

## **For Researchers – How to Use the Laboratory Service and Test List to develop preliminary budget for a trial or study**

**Purpose:** This document is provided to assist you with using the laboratory list of services and tests to prepare preliminary budgets. The examples provided were created as examples, and do not reflect any trial/study or current costs. For current costs, please refer to the effective Laboratory Services and Test List for Clinical Trials and Research Studies.

- The Laboratory Service and Test List is built using costs for individual services and tests. Items are then combined to obtain the total cost. This creates maximum flexibility.

**Individual services and tests must be added to get the final total cost – see the examples that follow**

### **Example 1:**

Your protocol requires set up for blood collection with glucose and potassium tests done locally for 100 patients.

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Setup/administrative fee		1	350.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Sample collection including PK and time samples per patient per collection	\$12.00	100	1200.00
Sample centrifugation only per collection	\$5.00	100	500.00
Glucose – serum/plasma	\$5.00	100	500.00
Potassium	\$5.00	100	500.00
		<b>Total</b>	<b>\$3050.00</b>

**Example 2:**

Your protocol requires set up for the kit provided by the pharmaceutical company to be collected, processed and the samples shipped to the central laboratory. Three tubes need to be collected, centrifuged with one aliquot prepared for each tube. Each patient's samples need be shipped at ambient temperature as soon as they are collected. The trial will involve 20 patients.

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Setup/administrative fee		1	350.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Sample collection including PK and time samples per patient per collection	\$12.00	20	240.00
Sample basic processing per collection	\$20.00	20	400.00
Packaging charge per patient per visit per shipping location at ambient temperature	\$20.00	20	400.00
Note: shipping containers need to be provided by the trial/study			
Note: prepaid waybill required for shipping charges			
		<b>Total</b>	<b>\$1390.00</b>

**Example 3:**

For a three year trial, you want the kit provided by the pharmaceutical company collected, processed and the samples shipped to the central laboratory. Three tubes need to be collected, each of the tubes needs 20 aliquots prepared. Each patient samples will be shipped on dry ice as soon as they are collected. There are 10 patients in the trial.

- 1) The following items need to be added to provide per patient per collection cost, and then the costs in year 2 and 3 need to be estimated (a 5% increase per year is used in the example).

<b>Service/Test</b>	<b>Cost Year 1</b>	<b>Cost Year 2 Using 5% increase</b>	<b>Cost Year 3 Using 5% increase</b>
Sample collection including PK and time samples per patient per collection	\$12.00	12.60	13.23
Sample complex processing per collection	\$33.00	34.65	36.38
Packaging charge per patient per visit per shipping location with dry ice	\$30.00	31.50	33.08
Note: shipping containers need to be provided by the trial/study			
Note: prepaid waybill required for shipping charges			
<b>Subtotal</b>	<b>\$75.00</b>	<b>78.75</b>	<b>82.69</b>

- 2) The total cost needs to be calculated. See table below.

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Setup/administrative fee		1	350.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Year 1 - Cost of kit collection, processing and packaging	75.00	10	750.00
Year 2 - Cost of kit collection, processing and packaging	78.75	10	787.50
Year 3 - Cost of kit collection, processing and packaging	82.69	10	826.90
		<b>Total</b>	<b>\$2714.40</b>

**Example 4:**

Your protocol involves 5 patients and requires set up for blood collection with glucose and potassium tests done locally. Then pulling a block on each patient with 5 H&E stained slides prepared. The researcher will be requesting H&E slides on a specific block that they will select from the report information. When all the slides have been prepared, they need to be packaged as a batch and shipped.

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Setup/administrative fee		1	350.00
Additional department set up fee		1	50.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Sample collection including PK and time samples per patient per collection	\$12.00	5	60.00
Sample centrifugation only per collection	\$5.00	5	25.00
Glucose – serum/plasma	\$5.00	5	25.00
Potassium	\$5.00	5	25.00
Pull case slides or blocks off site stored (If case slides or blocks are stored on site, cost will be lower)	\$52.00	5	260.00
Microtomy – per slide @ \$6.00 per slide X 5 slides = \$30.00	\$30.00	5	150.00
H & E stain slides @ \$5.00 per slide X 5 slides = \$25.00	\$25.00	5	125.00
Batch shipment packaging charge per container per shipping location (when trials coordinators are not performing the packaging services)			40.00
Note: shipping containers need to be provided by the trial/study			
Note: prepaid waybill required for shipping charges			
		<b>Total</b>	<b>\$1110.00</b>

**Example 5:**

Your protocol involves 10 patients and requires that the laboratory select a representative block on each patient. Prepare 5 unstained slides per block. When all the slides have been prepared, you will pick up the slides.

The laboratory will need to pull slides in order to select the representative block. Slides and blocks are not stored together as each has unique storage requirements. The lab will have to pull the case slides and case blocks. This requires two pulls – one for the slides and then one for the blocks.

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Setup/administrative fee		1	350.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Pull case slides off site stored (If case slides or blocks are stored on site, cost will be lower)	\$52.00	10	520.00
Pull case blocks off site stored (If case slides or blocks are stored on site, cost will be lower)	\$52.00	10	520.00
Evaluation of slides for representative block	\$55.00	10	550.00
Microtomy – per slide @ \$6.00 per slide X 5 slides = \$30.00	\$30.00	10	300.00
		<b>Total</b>	<b>\$2240.00</b>

**Example 6:**

You are a researcher who needs to request blocks from a site other than the primary site where your study was set up. For example, this would occur when patients are enrolled in a study in one Alberta zone and where they had surgery in another zone. You will be providing 2 patient’s case numbers. You want the 2 case blocks pulled. The blocks need to be packaged as a batch and shipped.

***Alternative service to block release:***

The laboratory may ask you if there is an alternative service to releasing the paraffin embedded block that will meet your needs. For example, you may request 20 unstained slides be cut rather than the block release. You will be charged for the additional service. Please add the additional costs to obtain the total cost.

***Note: Please include your ethics approval and include details on block use (ie: TMA) with the request.***

<b>Study setup/administrative fees</b>	<b>Cost</b>	<b>Units</b>	<b>Subtotal</b>
Additional department set up fee		1	50.00
<b>Services/Tests</b>	<b>Cost</b>	<b>Number of Patients</b>	<b>Subtotal</b>
Pull case slides or blocks off site stored (If case slides or blocks are stored on site, cost will be lower)	52.00	2	104.00
Batch shipment packaging charge per container per shipping location (when trials coordinators are not performing the packaging services)			40.00
Note: shipping containers need to be provided by the trial/study			
Note: prepaid waybill required for shipping charges			
		<b>Total</b>	<b>\$194.00</b>