quotation that includes a service specification and negotiated fees.

1.3 "Routine Sequencing Services" means any of the DNA sequencing services ordered by you which do not fall under the definition of Contract Research Services and Custom Sequencing Projects.
2 Publications

2.1 Unless we expressly agree otherwise, you shall acknowledge us by making reference to our name in any resulting publication involving information and/or results generated by us in the course of the conduct of performing the Services. We agree that such acknowledgement should simply state that: "Contract Research/Sequencing services (as applicable) were provided by Source BioScience [www.sourcebioscience.com]."

3 Affymetrix Services

3.1 You acknowledge that we are performing the Affymetrix Services subject to a license agreement with the beneficial owner of Affymetrix Genechips™. All sales of Affymetrix Services shall subject to the conditions set out in the Customer Service Provider Addendum, which is incorporated into this Product Schedule by reference. The Customer Service Provider Addendum is as attached or where you are placing an order through the Website can be found at www.lifesciences.sourcebioscience.com or you may request a hard copy of the Customer Service Provider Addendum by contacting us directly on Tel: + 44 (0)115 9739021. By submitting an Order for Affymetrix Services you accept the Customer Service Provider Addendum.

3.2 "Affymetrix Services" the genomic services to be provided by us under the Contract which may include any of custom expression analysis, genotyping services and related bioinformatics services using Affymetrix technology including, without limitation, Affymetrix microarrays and scanning device.
Product Schedule – Stability Storage Equipment Validation, Calibration, and Maintenance Services

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Ordering and Duration

1.1 To order stability storage equipment validation, calibration, and maintenance services you must provide us with a description of the relevant equipment and the initial period for which you require the services, so that we can prepare our Quotation.

1.2 If we provide you with a Quotation you may then order the Services set out in the Quotation by submitting an Order for them in writing to us. You shall ensure that your Order is consistent with the Quotation.

1.3 Your Order is accepted by us only when we issue our written acceptance of the Order or when we start providing the Services (whichever happens first) (the Commencement Date).

2 Services

2.1 We shall provide the Services to you from the Commencement Date until the expiry of the initial service period set out in our Quotation (the Initial Period of Service), subject to paragraph 2.2 below. We will continue to provide the Services after the Initial Period of Storage until either party gives one month’s notice to end the Services.

2.2 During the Initial Period of Service either party may end the Services early by giving the other at least three months’ written notice.

2.3 We shall keep appropriate records in relation to the performance of the Services, including in relation to the supply and fitting of any spare parts, and we shall provide you with copies of such records upon request.

3 Premises

3.1 You shall:

3.1.1 provide us and our agents, subcontractors, consultants and employees, with such access to your premises as we may reasonably require for the purposes of providing the Services;

3.1.2 prepare and maintain the relevant premises in a fit state for provision of the Services, including by ensuring the premises are clean and accessible, and by identifying, monitoring, removing and disposing of any hazardous materials from the premises in accordance with applicable laws before and during the provision of the Services;
3.1.3 prior to the provision of the Services inform us of all health and safety rules and security requirements that apply at your premises.
Product Schedule – Supply of Stability Storage Equipment

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Ordering and Duration

1.1 To order stability storage equipment (Equipment) you must provide us with a description of the equipment you require so that we can prepare our Quotation.

1.2 If we provide you with a Quotation you may then order the Equipment set out in the Quotation by submitting an Order for them in writing to us. You shall ensure that your Order is consistent with the Quotation.

1.3 Your Order is accepted by us only when we issue our written acceptance of the Order.

1.4 Any references to the Goods in our Terms and Conditions of Business include the Equipment.

2 Your premises

2.1 You shall:

2.1.1 provide us and our agents, subcontractors, consultants and employees, with such access to your premises as we may reasonably require for the purposes of providing the Equipment and any associated Services;

2.1.2 prepare and maintain the relevant premises in a fit state for provision of the Equipment and related Services, including by ensuring the premises are clean and accessible, and by identifying, monitoring, removing and disposing of any hazardous materials from the premises in accordance with applicable laws before and during the provision of the Equipment and Services;

2.1.3 prior to the provision of the Equipment and related Services inform us of all health and safety rules and security requirements that apply at your premises.

3 Delivery, risk and title

3.1 We shall deliver the Equipment CIP (Incoterms 2010) at the delivery address specified in the Quotation, unless we expressly agree otherwise in writing with you.

3.2 Until title in the Equipment passes to you under the Terms and Conditions of Business, you shall:

3.2.1 hold the Equipment on a fiduciary basis as our bailee;
3.2.2 store the Equipment separately from all other goods such that the Equipment remains readily identifiable as our property;

3.2.3 ensure the Equipment is clearly labelled as our property, and

3.2.4 grant us and our agents, subcontractors, consultants, and authorised representatives the right to enter any premises where the Equipment is stored in order to recover the Equipment if you fail to pay any sums due to us when they fall due or if we become entitled to terminate the Contract for any reason.

4 Warranties

4.1 We warrant that the Equipment shall comply with its specification in all material respects for a period of 12 months from the date of delivery. This warranty replaces the warranty in clause 9.4 of our Terms and Conditions of Business, but is subject to the remainder of that clause.

4.2 We shall not be responsible for any defect in the Equipment that is attributable to the acts or omissions of any third party that you appoint to maintain, alter, or repair the Equipment.
Product Schedule – Storage and Disaster Recovery Backup Services

This Product Schedule should be read with our Terms and Conditions of Business. Words and phrases in this Product Schedule have the same meaning as in those Conditions.

1 Ordering and Duration

1.1 To order storage and disaster recovery backup services you must provide us with a description or specification of the required services (the Stability Protocol), the dimensions, format, quantity and weight of Samples, and the initial period for which you require the services, so that we can prepare our Quotation.

1.2 If we provide you with a Quotation you may then order the Services set out in the Quotation by submitting an Order for them in writing to us. You shall ensure that your Order is consistent with the Quotation.

1.3 Your Order is accepted by us only when we issue our written acceptance of the Order (the Commencement Date).

2 Services

2.1 We shall provide the Services to you from the Commencement Date until the expiry of the initial storage period set out in our Quotation (the Initial Period of Storage), subject to paragraph 2.2 below. We will continue to provide the Services after the Initial Period of Storage until either party gives one month’s notice to end the Services.

2.2 During the Initial Period of Storage either party may end the Services early by giving the other at least three months’ written notice.

2.3 We will supply the Services to you in accordance with the Quotation, the Stability Protocol (subject to any amendments set out in the Quotation), and any Technical Agreement. A Technical Agreement is an agreement that we enter into with you, based on the Stability Protocol, which provides additional technical information about the Services and sets out quality standards for the Services.

3 Your obligations

3.1 You shall:

3.1.1 ensure that the Samples submitted to us in connection with the Services are of the same dimensions, format, quantity and weight as identified in the Quotation;

3.1.2 ensure that we receive the Samples within any timescales set out in the Quotation;
3.1.3 ensure that each Sample we receive is accompanied by the corresponding material safety data (MSDS) sheet and Stability Protocol, and that the Samples comply with that MSDS;

3.1.4 in the case of any Samples that pose a risk of infection or any other health and safety risk, notify us of the risk notify us before delivery of the Samples;

3.1.5 provide us with such information and materials as we may reasonably require in order to supply the Services, and ensure that such information is complete and accurate in all material respects;

3.1.6 obtain and maintain all necessary licences, permission and consents which may be required before the date on which the Services are to start.

3.2 If you do not ensure we receive the Samples within the timescales set out in the Quotation, or if any of the information you provided in relation to the Samples before or after your Order is inaccurate or incomplete then:

3.2.1 we may amend the Quotation in accordance with our then prevailing rates to take reasonable account of such delay, incompleteness or inaccuracy, and such amendment shall take effect from the date we notify you of it;

3.2.2 we may charge you for any wasted costs due to such delay, inaccuracy, or incompleteness. For these purposes wasted costs means non-refundable costs that we reasonably incurred in connection with the purpose building and/or preparation of an appropriate storage facility for the Samples pursuant to the Order and/or any losses we incur that we cannot reasonably avoid due to any non-use of all or part of such storage facility.

3.3 If you wish us to provide the Services in relation to Samples that do not conform with the dimensions, format, quantity, and weight identified in the Quotation then you shall submit a change request in accordance with paragraph 4 below no later than on month before submitting such Samples.

3.4 If you submit Samples that do not conform with the dimensions, format, quantity, and weight identified in the Quotation and you do not submit a change request in accordance with paragraph 3.3 above then:

3.4.1 we will either use reasonable endeavours to provide the Services in relation to those non-conforming Samples or return them to you at your risk and cost;

3.4.2 if we provide the Services in relation to those non-conforming Samples then we shall be entitled to charge you for those Services at our then prevailing rates.
4 Changes to the Services

4.1 No change shall be implemented unless agreed in writing in accordance with this paragraph 4 or unless permitted under clause 10.6 of the Terms and Conditions.

4.2 If you wish us to change the Services you may submit a change request to us in accordance with this paragraph 4. If we wish to change the Services we may submit a change request to you in accordance with this paragraph 4.

4.3 If either party requests a change pursuant to this paragraph 4 you shall provide us with such information as we may reasonably request to assess whether such change is technically feasible and to determine the effects of the change.

4.4 Within 14 days after receiving the information referred to in paragraph 4.3 we shall inform you whether the change is technically feasible and (if it is) provide you with a written proposal setting out what effects (if any) it would have on the performance of the Services and our fees.

4.5 If you wish to proceed with the change following receipt of the proposal we provide pursuant to paragraph 4.4 above you shall inform us in writing and the change shall take effect in accordance with our proposal.