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Summary of Feedback and Outcomes

from the

Industry Engagement Process

for

Laboratory Biochemistry Analysis of Blood (whole blood, serum and plasma) and Urine

Solicitation No. 45045-140012/B

www.pwgsc-tpsgc.gc.ca

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1. Introduction

On 19 March, 2015, Public Works and Government Services Canada (PWGSC) published a Letter of Interest (LOI) on the Government Electronic Tendering Service (GETS) seeking to engage with the Industry on behalf of Statistics Canada. As part of that engagement, Participants were asked to provide a written response to questions related to both the technical aspects of the Work to be undertaken and the procurement strategy. A draft Request for Proposal (RFP) was provided, which included the Statement of Work, Evaluation Criteria and the Basis of Selection.

The purpose of the Industry Engagement was twofold:

a) to seek information from industry on its interest, capacity and ability to perform the laboratory biochemistry analysis of blood (whole blood, serum and plasma) and urine for Statistics Canada's requirement; and,
b) to provide industry the opportunity to give feedback on the procurement strategy.

Participants were encouraged to ask questions and provide comments with the objective to receive feedback that may be incorporated into the solicitation document, creating a procurement that is fair and transparent to suppliers, enhances competition, and results in best value to Canada.

The publication of this document and any resulting RFP effectively concludes the Industry Engagement process. The information gathered through this process was considered when finalizing the procurement strategy and should meet the needs of the Government of Canada and be compatible with Industry standard practices.

2. Requirement

Statistics Canada has a requirement for Medical/Dental Laboratory Services in support of the Canadian Health Measures Survey (CHMS).

Statistics Canada requires the services of one Contractor to perform Sample Biochemistry Analysis and Storage Services for the CHMS cycle 5 and the CHMS cycle 6.

2.1 Analytes/Measures

Canada no longer has a need for the Category 2 and 3 (Urine) Analytes/Measures and some Category 1a (Blood) Analytes/Measures. Therefore, Canada intends to remove all Category 2 and 3 (Urine) Analytes /Measures from any potential resulting RFP. Canada also intends to remove several Category 1a (Blood) Analytes /Measures from Table 2, Task Authorized Sample Biochemistry Analysis of Appendix 1 to Annex A; including, Red blood cell folate, Folate, Thyroid Status Profile, Thyroid-stimulating Hormone and Free Thyroxine.

Additioanlly, all requirements related to these Analytes/Measures would also be removed from any potential resulting RFP.

3. Industry Engagement Process

Industry Engagement Period	• Posting of Letter of Interest (LOI): 19 March 2015 • Responses to LOI requested: 26 March 2015 • Publication of the Request for Proposal: June 2015 (estimated).
Participants	Three organizations provided responses to the LOI: ➢ Bio-Test Laboratory Inc. ➢ Gamma-Dynacare Medical Laboratories ➢ LifeLabs Medical Laboratory Services Two organizations participated in one-on-one Meetings: ➢ Bio-Test Laboratory Inc. ➢ Gamma-Dynacare Medical Laboratories.

4. General Overview of the Industry Engagement Process Feedback

The consultative process provided Participants with an opportunity to participate in the procurement process by providing comments, questions and recommendations for improvement of the draft RFP, as well as seeking clarification on technical issues.

Overall, Participants indicated that the draft RFP was fair, and there was consistency in the comments regarding the Statement of Work, evaluation criteria and basis of selection. As a result Canada has adjusted some specific requirements as necessary to address technical questions, and some changes have been made to the draft RFP to address key issues.

This document details the feedback received during the Industry Engagement Process and the outcomes on the draft RFP.

5. Summary of Feedback and Outcomes

The following represent questions posed in the Letter of Interest and the resulting responses from Industry provided in written format and in one-on-one meetings. Administrative questions have been removed.

SECTION 1 – Administrative	
SECTION 2 - Statement of Work (SOW)	
2.1	***Please provide a statement regarding your capability to meet the requirements.***
Outcome	Three (3) suppliers identified they were capable of performing the Work.
2.2	***Are any aspects of the Statement of Work unclear?***
Respondents	**1.** Could you please clarify the following: a) Will Canada provide all pre-paid shipping waybills for the return shipping boxes, data loggers, specimens, reports if applicable? b) If there is no residual volume after testing, disposal protocol is unclear. c) Will we be requested to store empty containers? d) Can the matrix be combined to meet testing requirements if volume of 1 tube is insufficient? For our larger instruments 0.3ml is the dead volume. e) Could you please provide the size and type of tubes to be received for instrument/ specimen workflow? With respect to the tubes, the minimum tube size that you do not have to aliquot again is 12x75mm. Format of barcode will be required, when awarded, for scanner compatibility. **2.** It is unclear why the samples will arrive without a requisition, gender and date of birth.
Outcome	With respect to the clarifications requested, Canada offers the following information: **1.** a) Shipping of boxes, data loggers and specimens will be paid for by Canada. The Contractor must use the courier account information to be provided by Canada after Contract award for the return of shipping boxes and ice packs, as well as, specimens “as and when” shipment to the CHMS Biobank is requested. Pre-paid return envelopes will be provided for data loggers as detailed in Appendix 3 to Annex A, Shipping Instructions. Additionally, all reports are to be delivered in electronic format as detailed in article 11.0, Technical Environment of Annex A. b/c) As Canada intends to provide the Optimal Sample Volume (intended for the initial analysis and a repeat) in most cases, Canada anticipates that there should always be a residual volume leftover from the sample biochemistry analysis that will need to be stored immediately after analysis. In instances where there is 0.3ml or less leftover in the tube, Canada is considering allowing that the residual sample be stored in the tube until one rack is completed with tubes containing less than 0.3ml leftover at which time Canada may allow the entire rack to be destroyed in accordance with the procedures outlined in Appendix 2 to Annex A, CHMS Sample Destruction Instructions and Form. d) Yes, the matrix can be combined up to a volume of 1.8ml when the sample size is the same but the combinations need to be provided with the proposal, as detailed in article 6.2 Sample Biochemistry Analysis of Annex A. Additionally, Measures in Appendix 1 to Annex A, Table 1, Sample Biochemistry Analysis Parameters (Category 1), are the Statistics Canada Analytes and

	cannot be combined with Measures in Table 2, Task Authorized Sample Biochemistry Analysis Parameters (Category 1a) which are client based Analytes and may be subject to change, unless expressly stated otherwise in any potential RFP. If Analytes/Measures are not from the same sample size the Contractor can use the residual volume from any other tube they have received in the same matrix with the same first 8 digits in the barcode label (which correspond to the respondent). e) Canada will provide the tube catalogue information in any potential resulting RFP. Canada intends to utilize 2.0ml Wheaton cryoElite vials for Category 1 and1a. Furthermore, Canada intends to utilize linear barcodes (code 128) rather than 2D. **2.** Canada will not send samples with a requisition as the analyses are not diagnostic, no physician will be ordering the testing and interpretation is not required by the laboratory. Additionally, only one identifier will be provided to comply with the *Statistics Act*. Canada is able to provide a waiver for laboratory's accreditation requirements if required.
2.3	***Even though the analyses requested are not for diagnostic or treatment purposes, is it clear in the draft Statement of Work that all samples shipped to the accredited laboratory need to be analyzed as no other samples can be obtained from the respondent and, furthermore, the results must be valid?***
Respondents	**1.** It is clear that no other sample can be obtained from the respondent and results must be valid. However, it must be noted, that there needs to be consideration for problems which are beyond the control of the laboratory (i.e. transportation and packaging issues). **a)** Has Canada procured these services in the past? And if so, were there any human errors or leakages during/due to transportation? **b)** If there is insufficient volume to perform the analysis due to damage or leakage what is the protocol?
Outcome	In the past, Canada has performed sample biochemistry analysis services for the CHMS Cycles 1 through 4. There have been shipping delays; however, the Statement of Work includes a series of checks and balances to ensure each shipment is received in good condition. Canada intends to send Category 1 and 1a shipments with numeric tie locks on the boxes, when possible. Canada has never experienced leakage in these shipments in the past. In the event that there is insufficient volume due to leakage etc., the Contractor must notify Canada in accordance with Appendix 3 to Annex A, Shipping Instructions. Canada intends to provide approximately 13 "No Result Codes" to the Contractor which are to be used for these reporting purposes.

2.4	***It is Canada's intent to award a Contract to one (1) Contractor with a maximum of two (2) laboratories that would perform the services required for Category 1 Samples. Please comment on the feasibility and suitability of this approach.***
Respondents	**1. a)** In order to benefit from the best price possible, we feel it is most appropriate and feasible to award a contract to one contractor with one laboratory. By having more than one laboratory, other variables are introduced to the service, which could negatively affect standardization of results. For example, as analysis equipment is different at each laboratory, though the prescribed range can be achieved, there will be varying degrees of precision and sensitivity between the results. This would further impact the proficiency testing. **b)** Alternately, would Bidders be able to bid on specific tests only rather than the whole lot?
Outcome	Canada intends to retain the requirement to award a Contract to one (1) Contractor with a maximum of two (2) laboratories that would perform the services required for Category 1 Samples. With respect to the responses provided, Canada offers the following clarifications: **1. a)** As detailed in Part 4, article 1.1.3, Item MR-1 of the draft RFP, Canada intends to accept a maximum of two Laboratories for Category 1 and 1a. Canada intends to remove all Category 2 and 3 sample analysis from any potential resulting RFP. To clarify further, as instruments and sample biochemistry analysis methods, including combinations, must remain consistent until the end of the Contract, the proposed laboratory/ies for each analyte/measure must perform the analysis for those tests/Measures until the end of the Contract. **b)** As detailed in Part 4, article 1.1.3, Item MR-1 of the draft RFP, the Bidder must be capable of performing biochemistry analysis for all analytes identified under Category 1 of Appendix 1 to Annex A. Canada intends to remove all Category 2 and 3 sample analysis from any potential resulting RFP, thus these requirements would be removed from MR-1. Additionally, all analytes/measures identified under Category 1a will be optional to the Contract and thus will be included as Point Rated Technical Evaluation Criteria. It is not Canada's intention to award multiple Contracts to multiple Contractors for specific tests. Furthermore, Canada intends to revise the Basis of Selection.

2.5	***Statistics Canada is considering limiting the number of laboratories that would perform the services required for both Category 2 and Category 3 Samples to one (1). Please comment on the feasibility and suitability of this approach.***
Respondents	**1.** Iodine testing will be analyzed at 1 laboratory due to the technical requirements for the test. The urine electrolytes can also be tested there. Urine electrolytes (sodium and potassium) analysis would commonly be performed in a main laboratory as these are routine tests that a full service medical laboratory would perform in high volumes in a single laboratory. Iodine testing is less frequently ordered, and certain medical laboratories would perform this testing at a different laboratory facility specializing in lower volume tests. In these cases, it would be easier to perform iodine analysis in a different laboratory than the urine electrolytes. The logistics for allowing 2 laboratory facilities with category 2 specimens would be relatively simple as different tubes are to be collected for urine electrolyte and iodine analysis. For category 3 specimens either a separate tube for iodine could be collected (as in category 2) or the specimen could be split upon arrival at the laboratory. It is proposed that Iodine testing be performed at another laboratory, which is not a laboratory, rather it would be a referral laboratory to satisfy the requirement and send all three tests for Category 2 and 3 to that laboratory. Currently the volume requirements for iodine are very low so the referral laboratory does this testing and participates in proficiency testing but they do not have 10 comparable participants. **2.** We can perform the services for Category 2 and Category 3 in one laboratory. We would like to make the recommendation that samples continue to be sent to both of our proposed laboratories as this will eliminate the possibility of compromising the specimen. **3.** In order to benefit from the best price possible, the respondent feels it is most appropriate and feasible to award a contract to one laboratory.
Outcome	Canada intends to remove all Category 2 and 3 (Urine) Analytes/Measures from any potential resulting RFP. Thus, all requirements related to these categories would also be removed from any potential resulting RFP.

2.6	***As described in the draft Statement of Work, samples will only be sent with an anonymous barcode label composed of 8 numbers (clinic ID + 3 numbers identifying the test). No requisition or other information to validate the results (for example; age and gender) will be shared with the accredited laboratory along with the samples. Please comment on any challenges your company/accredited laboratory might need to overcome in order to perform the Work as described?***
Respondents	**1.** We are able to provide results with only one identifier with appropriate waiver. However, according to regulatory requirements, 2 identifiers are required on all specimens to ensure accurate identification of specimens with data entry process. In addition, reference intervals are dependent on gender and year of birth. **a)** Could you please clarify how critical results are responded to? **b)** Could you provide a private client number? For example, is it possible to add to an additional form or notation to indicate the client number? **2.** We are capable of processing the samples as outlined in the Statement of Work. We would like to make the recommendation that all samples are sent with a requisition as well as date of birth and gender. An accompanying requisition is strongly recommended as it is used to reduce misidentification of the specimen. Recording date of birth and gender will allow for accurate reporting on reference ranges. If a date of birth or gender is not supplied the system will publish all of the ranges as a comment; reports can become rather lengthy and abnormal results are unlikely to flag as such. For the proposed Work it is recommended that the clinic ID is reported along with the participant's date of birth. **3.** A change in workflow will occur, due to the method of tube identification and lack of paperwork being provided to the laboratory. This requirement can be satisfied; however, some form of electronic communication will be required by the laboratory for each shipment being sent to the laboratory. This is required for authenticating number of samples received. For example, if 10 samples are shipped but the laboratory claims only 7 are received, without a proper chain of custody form, there is a possibility of an operational problem.

Outcome	Canada does not intend to send a requisition with the sample shipment. With respect to the clarifications requested, Canada offers the following information: **1**. Please see Question 2.2, Outcome 2. **a)** Canada has a set of predetermined measures or reference intervals that are considered critical and reportable to the respondent. These ranges will be provided to the laboratory at contract award. If a result falls within these reportable ranges, Canada will request that the laboratory complete a secondary/confirmatory test. The Contractor must then send an e-mail to the Technical Authority confirming that these results were repeated and confirmed. Statistics Canada will then determine and carry out the next steps to inform the respondent if necessary. **b)** Canada intends to send a waybill with each shipment providing shipment details. Canada will also send the Mobile Examination Centre (MEC) shipment schedule to the laboratory in accordance with Appendix 3 to Annex A, Shipping Instructions. The Contractor may provide comment on the schedule within three business days following the receipt of the schedule. The shipping schedule can be adjusted if needed and approved by the Technical Authority. **2.** Please see Question 2.2, Outcome 2. **3.** The Contractor is responsible for the condition of the samples while they are in the possession of their laboratory/ies. As detailed above, Canada will send a waybill with the shipment detailing the tubes shipped. As detailed in Appendix 3 to Annex A, Shipping Instructions, the Contractor will be required to send an acknowledgement to Canada upon shipment receipt identifying whether there are any issues with the shipment. The Contractor is also required to send a reconciliation file of the samples received including an Excel or Comma Separated Values (CSV) log of the scan of the individual sample labels/barcodes.

2.7	***Would it be possible for your accredited laboratory to ship (transportation of dangerous goods) some samples (according to Appendix 3 Annex A Statement of Work) to the CHMS biobank at the end of the collection period, which is December 2018 for cycle 5, until the end of the contract, which is January 31, 2019 for cycle 5. Please comment on the feasibility and suitability of this approach.***
Respondents	**1.** Yes, it is possible for our accredited laboratory to ship some samples to the CHMS biobank at the end of the collection period. **a)** For the purposes of our response and calculation of costs, could you please estimate the potential number of specimens and potential number of shipments required? **b)** How many requests will there be? How does this process Work. We understand there are 60 hours allotted for this Work. Will there be one single disposal request or will disposal be requested by batch? **2.** We can ship samples to the CHMS biobank at the end of the collection period. However, given the volumes of samples, we feel it would be more appropriate to do so every month.
Outcome	Canada intends to retain the requirement for the accredited laboratory to ship (transportation of dangerous goods) some samples (according to Appendix 3 Annex A Statement of Work) to the CHMS biobank at the end of the collection, analysis and storage period. With respect to the clarifications requested, Canada offers the following information: **1. a)** The sample size per measure/tube is shown in Appendix 1 to Appendix A. In addition the estimated number of tubes to be stored, shipped or destroyed is provided in the Additional Storage of Samples Firm Monthly Rate Table of the Financial Bid Presentation Sheet. With respect to the shipments, Canada intends to elaborate further in any potential resulting RFP on number of boxes etc. **b)** The Technical Authority will issue a Task Authorization at the end of the Cycle, or additional storage of samples period, requesting that the laboratory either destroy or ship the samples to the CHMS Biobank.The 60 hours are provided as an estimate and as a basis of evaluation for this Work, but potentially more or less hours could be required. Additionally, all rack and tube barcodes must be scanned prior to being shipped. Typically, one request will be sent to either send the leftover samples to the CHMS Biobank or dispose of samples at the end of the Cycle. During the collection and analysis period, Canada intends to limit the number of requests to a maximum of 5 to destroy full racks or trays containing samples with 0.3ml or less in each tube. **2.** Each CHMS Cycle covers three years, the first two years are for collection, analysis and storage with the third year for storage only. At the end of the third year, or the additional storage of sample period, it is intended to request a one time disposal or shipment of samples through a Task Authorization.

2.8	***Are the timelines to return the results adequate for all Analytes/Measures, including, iodine?***
Respondents	No concerns were presented.
Outcome	Canada intends to retain the Turnaround Times provided in Appendix 1 to Annex A of the draft RFP.
2.9	***Available blood and urine volumes are limited for this survey.*** ***A. Are you able to analyze for all Analytes or groups of Analytes with the volumes (minimal and optimal) available per matrix identified in Annex A?*** ***B. What additional Analyte grouping(s) would you recommend?*** ***C. Should the volume and additional Analyte grouping(s) be imposed?***
Respondents	**1. A.** Yes, but we would need to "regroup some testing in the same tube when it is the same sample size and matrix…" as stated on page 54 of the RFP document. **B.** Our instrumentation is set up to perform multiple analyses on a single sample using modular pre-analytics. As such we could perform analysis for each of: 1. Fasting / Non-fasting Lipids 2. Chemistry panel 3. Thyroid status 4. Ferritin 5. B12 6. Apolipoproteins 7. Insulin 8. Folate serum ...on a minimum sample of 1.2ml of blood, obtained by combining the serum samples from the multiple tubes aligned with these analyses as indicated in Appendix 1 to Annex A. High Sensitivity C-Reactive Protein requires a dedicated aliquot of 1 ml serum and cannot be combined with other tests. However, the instrument can take as low as 0.8ml (including a repetition). The minimum collected volumes of serum should allow us to meet this volume requirement. If we combine the Non-fasting Lipids with chemistry panel, can we use the residual volume of 0.7ml intended for Non-fasting Lipids for the High Sensitivity C-Reactive protein. We can perform PTH and Homocysteine analysis on a single plasma sample of 0.8ml. This sample requirement is in line with the minimum volume provided for the two separate tubes dedicated to the collection of plasma for theses analyses. **2. C.** We would recommend that additional volume is collected on the samples. **3. A.** Blood/urine volumes and Analyte groupings are not adequate. We are not able to analyze for all Analytes or groups of Analytes with the volumes available per matrix identified in Annex A, as we are not currently licensed to do all the testing. Though in our view, it is an administrative exercise to apply for licensing. Furthermore, we cannot provide proficiency testing results for all Measures. That said, all tests are fairly readily available and we are not concerned with our technical ability to meet the requirements.

	B. We would recommend grouping all Lipid testing and High Sensitivity C-Reactive Protein with chemistry tests. Ferritin, Vitamin B12, TSH, Free Thyroxine and serum folate can be grouped together. Furthermore, the use of Redtop tubes is fine, however serum will need to be transferred to another tube for analyzer handling. **C.** We would like to see an imposed minimum of 1ml for each Analyte grouping. Additionally could you please clarify whether the Optimal Sample Volume will always be available?
Outcome	Canada intends to impose the following additional Category 1a Analyte grouping; Ferritin and Vitamin B12. Canada also intends to include additional Analytes under Table 2, Task Authorized Sample Biochemistry Analysis (Category 1a) as an optional service. With respect to the clarifications requested, Canada offers the following information: **1. A.** Wherever possible, Canada intends to send the Optimal Sample Volume to the Laboratory for analysis. The Optimal Sample Volume is intended for the initial analysis and a repeat if required. As stated in the Statement of Work, the laboratory may regroup some testing when it is the same sample size and matrix. To facilitate possible grouping, Canada intends to indicate which tests can be combined in any potential RFP. The chosen combinations will need to be stated with the proposal and be done within the allowable matrix volume, as detailed in article 6.2, Sample Biochemistry Analysis of Annex A. If the minimal volume is provided or in other occasional situations, the Contractor can use the residual volume from any other tube in the same matrix they have received with the same first 8 digits (which are specific to the respondent) in the barcode label. **B.** Specifically, Ferritin and Vitamin B12 are to be combined as they will be imposed as an additional Analyte grouping under Category 1a task authorized sample biochemistry. Canada intends to remove Thyroid and Folate Serum from any potential resulting RFP. Fasting Lipids, Apolipoproteins and Insulin cannot be combined with the other Analytes/Measures listed as they do not have the same sample size. However, Fasting Lipids and Insulin can be combined with each other as they do have the same sample size. Non-fasting Lipids/chemistry panel can be combined. For High Sensitivity C- Reactive Protein only 0.5ml with up to 0.6ml (10% extra as per Appendix 5 to Annex A) will be provided. However, Canada intends to allow the reassignment of leftover volumes from one Analyte grouping to another if the grouping is in the same matrix. For PTH and Homocysteine only 0.5ml will be provided (each). These cannot be combined as they are not from the same table. **2. C.** There are hundreds of analyses that are performed on blood and urine samples collected during a respondent/participant's unique visit to the CHMS Mobile Examination Centre (MEC). Statistics Canada requires the services of one Contractor to perform a portion of these analyses. For that reason, we are limited in sample volume available for children aged 3-11 years and therefore cannot send or collect additional volume according to the Research Ethic Board (REB).

	3. A. As the Contract will not be awarded for specific tests only, but rather for all tests, the Contractor must participate in proficiency testing for all required Category 1 (Blood) Analytes/Measures provided in Table 1, Core Sample Biochemistry Analysis Parameters, of Appendix 1 to Annex A. **B.** As noted above, Ferritin and Vitamin B12 are to be combined as they will be imposed as an additional Analyte grouping under Category 1a Task Authorized Sample Biochemistry Analysis. Canada intends to remove TSH, Free Thyroxine and Serum Folate from any potential resulting RFP. Non-fasting Lipids, High sensitivity C-Reactive Protein and chemistry panel could be combined as they have the same sample size and are all from Table 1, Sample Biochemistry Analysis Parameters of Appendix 1 to Annex A. Additionally, Canada will be providing aliquotted serum samples from Red Top Tubes into 2.0ml cyrovials for Category 1 and 1a samples which will be provided to the laboratory. Canada will provide the tube catalogue information in any potential resulting RFP. Canada intends to utilize 2.0ml Wheaton cryoElite vials for Category 1 and1a. **C.** Please see Outcome 2(c) above. As volumes are very limited for this study, we cannot impose a minimum by sample. The Optimal Sample Volume should be available for approximately 90 percent of the samples.
2.10	***Is the storage of the leftover samples at the same location where the sample is analyzed up to July 31, 2019 for cycle 5 and July 31, 2021 for cycle 6 a difficult requirement to meet?***
Respondents	**1.** Given the volume of samples, storage of leftover samples are difficult to satisfy. We would suggest a return of leftover samples on a monthly basis. Additionally, could you please clarify the purpose of storing the samples as there could be an issue with sample integrity as some tests are less sensitive on samples stored over time.
Outcome	Canada intends to retain the requirement for storage of the leftover samples at the same location where the sample is analyzed up to July 31, 2019 for cycle 5 and July 31, 2021 for cycle 6. With respect to the clarifications requested, Canada offers the following information: **1.** Canada requires the residual volumes to be stored in the event that there is a need to re-run analysis or if there is a problem with the results. Additionally, Canada may chose to conduct more analyses later. Canada understands that the integrity of samples will reduce over time but we still require the samples to be stored as detailed in the draft RFP.

2.11	***Can all data from your analysis instruments be directly transferred in an Excel format? Is there a reason that you would need to manually enter data from sample reception to destruction? For example, is it possible to scan the identifier? Would you need to change tubes to perform the analyses or send the results?***
Respondents	**1.** All data from analysis instruments is stored within our Laboratory Information Management System (LIMS) and this data can be exported, formatted and encrypted according to requested Excel file requirements from a single computer. Residual Specimen storage may require some manual data entry if all tubes (~16/individual) are required to be stored until requested destruction procedure is directed. However the manual data entry is limited to manually moving specimens into a freezer. The freezers use a separate LIMS to scan the samples. **2.** Results can be reported in an Excel format or via electronic reporting. We are able to supply the tubes for collection, however, if Canada requires other tubes to be used then we will be able to accommodate. ***3.*** Data from analysis instruments may need to be transferred to our LIMS, which then has the capability to transfer in Excel format. In order to do this, we would need to enter manually data into the LIMS. At the same time, we have communicated with our instrument vendors and they feel confident that they will be able to customize their software, allowing data to be extracted directly from the analyzers. We may need to change some tubes, depending on the volume received, in order to perform the analyses. With respect to specifically what data entry is required, we are looking into it and cannot provide an answer at this time. Conceptually it has been discussed and the analyzers can store raw data, it is a matter of extracting it. Could you please clarify whether CSV files would be acceptable rather than Excel?
Outcome	Canada intends to retain the requirement that all data from the analysis instruments be directly transferred to Canada in an Excel format. With respect to the clarifications requested, Canada offers the following information: **2.** For Category 1 & 1a, Canada will supply the tubes. Canada intends to provide the tube catalogue information in any potential resulting RFP. The Contractor must not change the Tubes from those provided for Category 1 and 1a samples. Canada intends to remove all Category 2 and 3 (Urine Measures) Analytes from any potential resulting RFP. Thus, all requirements related to these categories would also be removed from any potential resulting RFP. **3.** Canada will accommodate CSV or Excel file formats.

2.12	***Statistics Canada might add or perform solely the folate analysis in the serum.*** ***A. Could your accredited laboratory perform this analysis and if so, within what minimal precision and analytical range?*** ***B. Could you please provide an estimated minimal and optimal volume necessary to perform the serum folate analysis? Please consider that the volumes of blood available are very limited as identified in Annex A.*** ***C. Would you combine it with another test (full sample size-6020)? In the positive, which one?***
Respondents	**1.** **A.** Folate analysis in serum can be performed in our laboratory. The minimum volume for a single test is 0.5ml. Precision for specimens containing: □ <5 nmol/L is 0.5 nmol/L □ 5 nmol/L or greater is 10% **B.** Serum folate could be conducted in the same 1.2ml sample on which the following tests are conducted: □ Fasting / Non-fasting Lipids □ Chemistry panel □ Thyroid status □ Ferritin □ B12 □ Apolopoproteins □ Insulin **2.** **A.** We can perform the analysis with a recommended range of 0.4 ml. **B.** Yes, as the minimal volume is 0.4 ml. **C.** We can perform 5-10 tests on one 5.0ml SST tube. **3.** We could perform the serum folate testing based on the volumes provided in annex a. we would combine it with b12/ferritin/TSH. we are waiting to hear back from our vendors on minimal precision and analytical range.
Outcome	Canada intends to remove Serum Folate from any potential resulting RFP.
2.13	***The volume of whole blood for Red Blood Cell (RBC) folate indicated in Appendix 1 Annex A is very small.*** ***A. Do you have enough volume to provide a result? If not, do you understand that you do not need to test for the hematocrit to derive the RBC folate as it would be derived after you send to the Technical Authority the pre-folate results?*** ***B. If you do not need to test for the hematocrit, is the volume planned to be provided adequate?***
Respondents	**1.** We collect 4.0ml when testing RBC. The RBC folate would require 3.0ml to provide a result. The volume is less than what we usually require.
Outcome	Canada intends to remove RBC Folate from any potential resulting RFP.

2.14	***Can all analyses be performed in the tubes as received or would the specimens need to be transferred into another type of container?***
Respondents	**1.** Analyses could be performed in tubes as received but will be dependent on tube size. The minimum tube size that can be utilized for direct application to the instruments is 12x75mm. As stated above, urine specimens for iodine testing and electrolyte (sodium and potassium) testing could be received in separate tubes, to enable faster resulting for the electrolytes and more focused analysis of the esoteric iodine test. If the single laboratory requirement for category 2 and 3 specimens remains, we expect to be able to comply without transferring specimens to a separate container. **2.** We can supply collection tubes. Otherwise, we would need to know the brand of the tubes being utilized to assess if the sample could be tested in the tubes provided or if the sample would need to be transferred into another container. **3.** Some Analytes would require the specimen to be transferred to another type of container for testing
Outcome	Please see Question 2.11, Outcome 2 for additional details regarding the tubes.

SECTION 3: Evaluation Criteria and Basis of Selection	
3.1	***Is it clear how Canada proposes to evaluate the bids?***
Respondents	**1.** The response criteria are clear although weighting factors for each section would be helpful. For example, how will the Security requirements be weighted against the rest of the Proposal? More specifically, the IT Security Requirements are not easy to comply with.
Outcome	Each of the proposed accredited laboratories must obtain the required level of Security detailed in the RFP prior to the award of a Contract. The projected start date is detailed in the draft RFP as October 15, 2015. However, Canada intends to revise this date to October 1, 2015. Regarding the IT Security Requirements, IT inspections are contract specific, and are therefore performed following contract award. However the Contractor will not be permitted to electronically process and/or transmit Protected “A” or “B” information. If you do not have the required level of security you can submit a request to the Contracting Authority to be sponsored for this process. **It is important to start this process now as it is a lengthy process.** That said, the Security Requirements are a condition of Contract Award.

3.2	***Does the Basis of Selection seem fair and reasonable?***
Respondents	No concerns were presented.
Outcome	Canada intends to revise the Basis of Selection included in the draft RFP from Lowest Evaluated Price to Highest Combined Rating of Technical Merit and Price to accomodate the inclusion of Point Rated Technical Evaluation Criteria.
3.3	***Provide any suggestions that, in your opinion, could improve the evaluation and contractor selection methodology and criteria.*** ***A. Please provide feedback on the mandatory criteria that are described in the draft Request for Proposal. In your opinion, is each of the criteria appropriate given the work described? Would any of these criteria not be attainable for your company? Specifically,*** ***i. Could you provide feedback regarding the elements and the feasibility to return the information in the format of the Condensed Standard Operating Procedure (SOP) (according to Appendix 4 Annex A).*** ***1. Are there elements that need more explanation?*** ***2. Do you already have the information in another format that you would prefer to submit?*** ***3. Would there be difficulties to achieve minimal requirements for the analytical range and precision?*** ***ii. Statistics Canada is requesting that the Contractor's laboratory be accredited for at least 2 consecutive years measured back from the date of Bid Closing. Do you feel that 2 years is an appropriate period to request for the Work described?*** ***iii. The Contractor must have an established proficiency testing with a recognized program, such as College of American Pathologists (CAP) or Quality Management Program-Laboratory Services (QMP-LS), with at least 10 comparable laboratory participants for Category 1: blood.*** ***1. Can you achieve this requirement for all blood Analytes/Measures?*** ***2. Should this requirement be variable depending on the specific Analyte (for example, 5-15 comparable participants depending on the Analyte)?*** ***3. Could the criteria be achieved for the urine Analytes/Measures (categories 2 and 3) as well?*** ***4. What issues would you face in sharing your proficiency testing results and participant identifiers with the Technical Authority?***
Respondents	Reference ranges for proficiency testing programs may vary based on analytical methodology and instrumentation cut-offs, thus we believe at this time that we will need further evaluations to confirm if we can achieve the requirement for the blood Analytes/Measures. We suggest the requirements should be variable depending on specific Analytes as age and gender may also affect results. We noticed no period was given for previous participation in proficiency testing. Is there a specific period of participation required?

Outcome	With respect to the clarifications requested, Canada offers the following information: Canada intends to revise Mandatory Requirement MR-1 to request that laboratories submit their current certification showing the date of expiry and either the previous certification showing the date of expiry insofar as it demonstrates the currency of the accrediation and the two previous years of accreditation required OR a letter from the accreditation body demonstrating that the accreditation has been valid for the period required under MR-1. Canada intends to retain the requirement that the Contractor must have an established proficiency testing with a recognized program, such as College of American Pathologists (CAP) or Quality Management Program-Laboratory Services (QMP-LS), with at least 10 comparable laboratory participants for all Category 1 (Blood) Analytes/Measures identified in Table 1: Core Sample Biochemistry Analysis of Appendix 1 to Annex A.. Canada intends to remove all Category 2 and 3 (Urine) Analytes/ Measures from any potential resulting RFP. Thus, all requirements related to these categories will also be removed from any potential resulting RFP. Canada will accept the portion of the proficiency testing report related to the measure they are analyzing for Canada. Additionally, Canada intends to accept at least one previous successful proficiency testing report issued within the past eight (8) months measured back from the date of bid closing for each Category 1 (Blood) Analyte/Measure identified in Table 1, Core Sample Biochemistry Analysis of Appendix 1 to Annex A.

SECTION 4: PAYMENT	
4.1	***Do you have any comments on the Basis of Payment and Method of Payment? Are the proposed Basis of Payment and Method of Payment reasonable?***
Respondents	No concerns were presented.
Outcome	Canada intends to retain the Basis of Payment provided in the draft RFP with adjustments to reflect the revisions to Appendix 1 to Annex A.
4.2	***Do you foresee any issues with providing fixed sample prices until 2021?***
Respondents	No concerns were presented.
Outcome	Canada intends to retain the Basis of Payment provided in the draft RFP with adjustments to reflect the revisions to Appendix 1 to Annex A.

SECTION 5: Other	
5.1	***Please identify any other issues, concerns, recommendations not addressed above.***
Respondents	**1. a)** Please provide the size of the aliquot tubes, the minimal tube size required for the instrument is 12x75mm. **b)** Please confirm the specific requirements for storage of these samples (i.e. -20˚C). **2.** Could you please advise when and for how long the potential resulting RFP will be posted?
Outcome	With respect to the clarifications requested, Canada offers the following information: **1. a)** As previously stated, Canada will provide tube details in any potential RFP. **b)** The minimum is -20ºC, however we prefer -80ºC. **2.** We are estimating mid to late June and any potential resulting RFP will be posted on the Government Electronic Tendering Service (GETS) for a period of no less than fifteen (15) calendar days. All Participants also indicated that the imposed Method for Glucose analysis was acceptable.

5.2	***The IT Security Requirements are provided in Annex G of the draft Request for Proposal. Could you please comment on the capacity and ability of meeting these requirements?***
Respondents	**1.** We comply with the IT security requirements in the areas of network firewall, server, data centre access and communication and transmission of data. Minor deviations may exist with respect to wireless access, printers and copiers that requires further discussion to understand the client's requirements and our current polices, standards and processes for these devices. Specifically, we cannot meet the requirements regarding Administrator Access. We also cannot meet the requirement regarding WI-FI in the laboratory. Typically we implement the encryption program with the client. Internally there is a firewall preventing access. This is standard laboratory protocol**.** **2.** No presence of cell phones in certain areas could be a problem.
Outcome	With respect to the clarifications requested, Canada offers the following information: Based on the feedback received Canada may consider modifying the IT Security Requirements identified in the draft RFP to indicate that alternatives or exceptions may possibly be approved for select requirements where the proposed alternative provides the same level of data protection and security as the original requirement identified in Annex G, IT Security Requirements. **1.** The requirement of the computer system [that processes or stores Canada's data] requiring a user account without administrator privileges ensures that only an administrator knowledgeable of the security requirements has access to modify the computer system settings. This restricts other employees from inadvertently or purposefully modifying the computer system settings in a manner that could possibly breach the security requirements. This requirement is mandatory and alternative processes will not be considered. The data for Canada must be processed and/or stored on a computer system and network that is not WiFi enabled. Exceptions may possibly be made for the requirements related to WiFi in the laboratory for "other" networks provided that the security of the "other" networks and the security between networks can be shown to maintain the equivalent level of security as the original requirement identified in Annex G, IT Security Requirements. **2.** Presence of cell phones within the area is prohibited when the device is connected to the computer or network that processes or stores Canada data. Exceptions may possibly be made for cell phones on a separate or outside network that are not attached to a workstation or the closed network.

6. Conclusion

Industry feedback has informed Canada of areas of potential concern for some Participants which resulted in improvement of the procurement process through the implementation of changes to the final RFP that will address the key concerns.

PWGSC and Statistics Canada would like to thank all Participants who provided responses. The two-way dialogue and information that resulted was invaluable in assisting Canada in finalizing the procurement strategy.