HEALTH PURCHASING VICTORIA

Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	HPVITS2017-042
Invitation to Supply Name:	Pathology Consumables
HPVTIS2017-042 Closing Date and time:	13 December 2016 14:00 AEDT

Authorised Contact Person

Tom O'Reilly

Category Manager

Contact through the HPV Procurement Portal

https://www.hpv.org.au/

Published: 16 November 2016

HEALTH PURCHASING VICTORIA

Table of Contents

A Introduction

1 Purpose

a. The purpose of this Part 5 - Statement of Requirements, is to:

(i) detail the scope and range of products sought under this Invitation to Supply (ITS)
(ii) specify the requirements that Respondents and / or their offered products must meet (these requirements also form part of any resulting Agreement between HPV and any successful Respondent)

2 Scope

a. HPV is seeking responses for Pathology Consumables for use in Participating Health Services. The envisaged Term of the Agreement is four (4) years plus one (1) optional two year extension period (4+2).

b. The scope of this ITS includes the supply of generic pathology consumables listed in Part 5 A 3 Product Categories (standard purchases)

c. The scope of this ITS does not include:

(i) consumables and reagents that are proprietary to pathology analysers and equipment
(ii) winged intravenous devices that are currently included on HPVC2013-079 Intravenous Access Devices and Administration Consumables Agreement
(iii) hypodermic syringes and needles currently included on HPVC2015-005 Hypodermic Needles and Syringes
(iv) core biopsy needles and access needles included in on HPVC2016-061 Interventional Radiology

d. Indicative volumes are listed **in the HPV Procurement Portal**.

3 Product Categories

a. The categories of Pathology Consumables required under this ITS include:

(i) Category 1 - Blood Gas Syringes
(ii) Category 2 - Blood Collection Tubes
(iii) Category 3 - Blood Collection Equipment
(iv) Category 4 - Blood Collection Lancets
(v) Category 5 - Capillary Tubes
(vi) Category 6 - Culture Swabs
(vii) Category 7 - Genetic Testing Swabs
(viii) Category 8 - Specimen Collection Containers (Non Blood)
(ix) Category 9 - Bone Marrow Biopsy and Aspiration Needles
(x) Category 10 - Urine Test Strips
(xi) Category 11 - Liquid Based Cytology Collection Kits for Human Papillomavirus
(xii) Category 12 - Prefilled Specimen Containers for Histology

(xiii) Category 13 - Laboratory Chemicals
(xiv) Category 14 - Embedding Cassettes
(xv) Category 15 - Foam Biopsy Pads
(xvi) Category 16 - Embedding Media
(xvii) Category 17 - Microtome Blades
(xviii) Category 18 - Trimming Blades
(xix) Category 19 - Tissue Marking Dye
(xx) Category 20 - Cytology Consumables
(xxi) Category 21 - Tubes for Internal Laboratory Use
(xxii) Category 22 - Petri Dishes
(xxiii) Category 23 - Transfer Pipettes
(xxiv) Category 24 - Pipette Tips
(xxv) Category 25 - Disposable Loops and Spreaders
(xxvi) Category 26 - Microtitre Plates
(xxvii) Category 27 - Microscope Slides
(xxviii) Category 28 - Cover Slips
(xxix) Category 29 - Microscope Slide Mailers
(xxx) Category 30 - Urine Cell Counting Chambers/Haemocytometers
(xxxi) Category 31 - Labels
(xxxii) Category 32 - Packaging Requisites for Surface and Air Transport
(xxxiii) Category 33 - Bags for Specimen Transport

b. The Respondent may offer products in one, some or all categories.

c. HPV reserves the right not to consider any additional products offered.

d. For a full list of product categories and subcategories, see Appendix 1 - Product List.

4 Product Conditions

4.1 Clinical Trials

a. Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

4.2 Product Duplication

a. HPV may not consider any product that is subject to a current HPV Agreement, other than the current Agreement for Pathology Consumables (HPVC2012-042).

b. The Respondent will ensure that each product is offered in only **one** subcategory.

It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

4.3 Product Information

a. The Respondent will submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

b. Where research papers or relevant scientific information is available, this should be submitted with the Response.

c. All product information submitted should:

(i) be in electronic format
(ii) be in English
(iii) be specific to the product offered
(iv) contain the Respondent's company name
(v) include the product code
(vi) include a detailed specification of the product
(vii) include clear diagrams/pictures of the product.

d. To assist in managing this material, all product information submitted needs to be labelled with the relevant HPV category and subcategory number.

Electronic copies must include the HPV Category and subcategory numbers in the filename or identifying metadata.

HPV may not consider unlabelled submissions.

e. Product information will not be evaluated, but is necessary to assist in accurately identifying products offered.

f. HPV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per Part 5 A 4.3 d above; or
(ii) Is incomplete as to Part 5 A 4.3 c.

g. The Respondent should not submit information relating to products that are not called for in this ITS.

h. Respondents are to provide for evaluation purposes samples of submitted products and accessories as follows:

(i) Only samples for products not on the current contract HPVC2012-042
(ii) Samples for products that are on the current contract HPVC2012-042 where there has been a change in the specification of the product
(iii) No other samples are to be submitted.

i. Respondents are not to provide samples of hazardous and/or refrigerated materials. Rather than providing samples of these products, Respondents are to provide photographs of the packaging.

j. For each sample:

(i) one (1) sample of one (1) size for each product type of each range or sub-category;
(ii) single use or re-usable;
(iii) sterile or non-sterile;
(iv) a list of all samples provided; and
(v) instructions for use, where applicable.

k. All samples provided should be:

(i) new and unopened;
(ii) packed, sealed and labelled;
(iii) packed in boxes with products of the same category; and
(iv) include supporting specifications and relevant data.

l. Each sample submitted should be clearly labelled with the following information:

(i) name of the Respondent;
(ii) ITS name and number;
(iii) name and number of the sub-category that the product has been tendered into; and
(iv) Respondent's product code and description.

m. All samples submitted will be disposed of upon completion of the evaluation process unless collection or return instructions are supplied with each sample. Samples to be returned will be at Respondent's cost.

n. For samples to be returned, Respondents are to include instructions with the samples with the following:

(i) clear instructions to indicate if the samples are to be collected from HPV or are to be sent back at the Respondent's cost. For samples that are to be sent back, instructions are to include the freight account or 'con note', an address print out and any necessary paperwork that is to be used by HPV to enable the return to occur.

o. Samples are to be sent to the following address:

Attention to: Tom O'Reilly
HPVITS2017-042
Health Purchasing Victoria
Level 34, Casselden Place, 2 Lonsdale Street
Melbourne, VIC 3000

p. All samples are to arrive at the above address before the Tender Closing Date and Time.

4.4 Product References

a. Respondents are required to provide in the relevant column of the Tender Response Worksheet a minimum of three (3) Australian clinical references that are using or have trialled and evaluated each class or category of product offered in this submission unless the product offered is currently on HPVC2012-042 Pathology Consumables.

b. Where a Product Category contains a variety of specific subcategories, Tenderers are to ensure that the Reference Sites provided are representative of the full range of products tendered.

c. HPV reserves the right to verify this information with hospital personnel and seek user feedback as to the acceptability of these products.

d. Respondents should not nominate a referee without their express permission.

5 Definitions

a. The following definitions apply to this Part 5 – Statement of Requirements, unless otherwise stated.

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of **Pathology Consumables**. Comprises the General Conditions, and all Schedules, Annexures of any kind and any attachments.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.
Business hours	From 8:30am to 5:00pm during Business days
may	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
must	Indicates a mandatory requirement; failure to meet this requirement will result in the submission being eliminated from further consideration.
Participating Health Services	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic), that are described in **Appendix 4 of Part 8**.
should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may impact evaluation.
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
will	Indicates an anticipated future condition or requirement to be met.

B Service, delivery, and support

1 Delivery

a. Pathology Consumables must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed seven (7) days from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Draft Agreement, Part 7 – 9 Acceptance and Rejection of Deliverables.

2 Urgent Deliveries

a. For the purposes of this section, urgent deliveries refers to urgent requests placed by an individual Participating Health Service, and does not include state-wide emergency situations.

b. The Respondent must be able to receive and action urgent delivery requests during Business hours.

c. Urgent deliveries should be received by Participating Health Services on the same day if made urgent delivery request is made before midday or within 24 hours if the urgent delivery request is made after 12:00pm.

3 Training

a. Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of their Pathology Consumables to clinicians in their operating environment for products related to sample collection.

b. Training requirements may include (but are not limited to):

(i) face-to-face training at Participating Health Service sites (i.e. in-service training)
(ii) off-site study days for clinicians
(iii) updates and refresher training on new products and/or equipment and surgical techniques
(iv) training on cleaning and sterilisation to nominated personnel and the Participating Health Services' CSSD and SSU (for reusable instruments)
(v) training materials.

4 Customer Service and Support

a. The successful Respondent must be able to deliver customer service within Business hours and support to Participating Health Services.

b. The successful Respondent will provide Participating Health Services with representatives that are:

(i) inherently familiar with the contracted products
(ii) appropriately qualified
(iii) technically/clinically knowledgeable about the contracted products
(iv) available to respond to Participating Health Services' queries 24 hours a day.

c. It is desirable that nominated Representatives have a clinical background or experience.

d. The level of customer service and support required of Representatives is expected to include (but is not limited to):

(i) liaising with clinicians/healthcare worker to recommend products and solutions
(ii) promptly answering clinicians' queries (including after hours)
(iii) liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)
(iv) providing on-site clinical support during cases (if requested)
(v) providing informational materials
(vi) providing education and in-service training upon request.

5 Warranty

a. All products covered in this ITS (including relevant instrument sets and loan kits) are to be issued a warranty for a minimum or twelve (12) months from the delivery date for normal use.

b. Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty.

5.2 Repairs and Replacements under Warranty

a. The repair or replacement of any item under warranty will be at no cost to the Participating Health Service.

b. The cost of any pickup or delivery associated with a repair or replacement under warranty will be borne by the successful Respondent.

c. It is highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

6 Key Performance Indicators

a. Refer to **Part 7 Supply Schedule – 17. Key Performance Indicators**.

7 Reporting

a. Refer **Appendix 5 – Reporting Guidelines**.

8 Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s). The SLA may cover arrangements including, but not limited to:

(i) requirements for stock management and rotation
(ii) arrangements for ordering, invoicing and delivery
(iii) education/clinical support, including attendance requirements for Representatives in relation to education and training
(iv) communication arrangements for product recalls and safety alerts (refer to C3 Recall Process).

b. The SLA will be in addition to the Agreement between the successful Respondent(s) and HPV, and will not alter any terms of the Agreement.

c. HPV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.

C General Requirements

1 Standards and Compliance

a. All items offered must comply with relevant Australian Standards (or their equivalent International Standards). Refer to Appendix 2 - References for a list of the minimum relevant standards.

b. All items offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response.

c. The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

2 Packaging and Labelling

a. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

b. All labels must comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.

c. Items will be delivered in accordance with the manufacturer's instructions, including:

(i) Data loggers where applicable
(ii) At the request of the Participating Health Service, the successful Respondent is to supply evidence that transport conditions are maintained.

d. It is desirable for individual product packaging to include (where applicable):

(i) whether the product is sterile;
(ii) whether the product is MRI compatible (implantable products);
(iii) whether the product (or packaging) contains latex or is latex-free; and
(iv) tracking labels
(v) storage conditions
(vi) date of manufacture and expiry (shelf life)

e. At the request of the Participating Health Service, the successful Respondent is to provide the product's Materiel Safety Data Sheets (MSDS) that complies with the MSDS Australian Standards.

f. All products packaged together are to have the same expiry date.

3 Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2004).

b. Within six (6) months of contract commencement, all recalls and/or hazard alerts will be completed using GS1 Recall.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 - B5 Warranty, where applicable.

3.2 Backorders and Discontinued Lines

a. In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent will contact (at a minimum) the following:

(i) Procurement Officers of all Participating Health Services
(ii) Supply Manager / Business Managers of all Participating Health Services
(iii) HPV

b. In the event that an item is discontinued, successful Respondents will notify Participating Health Service staff and HPV (as per clause a) as soon as possible, but no less than six (6) months before the last date of manufacture.

c. Successful Respondents will inform the affected Participating Health Services and HPV of:

(i) the anticipated timeframe for resolving the issue
(ii) the availability of an agreed substitute product

3.3 Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products.

c. At the request of the Participating Health Service, successful Respondents are to provide instructions for the disposal of used or contaminated products/waste.

D Product Specifications

1 Substances of Concern

a. Preference will be given to products (including their accompanying packaging) that are latex-free, unless otherwise stated.

b. Preference may be given to products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP).

2 Category Specifications

a. A complete range of Pathology Consumables is required for treatment of patients across Victorian Public Health Services.

Category 1 - Blood Gas Syringes

a A full range of sterile, single use Blood Gas Syringes is required to meet clinical needs for the collection and analysis of blood samples.

b Blood Gas Syringes will:

(i) Contain dry anticoagulant that does not adversely affect the measurement of ionised calcium or other electrolyte assays

(ii) Ensure air and liquid tight containment of the specimen following collection

(iii) Be clearly labelled with the:

- Recommended fill volume
- Lot number and expiry date

(iv) Be marked with gradients to the maximum fill capacity.

c Product Description:

For each Blood Gas Syringe offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Volume in millilitres

(iii) Method of collection (e.g. aspiration, autoventing)

(iv) Gradient markings in millilitres (e.g. 0.1 mls)

(v) Containment/Sealing mechanism (e.g. syringe cap)

(vi) Venting cap (where applicable)

(vii) Anticoagulant:

- Form (e.g. dry sprayed)
- Concentration in international units/millilitre

(viii) Suitable for use with ionised calcium (where applicable)

(ix) Barcoding (where applicable).

d For each Blood Gas Syringe offered, Respondents will advise the brand and model of analyser with which they are compatible on the Tender Response Worksheet.

e Respondents will provide documented evidence for validation of clinical accuracy where compatibility is indicated in the HPV Procurement Portal.

Category 2 - Blood Collection Tubes

a A full range of single use Blood Collection Tubes is required to meet clinical needs.

b Preference will be given to Blood Collection Tubes that are supplied with patient identification labels that have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Date of Birth

(iv) Date and Time of Collection

(v) Signature of collector (where applicable)

(vi) Clearly marked fill line.

c For each Blood Collection Tube offered, Respondents will advise on the Tender Response Worksheet the information required on the Patient label.

d All Blood Collection Tubes offered will be clearly marked with a Lot Number and Expiry Date.

e Product Description:

For each Blood Collection Tube offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Diameter in millimetres

(iii) Length in millimetres

(iv) Evacuated (where applicable)

(v) Recommended fill volume in millilitres

(vi) Type of base (e.g. flat)

(vii) Tube material (e.g. glass)

(viii) Gel or other (where applicable)

(ix) Additive:

- Type (e.g. K2 EDTA)
- Form (e.g. spray, liquid)
- Concentration in international units or milligrams/millilitre

(x) Cap:

- type of securement (e.g. screw, push on)
- colour

(xi) Barcoding (where applicable).

f For each Blood Collection Tube offered, Respondents will advise on the Tender response Worksheet:

(i) Minimum shelf life

(ii) Recommended storage temperature in degrees Celsius

(iii) Recommended centrifuge time in minutes at relative centrifuge force and temperature.

g Additional Information

The following information will be readily available for all contract users in electronic and/ or hardcopy:

(i) Centrifuge time in minutes

(ii) Recommended order of draw when collecting blood for multiple tests.

Category 3 - Blood Collection Equipment

a A full range of Blood Collection Equipment is required to meet clinical needs for the collection of blood specimens. This includes:

(i) Sterile, single use, safety and non-safety multi sample needles

(ii) Sterile, single use, safety winged infusion sets with integral adaptor

(iii) Single use tube holders, sterile and non-sterile, for use with blood collection tubes and other collection devices including culture bottles

(iv) Single patient use and reusable tourniquets.

b For each winged infusion set offered, Respondents will advise the Magnetic Resonance Imaging (MRI) compatibility in the Tender Response worksheet.

c Product Description:

For each item of Blood Collection Equipment offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Type of equipment (e.g. Luer adaptor, tube holder, winged infusion set)

(iii) Sterile (where applicable)

(iv) Single use or reusable

(v) Safety features (where applicable)

(vi) Multi Sample Needles (where applicable)

- Safety or non-safety
- Size in French Gauge
- Length in millimetres

(vii) Safety Winged Infusion Sets with integral adaptor (where applicable)

- Needle size in French Gauge
- Needle length in millimetres
- Colour coding (where applicable) (e.g. blue)
- Tubing length in millimetres (where applicable)

(viii) Tourniquet (where applicable)

- Single patient use or reusable
- Dimensions (length and width in millimetres)
- Material of construction (e.g. polyester with elastic, rubber)
- Colour
- Closure (e.g. velcro, buckle), where applicable

d Additional Information

The following information for all reusable products will be available in electronic and/ or hardcopy and supplied at the request of the Participating Health Service:

(i) Information regarding the cleaning and sterilisation of the product

(ii) Any contraindications to reuse

(iii) Information relating to the anticipated life or number of reuses when used and reprocessed in accordance with the manufacturer's instructions.

e Respondent's Note:

The scope of this ITS does not include:

(i) winged intravenous devices that are included in the scope of HPVC2013-079 Intravenous Access Devices and Administration Consumables Agreement

(ii) hypodermic syringes and needles included in the scope of HPVC2015-005 Hypodermic Needles and Syringes

Category 4 - Blood Collection Lancets

a A full range of sterile, single use retractable Blood Collection Lancets with blades is required to meet clinical needs.

b Product Description:

For each Blood Collection Lancet offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Blade:

- Shape (e.g. v-blade, conical)
- Width in millimetres
- Length in millimetres

(iii) Colour (e.g. yellow)

(iv) Recommended flow (e.g. low, high)

(v) Puncture mechanism (e.g. puncture, slice)

(vi) Finger or heel

c Respondent's Note:

This category excludes lancet devices (needle point) specifically intended for use with point of care systems.

Category 5 - Capillary Tubes

a A full range of plastic Capillary Tubes is required to meet clinical needs.

b Capillary Tubes will be:

(i) Visibly clean and free from lint, grease and debris

(ii) Sufficiently durable to minimise breakage and damage to edges during normal storage, transport, handling and use

(iii) Packaged in a manner that is sufficiently durable to protect the tubes from contamination and damage during normal storage, transport, handling and laboratory use

c Capillary Tubes with anticoagulant will be clearly marked with the expiry date and lot number.

d Product Description:

For each Capillary Tube offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Length in millimetres

(iii) Anticoagulant:

- Form (e.g. dry sprayed)
- Concentration in international units/millilitre

(iv) Mixing wire (where applicable)

(v) End caps (where applicable).

Category 6 - Culture Swabs

a A full range of single use Culture Swabs is required to meet clinical needs.

b Culture Swabs will be:

(i) Pyrogen free

(ii) Clearly labelled with the transport media (where applicable).

(iii) Clearly marked with a lot number and expiry date.

c Preference will be given to Culture Swabs that are supplied with labels that have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Site

(iv) Date of birth

(v) Date and time of collection

(vi) Signature of collector (where applicable).

For each Culture Swab offered, Respondents will advise on the Tender Response Worksheet the information required on the Patient label.

d Product Description:

For each Culture Swab offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Sterile or non-sterile

(iii) Package Presentation (e.g. bulk pack, multi pack)

(iv) Tip:

- Configuration (e.g. flocked)
- Material (e.g. rayon)

(v) Lid:

- Colour
- Type of securement (e.g. screw on)

(vi) Shaft:

- Material (e.g. polyester)
- Distance of break point from tip in millimetres (where applicable)

(vii) Transport media (where applicable) (e.g. Liquid Amies Medium)

(viii) Purpose of use (e.g. bacterial, culture and viral PCR)

(ix) Specimen type (e.g. viral, anaerobic).

e For each Culture Swab offered, Respondents will advise on the Tender Response Worksheet:

(i) Recommended shelf life

(ii) Recommended storage conditions.

(iii) The capacity to supply Culture Swabs with customised labelling and /or barcoding.

Category 7 - Genetic Testing Swabs

a A full range of single use sterile Genetic Testing Swabs are required to meet clinical needs.

b Preference will be given to Genetic Testing Swabs that are supplied with labels that have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Site

(iv) Date of birth

(v) Date and time of collection

(vi) Signature of collector (where applicable).

For each Genetic Testing Swab offered, Respondents will advise on the Tender Response Worksheet the information required on the Patient label.

c **Product Description:**

For each Genetic Testing Swab offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Package Presentation (e.g. bulk pack, multi pack)

(iii) Tip (e.g. flocked or cotton)

(iv) Lid:

- colour
- type of securement (e.g. screw on)

(v) Shaft (e.g. plastic or wood)

d For each Genetic Testing Swab offered, Respondent will advise in the Tender Response Worksheet:

(i) Recommended shelf life

(ii) Recommended storage conditions

(iii) The capacity to supply Genetic Testing Swabs with customised labelling and/or barcoding.

Category 8 - Specimen Collection Containers (Non Blood)

a A full range of Non Blood Specimen Collection Containers with lids for the collection and transport of a range of specimen types and sizes is required to meet clinical needs. This includes containers for:

(i) Microbiological culture and cytology examination of urine, sputum, faeces, cerebrospinal fluid (CSF), tissue and other biological specimens

(ii) Twenty four hour urine and timed faecal (e.g. 48 hour) collection

(iii) Collection of intraoperative tissue specimens for histology examination.

b For specimen containers with a capacity in excess of one litre, preference will be given to those that:

(i) incorporate a handle

(ii) are leak proof

(iii) have ergonomic opening and closing processes

c Non Blood Specimen Collection Containers and lids will:

(i) Seal securely

(ii) Be able to be reopened in a manner that is safe for both the clinician and the specimen

(iii) Be leak-proof under conditions of normal use and transport.

d Preference will be given to Non Blood Specimen Collection Containers that are supplied with labels that have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Site

(iv) Date of birth

(v) Date and time of collection

(vi) Signature of collector (where applicable).

For each Non Blood Specimen Collection Container offered, Respondents will advise on the Tender Response Worksheet the information required on the Patient label.

e Preference will be given to containers for faecal collection that:

(i) incorporate a scoop or similar mechanism

(ii) are clear (see through; that are non-opaque).

f Tubes for the collection of cerebrospinal fluid (CSF) will:

(i) Have a v-shaped base surrounded by a flat rim or skirt

(ii) Be capable of standing in a vertical position

(iii) Be packaged sterile in a peel pack for ease of access and to minimise the risk of contamination when passing onto the sterile field

(iv) Where packaged in multiples, the tubes will be clearly numbered.

g Containers for the collection of histology specimens will:

(i) Be manufactured from a rigid, chemical resistant material

(ii) Be clean and free from debris.

h For histology specimen containers with a capacity in excess of one litre, preference will be given to those that:

(i) Incorporate a handle

(ii) Are leak proof

(iii) Have ergonomic opening and closing processes

i Product Description:

For each Non Blood Specimen Container offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Sterile (where applicable)

(iii) Lid:

- Colour
- Type (e.g. screw cap)

(iv) Container

- Type (e.g. cytology, faecal collection, urine)
- Volume in millilitres
- Graduations (where applicable)
- Material (e.g. polypropylene)
- Colour (e.g. translucent, opaque)

(v) Patient identification label (where applicable)

(vi) For CSF collection tubes (where applicable):

- Presentation (e.g. single or numbered multiple)

(vii) Containers for faecal collection (where applicable):

- Collection mechanism (where applicable) (e.g. scoop, spoon)
- Label for Collection Start and Finish time
- Timed faecal collection (where applicable) (e.g. 48 hour)

(viii) Containers for 24 hour urine collection (where applicable):

- Size of container opening (e.g. 70mm)
- Pour spout (where applicable)
- Handle (where applicable)
- Profile (e.g. horizontal)
- Collection cup (where applicable)
- Label for Collection Start and Finish time

(ix) Containers for histology specimens (where applicable):

- Handle (where applicable).

j For each Non Blood Specimen Collection Container offered, Respondents will advise in the Tender Response Worksheet:

(i) Whether the container is resistant to Hydrochloric Acid and/or metal free

(ii) The presence of patient collection instructions for each container for 24 hour urine or timed faecal collection

(iii) The capacity to supply Non Blood Specimen Collection Containers with customised labelling.

Category 9 - Bone Marrow Biopsy and Aspiration Needles

a A full range of sterile, single use Bone Marrow Biopsy and Aspiration Needles are required to meet clinical needs.

b Bone Marrow Aspiration needles will:

(i) Incorporate an adaptor that permits the connection of a Luer Lock syringe

(ii) Be packaged in a peel pack in a manner that protects the tip from damage and the operator from injury.

c Product Description:

For each Bone Marrow Biopsy or Aspiration Needle offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Needle:

- Size in French Gauge
- Length in millimetres

(iii) Procedure (e.g. Biopsy, aspiration)

(iv) Approach (e.g. Sternal or Iliac Crest)

(v) Sample collection device (where applicable)

(vi) Sample ejector (where applicable)

(vii) Safety features (where applicable)

(viii) Additional components (where applicable).

d Respondent's Note:

The scope of this ITS does not include core biopsy needles and access needles included in on HPVC2016-061 Interventional Radiology.

Category 10 - Urine Test Strips

a A full range of Urine Test Strips is required to meet clinical needs.

b Urine test strips will:

(i) Provide clear colour change when pathological changes are detected.

(ii) Be stored in a container that reseals to prevent degradation of the test strips.

c Urine Test Strip Packaging will incorporate:

(i) Clear, easy to read, test result indicators on the test strip container

(ii) Clear test strip instructions on the packaging

d **Product Description:**

For each urine test strip offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) The number of tests available on a single strip (e.g. 10, 12)

e Respondents will advise in the Tender Response Worksheet:

(i) The types of reagents or chemical pads available with each test strip

(ii) Length of time in 'seconds' for results e.g. 60 seconds

Category 11 - Liquid Based Cytology Collection Kits for Human Papillomavirus

a A full range of liquid based cytology collection kits for Human Papillomavirus are required to meet clinical needs.

b Preference will be given to collection containers that are supplied with patient identification labels that have space for the following information:

(i) Name

(ii) Patient registration number/UR number/reference Number

(iii) Date of Birth

(iv) Date and Time of Collection

(v) Signature of collector (where applicable)

c All liquid based cytology collection kits offered will:

(i) Be clearly marked with a Lot Number and Expiry

(ii) Seal securely

(iii) Be able to be reopened in a manner that is safe for both the clinician and the specimen

(iv) Be leak-proof under conditions of normal use

d **Product Description:**

For each Human Papillomavirus Kit offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Sterile (where applicable)

(iii) Package presentation (e.g. bulk pack, multi pack)

(iv) Contents (e.g. brush, preservative fluid)

e For each Human Papillomavirus Kit offered, Respondents will advise in the Tender Response Worksheet:

(i) Assays that have been validated under their TGA registration using the liquid based cytology preservative being offered.

(ii) Minimum shelf life

(iii) Recommended storage temperature in degrees Celsius prior to use

(iv) The stability of HPV in the collection device under the sample storage conditions recommended pre and post testing.

Category 12 - Prefilled Specimen Containers for Histology

a A range of Specimen Containers for Histology, prefilled with 10% tinted neutral buffered formalin, is required for the collection, transport, preservation and storage of specimens to meet laboratory needs.

b Prefilled Specimen Containers will:

(i) Comply with state and federal requirements for safe packaging and labelling of dangerous and hazardous goods

(ii) Have a screw cap

(iii) Be leak-proof and airtight

(iv) Be free of contaminants and precipitation

(v) Be packaged in a manner that maintains individual containers in an upright position

(vi) Be clearly marked with a lot number, expiry date and hazard label.

c Preference will be given to Prefilled Specimen Containers for Histology that are supplied with labels that have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Site

(iv) Date of birth

(v) Date and time of collection

(vi) Signature of collector (where applicable)

For each Prefilled Specimen Container for Histology offered, Respondents will advise on the Tender Response Worksheet the information required on the Patient label.

d Product Description:

For each Prefilled Specimen Container for Histology offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Packaging presentation (e.g. bulk pack, multi pack)

(iii) Container volume in millilitres

(iv) Formalin:

- Tint colour
- Volume in millilitres.

(v) Lid colour

(vi) Patient identification label (where applicable)

e For each Prefilled Specimen Container offered, Respondents will advise on the Tender Response Worksheet:

(i) The information requested on the patient identification label (where applicable)

(ii) Of any specific storage and handling conditions required for safe handling and use in accordance with the relevant Local, State and Federal regulations.

(iii) The capacity to supply Prefilled Specimen Containers with customised labelling.

f Additional Information

Current, manufacturer specific, Material Safety Data Sheets (MSDS) will be available for all Prefilled Specimen Containers.

(i) This information will be provided by the successful Respondents or via a third party MSDS solution management system

(ii) Respondents will advise in HPV Procurement Portal how this information can be accessed, in either hardcopy or electronic form, from the commencement of and throughout the duration of any resultant contract.

Category 13 - Laboratory Chemicals

a A range of volumes and concentrations of the following Laboratory Chemicals is required:

(i) Formalin

(ii) Xylene

(iii) Ethanol

(iv) Isopropanol

(v) Methanol

(vi) Acetone

(vii) Fast and slow decalcifying agents.

(viii) Schiff's Reagent

b All Laboratory Chemicals offered will:

(i) Be clearly marked with a Lot Number, Date of Manufacture and Expiry Date

(ii) Comply with Local, State and Federal requirements for the safe packaging and labelling of dangerous and hazardous goods.

c Where applicable, Respondents will comply with the Code of Practice for the Storage and Handling of Dangerous Goods, 2013.

d For chemical volumes of ≥15 litres, preference will be given to those that are supplied with an appropriate dispensing unit (e.g. cap tap).

e Product Description:

For each Laboratory Chemical offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Volume in litres or millilitres

(iii) Concentration (where applicable)

(iv) Buffered (where applicable)

(v) Percentage (where applicable)

(vi) Grade (e.g. AR, LR) (where applicable)

(vii) Decalcifying agent:

- Base chemical
- Soft or hard

(viii) Tint colour (where applicable)

(ix) Dispensing unit (where applicable (e.g. cap tap).

f Additional Information

Current, manufacturer specific, Material Safety Data Sheets (MSDS) will be available for all Laboratory Chemicals.

(i) This information will be provided by the successful Respondent or via a third party MSDS solution management system.

(ii) It is preferable that the MSDS for all Laboratory chemicals include the chemical formula.

(iii) Respondents will advise in the HPV Procurement Portal how this information can be accessed, in either hardcopy or electronic form, from the commencement of and throughout the duration of any resultant contract.

Category 14 - Embedding Cassettes

a A full range of Embedding Cassettes is required to meet histology needs for tissue and biopsy embedding.

b Product Description:

For each Embedding Cassette offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Dimensions in millimetres

(iii) Application (e.g. tissue, biopsy)

(iv) Colour

(v) Labelling area (where applicable)

- Dimensions in millimetres
- Angle

(vi) Lid (where applicable)

c Respondents will advise in the Tender Response Worksheet the brand and number of the compatible Block Labelling Device for machine specific Embedding Cassettes.

Category 15 - Foam Biopsy Pads

a A full range of Foam Biopsy Pads is required to meet histology needs for tissue and biopsy embedding.

b Foam Biopsy Pads will be of consistent thickness and fit a range of sizes of standard tissue and biopsy embedding cassettes.

c Product Description:

For each Foam Biopsy Pad offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Application (e.g. tissue or biopsy)

(iii) Colour

(iv) Dimensions in millimetres

(v) Textures and density.

Category 16 - Embedding Media

a A range of paraffin-based tissue Embedding Media is required for use in the laboratory.

b Embedding media will:

(i) Minimise tissue compression

(ii) Maintain ribbon continuity without crumbling, cracking or shredding

(iii) Be free from debris

(iv) Not discolour or produce resin precipitate

(v) Not leave plasticiser residue

(vi) Be in small pellets to be able to melt quickly

c Product Description:

d For each type of Embedding Media offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Composition (e.g. paraffin and synthetic resin)

(iii) Additive (where applicable) (e.g. dimethyl sulfoxide)

(iv) Presentation (e.g. pellets, block)

(v) Melting point in degrees Celsius

(vi) Degradation point in degrees Celsius

(vii) Weight in kilograms.

Category 17 - Microtome Blades

a A full range of Microtome Blades is required to meet clinical needs.

b Microtome Blades will:

(i) Provide consistent, uniform ribbons without any grooves, shredding or split sections

(ii) Be packaged in a manner that protects the user from injury and the blade from damage

(iii) Be long lasting and durable with standard tissue types.

c Product Description:

For each Microtome Blade offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Material of construction (e.g. stainless steel, carbon)

(iii) Coating (where applicable) (e.g. PTFE)

(iv) Dimensions in millimetres (width, length, thickness)

(v) Recommended type of specimen.

Category 18 - Trimming Blades

a A full range of Trimming Blades and Handles are required to meet clinical needs.

b Trimming Blades will:

(i) Provide consistent, uniform ribbons without any grooves, shredding or split sections

(ii) Be packaged in a manner that protects the user from injury and the blade from damage

(iii) Be long lasting and durable with standard tissue types.

c Trimming Blade Handles will be durable and long lasting.

d Product Description:

For each Trimming Blade and Handle offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Trimming Blade:

- Material of construction (e.g. stainless steel, carbon)
- Coating (where applicable) (e.g. PTFE)
- Dimensions in millimetres (width, length, thickness)

(iii) Trimming Handle

- Material of construction (e.g. plastic)
- Dimensions in millimetres (width and length)

(iv) Recommended type of specimen.

Category 19 - Tissue Marking Dye

a A full range of Tissue Marking Dye is required to meet clinical needs.

b Tissue Marking Dye will:

(i) Evenly coat the tissue without penetrating the tissue surface

(ii) Be able to be used on fresh or formalin-fixed tissues

(iii) Not interfere with diagnostic interpretation

(iv) Be quick drying

(v) Be easy to use with urgent frozen sectioning

(vi) Not run when applied to tissue.

c **Product Description:**

For each Tissue Marking Dye offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Colour (e.g. blue, black. No Colour)

(iii) Kit of multiple colours (if applicable)

(iv) Hazard information, MSDS (if applicable)

(v) Recommended specimen types for use of kit.

Category 20 - Cytology Consumables

a A full range of Cytology Cards and Disposable Funnels with cards attached are required to meet clinical needs.

b Cytology Cards and Funnels will:

(i) Be available as: filter cards only and disposable funnels with cards attached

(ii) Be made of appropriate material that will allow optimal deposition of sample components into slide

(iii) Be packaged to prevent build-up of moisture and contamination.

c **Product Description:**

For each Cytology Card and Funnel offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Plastic or Metal clips (where applicable)

(iii) Sample volume in millilitres (e.g. 0.5ml, 0.4ml)

(iv) Single or double configuration

(v) Colour (clear or opaque)

d Respondents will advise in the Tender Response Worksheet:

(i) A list of compatible centrifuges that each Cytology Card and Funnel offered is compatible with.

Category 21 - Tubes for Internal Laboratory Use

a A full range of Tubes and replacement caps is required for use internally within the laboratory.

b Product Description:

For each Tube for Internal Laboratory Use offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Application (e.g. aliquot tube, centrifuge tube)

(iii) Material of construction (e.g. polystyrene, polycarbonate)

(iv) Volume in millilitres

(v) Dimensions in millimetres

(vi) Base configuration (e.g. flat, star-shaped)

(vii) Sterile (where applicable)

(viii) Package presentation (e.g. bulk pack, multi pack)

(ix) Graduations (where applicable)

(x) Autoclavable (where applicable)

(xi) Freezable (where applicable)

- Temperature range

(xii) RNAse and/or DNAse free (where applicable)

(xiii) Cap:

- Colour
- Material
- Type (e.g. screw, snap, with O-ring)
- Fitted or provided separately

(xiv) Position of screw thread (e.g. interior surface of tube, exterior surface of tube)

(xv) Label or writing area (where applicable)

(xvi) Spare caps (where applicable).

Category 22 - Petri Dishes

a A full range of plastic Petri Dishes is required to meet laboratory needs.

b Petri dishes will be:

(i) Visibly clean

(ii) Free of rough or sharp edges

(iii) Packaged in a manner that is sufficiently durable to protect the dishes from damage during normal storage, handling, transport and use.

c Product Description:

For each Petri Dish offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Presentation (e.g. full plate, half plate)

(iii) Sterile or clean room

(iv) Dimensions in millimetres

(v) Stacking rings (where applicable)

(vi) Lid (where applicable).

Category 23 - Transfer Pipettes

a A full range of plastic Transfer Pipettes is required to meet laboratory needs.

b Where Transfer Pipettes are presented in a multi pack, preference will be given to packs where pipettes are oriented in the same direction.

c Product Description:

For each Transfer Pipette offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Packaging presentation (e.g. single, multi pack)

- Multipack presentation (where applicable) (e.g. single direction, multi direction)

(iii) Sterile (where applicable)

(iv) Volume in millilitres

(v) Length in millimetres

(vi) Tip configuration (e.g. fine, broad)

(vii) Graduation scale in centimetres (e.g. 0.5cm) (where applicable).

Category 24 - Pipette Tips

a A full range of Pipette Tips for use with manual systems is required to meet laboratory needs.

b Product Description:

For each Pipette Tip offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Sterile or non-sterile

(iii) Material of construction (e.g. polypropylene)

(iv) Length in millimetres

(v) Volume in microlitres

(vi) Filter (where applicable)

(vii) Conductive tip (where applicable)

(viii) Style (e.g. universal, Gilson)

(ix) Graduations (where applicable)

(x) Colour

(xi) Plugged (where applicable)

(xii) RNAse and/or DNAse free (where applicable)

(xiii) Pyrogen free (where applicable)

c Respondents will advise in the Tender Response Worksheet:

(i) A list of common brands and models of pipettes compatible with each Pipette Tip offered.

Category 25 - Disposable Loops and Spreaders

a A full range of sterile Disposable Loops and Spreaders are required to meet clinical needs.

b Disposable Loops will:

(i) Inoculate, and pick single colonies

(ii) Be free of lubricants, oils and electrostatic charges to facilitate streaking out cultures for single colonies and picking off colonies for transfer to other cultures, storage containers etc.

(iii) Have no rough edges

c Disposable Spreaders will:

(i) Spread small volumes of fluid across entire agar surface.

(ii) Be free of lubricants, oils and electrostatic charges to facilitate consistent wetting and complete liquid transfer

(iii) Have no rough edges

d Packets holding loops/spreaders should be re-sealable.

e **Product Description:**

For each Disposable Loop and Spreaders offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name and catalogue number

(ii) Loop or Spreader

(iii) Volume (where applicable) (e.g. 1µL, 10µL)

(iv) Material of construction (e.g. plastic, polystyrene)

(v) Colour (Different volumes should be different colours)

(vi) Number of loops/spreaders per pack.

Category 26 - Microtitre Plates

a A full range of Microtitre Plates is required to meet laboratory needs.

b Microtitre Plates will be coded for individual well identification.

c Product Description:

For each Microtitre Plate offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Well configuration:

- Number (e.g. 96 well)
- Type (V Bottom, U Bottom)
- Volume in microlitres

(iii) Material of construction (e.g. polystyrene, polypropylene)

(iv) Configuration (e.g. standard, strip)

(v) Lid (where applicable)

(vi) Detachable (where applicable).

Category 27 - Microscope Slides

a A full range of Microscope Slides is required to meet laboratory needs.

b Microscope Slides will:

(i) Be smooth, visibly clean and free from lint, grease, moisture and debris

(ii) Retain clarity for extended periods

(iii) Be supplied with a minimum of four months shelf life

(iv) Be sufficiently durable to minimise breakage and damage to edges during normal storage, transport, handling and use

(v) Be packaged in a manner that is sufficiently durable to protect the slides from contamination, moisture and damage during normal storage, transport, handling and laboratory use.

c Treated Microscope Slides used for immunohistochemistry will be adhesive to hold the tissue section in place without causing damage to the section if it needs to be moved or removed.

d Preference will be given to Microscope Slides where the gross carton weight does not exceed 10 kilograms.

e Product Description:

For each Microscope Slide offered, Respondents advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Dimensions in millimetres (length, width, thickness)

(iii) Frosted (where applicable)

- Single or double sided
- Colour
- Location

(iv) Electrical charge (where applicable)

(v) Treatment or coating (where applicable)

(vi) Corners (e.g. 90 degrees , 45 degrees)

(vii) Edge finish (e.g. ground, cut)

- Angle of ground edge (where applicable)

(viii) Number of wells (where applicable)

- Shape (where applicable)

f For each Microscope Slide offered Respondents will advise on the Tender Response Worksheet:

(i) The manner in which the microscope slides are packaged, including:

- All layers of packaging
- Total quantity of slides
- Quantity in any internal packs
- Presence of desiccants
- Whether the packaging is of a “Tropical” standard

(ii) The gross weight of cartons in kilograms

(iii) If the slides are suitable for use with automated stainers, slide writers and in immunohistochemistry.

Category 28 - Cover Slips

a A full range of Cover Slips is required to meet laboratory needs.

b Cover Slips will be:

(i) Visibly clean and free from lint, grease, moisture and debris

(ii) Sufficiently durable to minimise breakage and damage to edges during normal storage, transport, handling and use

(iii) Packaged in a manner that is sufficiently durable to protect the cover slips from contamination, moisture and damage during normal storage, transport, handling and use.

c Product Description:

For each Cover Slip offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Shape (e.g. round, rectangular)

(iii) Dimensions in millimetres (length, width, thickness)

d For each Cover Slip offered, Respondents will advise on the Tender Response Worksheet:

(i) Whether the packaging is of a “Tropical” standard

(ii) The presence of a “Use By” date.

Category 29 - Microscope Slide Mailers

a A full range of Microscope Slide Mailers is required to meet laboratory needs.

b Microscope Slide Mailers will hold each slide securely and minimise the risk of damage and breakage.

c Product Description:

For each Microscope Slide Mailer offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Dimensions of slide compartments in millimetres

(iii) Capacity (e.g. single, threes)

(iv) Material of construction (e.g. cardboard, plastic)

(v) Colour.

Category 30 - Urine Cell Counting Chambers/Haemocytometers

a A full range of plastic, single use Microscope Urine Cell Counting Chambers/ Haemocytometers is required to meet clinical needs.

b Product Description:

c For each Urine Cell Counting Chamber/Haemocytometer offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Overall volume in millilitres

(iii) Type of grid (e.g. double ruled)

- Dimensions of grid in millimetres
- Depth of grid in millimetres

(iv) Number of chambers

(v) Labelling or numbering (where applicable).

d Additional Information

(i) Successful Respondents will have information regarding the multiplication factor per litre available in hardcopy and/or electronic form available for all contract users.

Category 31 - Labels

a A full range of Labels and Ribbons are required to meet clinical needs.

b Labels will:

(i) Be blank to have patient information and barcodes printed onto them

(ii) Have a range of sizes to fit tubes and slides to be used in the laboratories

(iii) Be chemical and temperature resistant

(iv) Have permanent adhesive and be thermal coated

(v) Be long lasting and printing on labels will not fade

(vi) Be able to be written on with all conventional writing tools

c Labels will have space for the following information:

(i) Name

(ii) Patient registration number/ UR number/ Reference Number

(iii) Site

(iv) Date of birth

(v) Date and time of collection

(vi) Signature of collector (where applicable)

(vii) Barcoding

d **Product Description:**

For each Label offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand name

(ii) Dimensions in millimetres (width and length)

Category 32 - Packaging Requisites for Surface and Air Transport

a A full range of Packaging Requisites for Air and Surface Transport is required to meet clinical needs. This includes:

(i) Eskies

(ii) Cardboard boxes

(iii) Cardboard boxes with foam inserts

b All packaging materials offered will comply with the requirements of AS 4834-2007 Packaging for surface transport of biological material that may cause disease in humans, animals and plants.

c All packaging materials offered will support laboratory compliance with:

(i) NPAAC, Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)

d The eskies will be made of foam.

e Preference will be given to eskies that are:

(i) 4 litre capacity with dimensions of 270mm x 190mm x 190mm and/or

(ii) 6 litre capacity with dimensions of 260mm x 180mm x 210mm.

f The cardboard boxes will tightly package the eskies for transportation of samples.

g Cardboard boxes with foam inserts will be flat packed cardboard boxes with separate foam lining. Participating Health Services will construct the cardboard boxes with foam inserts to use for transportation of samples. The internal foam lining will completely line the cardboard box.

h It is preferred that the cardboard boxes with foam lined inserts:

(i) Are suitable for transportation of samples and dry ice

(ii) Have dimensions of approximately 275mm x 205mm x 160mm for the constructed box.

i Product Description:

For each type of packaging offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand

(ii) Shape

(iii) Dimensions in millimetres (length, width, depth/height)

(iv) Capacity in litres (where applicable)

(v) Materials of construction (e.g. foam, cardboard)

(vi) Additional features (where applicable) (e.g. vents, handles)

(vii) Compliance labelling (where applicable).

Category 33 - Bags for Specimen Transport

a A full range of Bags for Specimen Transport is required to meet clinical needs.

b Bags for Specimen Transport will:

(i) Incorporate a press seal pouch for containment of the specimen

(ii) Incorporate a separate pouch for the request slip

(iii) Minimum size of A5

(iv) Be sufficiently robust

(v) Not tear or split when in normal use

(vi) Be clearly marked with the biological hazard symbol

(vii) Be leak-proof

c The seal on the specimen pouch will be sufficiently durable to ensure that it will not spontaneously open during normal transport and use.

d Where Specimen Transport Bags are intended as the secondary receptacle for surface or air transport category A, B or C biological materials, they will comply with the requirements of AS 4834-2007 Packaging for surface transport of biological material that may cause disease in humans, animals and plants.

e Where Specimen Transport Bags are intended as the secondary receptacle for surface or air transport category A, B or C biological materials they will support laboratory compliance with:

(i) NPAAC, Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Fourth Edition 2013)

f Preference will be given to Specimen Transport Bags:

(i) Where the specimen pouch and request slip pouch are fused together across the edge of the bag to minimise the risk of a specimen or request slip being inadvertently incorrectly packed and lost in transit

(ii) That are available in a range of colours.

g Product Description:

For each Specimen Transport Bag offered, Respondents will advise the following information in the Product Description on the Tender Response Worksheet:

(i) Brand

(ii) Dimensions in millimetres (length and width)

(iii) Colour coding (where applicable)

(iv) Tear open option.

E Appendices

Appendix 1 - Product List

Category	Subcategories
01 - Blood Gas Syringes	01.01 Blood Gas Syringe, Without Needle
02 - Blood Collection Tubes	02.01 Blood Collection Tubes, Evacuated 02.02 Blood Collection Tubes, Paediatric/Neonatal
03 - Blood Collection Equipment	03.01 Blood Collection Equipment, Multisample Needles, Safety, Sterile, Single Use 03.02 Blood Collection Equipment, Multisample Needles, Non Safety, Sterile, Single Use 03.03 Blood Collection Equipment, Tube Holders, Single Use 03.04 Blood Collection Equipment, Luer Adaptors, Sterile, Single Use 03.05 Blood Collection Equipment, Winged Infusion Sets with Integral Luer Adaptor, Safety, Sterile, Single Use 03.06 Blood Collection Equipment, Tourniquets, Single Patient Use 03.07 Blood Collection Equipment, Tourniquets, Reusable 03.08 Blood Collection Equipment, Other
04 - Blood Collection Lancets	04.01 Lancets, Retractable
05 - Capillary Tubes	05.01 Capillary Tubes, with Anticoagulant, Plastic 05.02 Capillary Tubes, without Anticoagulant, Plastic 05.03 Capillary Tubes, with End Caps
06 - Culture Swabs	06.01 Culture Swabs, Plain 06.02 Culture Swabs, with Transport Media
07 - Genetic Testing Swabs	07.01 Genetic Testing Swabs
08 - Specimen Collection Containers (Non Blood)	08.01 Specimen Collection Containers (Non Blood), Sterile 08.02 Specimen Collection Containers (Non Blood), Non Sterile 08.03 Tubes for Cerebrospinal Fluid (CSF) Collection 08.04 Specimen Collection Containers for 24 Hour Urine Collection 08.05 Specimen Collection Containers for Timed Faecal Collection 08.06 Specimen Collection Containers for Histology Specimens

Category	Subcategories
09 - Bone Marrow Biopsy and Aspiration Needles	09.01 Bone Marrow Biopsy Needles 09.02 Bone Marrow Aspiration Needles 09.03 Bone Marrow Needles, for Biopsy/Aspiration
10 - Urine Test Strips	10.01 Urine Test Strips
11 - Liquid Based Cytology Collection Kits for Human Papillomavirus	11.01 Liquid Based Cytology Collection Kits for Human Papillomavirus
12 - Prefilled Specimen Containers for Histology	12.01 Specimen Containers Prefilled with 10% Tinted Formalin
13 - Laboratory Chemicals	13.01 Laboratory Chemicals, Formalin 13.02 Laboratory Chemicals, Xylene 13.03 Laboratory Chemicals, Ethanol 13.04 Laboratory Chemicals, Isopropanol 13.05 Laboratory Chemicals, Methanol 13.06 Laboratory Chemicals, Acetone 13.07 Laboratory Chemicals, Decalcifying Agents 13.08 Schiff's Reagent 13.09 Laboratory Chemicals, Pump Dispensers
14 - Embedding Cassettes	14.01 Tissue Embedding Cassettes, with Lid 14.02 Tissue Embedding Cassettes, without Lid
15 - Foam Biopsy Pads	15.01 Foam Biopsy Pads, Tissue
16 - Embedding Media	16.01 Embedding Media
17 - Microtome Blades	17.01 Microtome Blades
18 - Trimming Blades	18.01 Trimming Blades 18.02 Trimming Blade Handles
19 Tissue Marking Dye	19.01 Tissue Marking Dye

Category	Subcategories
20 - Cytology Consumables	20.01 Cytology Cards 20.02 Disposable Funnels with Cards
21 - Tubes for Internal Laboratory Use	21.01 Tubes for Internal Laboratory Use, Aliquot Tubes 21.02 Tubes for Internal Laboratory Use, Test Tubes 21.03 Tubes for Internal Laboratory Use, Centrifuge Tubes 21.04 Tubes for Internal Laboratory Use, Microcentrifuge Tubes 21.05 Tubes for Internal Laboratory Use, Cryopreservation Tubes 21.06 Tubes for Internal Laboratory Use, Additional Caps
22 - Petri Dishes	22.01 Petri Dish, Full Plate, with Stacking Ring 22.02 Petri Dish, Full Plate, without Stacking Ring 22.03 Petri Dish, Half Plate, without Stacking Ring
23 - Transfer Pipettes	23.01 Transfer Pipettes, Sterile, with Graduations 23.02 Transfer Pipettes, Sterile, without Graduations 23.03 Transfer Pipettes, Non Sterile, with Graduations 23.04 Transfer Pipettes, Non Sterile, without Graduations
24 - Pipette Tips	24.01 Manual Pipette Tips, Unplugged, Non Sterile 24.02 Manual Pipette Tips, Unplugged, Sterile 24.03 Manual Pipette Tips, Plugged, Non Sterile 24.04 Manual Pipette Tips, Plugged, Sterile
25 - Disposable Loops and Spreaders	25.01 Disposable Loops 25.02 Disposable Spreaders
26 - Microtitre Plates	26.01 Microtitre Plates, Standard
27 - Microscope Slides	27.01 Microscope Slide, Frosted, without Wells 27.02 Microscope Slide, Frosted, with Wells 27.03 Microscope Slide, Treated, without Wells
28 - Cover Slips	28.01 Cover Slips
29 - Microscope Slide Mailers	29.01 Microscope Slide Mailer, Single Slides 29.02 Microscope Slide Mailer, Multi Slides

Category	Subcategories
30 - Urine Cell Counting Chambers / Haemocytometers	30.01 Urine Cell Counting Chambers/Haemocytometers
31 - Labels	31.01 Labels 31.02 Ribbons
32 - Packaging Requisites for Surface and Air Transport	32.01 Esky 32.02 Cardboard Boxes 32.03 Cardboard Boxes with Foam Lined Insert 32.04 Other Packaging Requisites for Surface and Air Transport
33 - Bags for Specimen Transport	33.01 Specimen Bags for Transport

Appendix 2 - References

A 2.a Standards

The references to the below standards include any amendments, revisions or consolidations to those standards.

Standard Number	Standard Name
AS/NZS 4187:2014	Reprocessing of reusable medical devices in health service organisations.
ISO 15189:2012	Medical laboratories – Requirements for quality and competence
ISO 6710: 1995	Single Use Containers for Venous Blood Specimen Collection
GP39-A6	Tubes and Additives for Venous Blood Specimen Collection, Approved Standard, Sixth Edition
AS/NZS 2243.3: 2010	Safety in laboratories - Microbiological safety and containment
ISO 7713: 1985	Laboratory Glassware – Disposable Serological Pipettes
ISO 12772: 1997	Laboratory Glassware – Disposable Microhaematocrit Capillary Tubes
GP42-A6	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens, Sixth Edition
ISO 15190: 2003	Medical Laboratories – Requirements for Safety
ISO 12771: 1997	Plastics Laboratory Ware – Disposable Serological Pipettes
Auto02-A2	Laboratory Automation: Bar Codes for Specimen Container Identification, Second Edition
Auto12-A	Specimen Labels: Content and Location, Fonts and Label Orientation, First Edition
AS 4834-2007	Packaging for surface transport of biological material that may cause disease in humans, animals and plants

A 2.b Guidelines and Other References

The references to the below guidelines include any amendments, revisions or consolidations to those guidelines.

- NHMRC (2010), *Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia*
- Therapeutic Goods Administration (1991), *Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods*
- Therapeutic Goods Administration (2004*), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia*
- *Therapeutic Goods Regulations (Medical Devices) 2002, amended 1 July 2016*
- *MM13-A: 2005, Collection, Transport, Preparation and Storage of Specimens for Molecular Methods, Approved Guidelines*
- *M40-A2: 2014, Quality Control of Microbiological Transport Systems, Second Edition*
- *M29-A4: 2014, Protection of Laboratory Workers from Occupationally Acquired Infections, Forth Edition*
- *GP34-A: 2010, Validation and Verification of Tubes for Venous and Capillary Blood Specimen collection, Approved Guideline*
- *GP33-A: 2010, Accuracy in Patient and Sample Identification, First Edition*
- NPAAC standards and technical publications for pathology services
- NPAAC, *Guidelines for Point of Care Testing (First Edition 2015)*
- NPAAC, *The Provision of Direct to Consumer Genetic Tests, Guiding Principles for Providers (Second Edition, 2014)*
- NPAAC, *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials (Forth Edition 2013)*
- *Code of Practice for the Storage and Handling of Dangerous Goods, 2013*