Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing by Pathology and Laboratory Medicine

Between:

Nova Scotia Health Authority ("NSH")

-and-

Izaak Walton Killam Health Centre ("IWK")

-and-

SUPPLIER NAME (the "Supplier")

WHEREAS the Supplier wishes to have the blood and urine specimens that are collected privately by the Supplier (the "**Specimens**") processed, analyzed and resulted by the Pathology and Laboratory Medicine Laboratories (the "**Pathology Services**" NSH and IWK will provide the supplier) within NSH and the IWK ("**NSH/IWK Laboratories**");

AND WHEREAS the Supplier is an individual or a business, or the employer of an individual, who engages in phlebotomy (collects blood specimens) and obtains urine samples from individuals whose Specimens will be analyzed ("**Clients**") and resulted by NSH/IWK Laboratories for the purpose of laboratory testing;

AND WHEREAS NSH and IWK require certain conditions be met in order to ensure the integrity of Specimens and the accuracy of resultant Client data

AND WHEREAS NSH and IWK agree to provide the Testing Services to the Supplier subject to the terms and conditions of this Agreement;

NOW THEREFORE the parties hereto covenant and agree with each other as follows:

1.0 NSH AND IWK RESPONSIBILITIES:

1.1. NSH and IWK agree to accept Specimens from the Supplier at NSH/IWK Laboratories and provide the Pathology Services in accordance with the terms and conditions of this Agreement.

1.2. NSH and IWK will set standardization requirements for mandatory equipment, processes, and procedures, including but not limited to specimen collection, specimen packaging, and specimen transport.

1.3. NSH and IWK shall maintain a Pathology and Laboratory Medicine website ("Website") accessible by the Supplier.

1.3.1. The Website will support the Supplier by providing information required by the Supplier on how to access:

1.3.1.1. Mandatory laboratory forms to be completed by the Supplier and submitted with the completed Requisitions (as defined in subsection 2.5.1 herein) and Specimens;
1.3.1.2. Applicable NSH and IWK policies and procedures;
1.3.1.3. A list of all applicable Clinical Laboratory Standards Institute (CLSI) documents;
1.3.1.4. Contact information in the event the Supplier seeks additional information related to this Agreement; and
1.3.1.5. Testing site contact information.

1.3.2. NSH and IWK do not warrant the completeness or correctness of the Website. Suppliers shall remain solely responsible for ensuring they are knowledgeable regarding all applicable NSH and IWK policies

1.3.3. The Supplier is responsible for ensuring they comply with the Clinical Laboratory Standards Institute for the collection storage and delivery of the Specimens ("**CLSI Standards**") and guidelines, updates, forms and other relevant information.

2. SUPPLIER RESPONSIBILITIES

2.1. *Strict Compliance & Consequences of Breach*

2.1.1. The Supplier shall collect, label, store, package, transport and deliver Specimens in strict accordance with the specifications and procedures set out in section 2.0 "SUPPLIER RESPONSIBILITIES" of this Agreement. The first instance of breach by the Supplier of one or more if its responsibilities in section 2.0 may lead to immediate termination in accordance with subsection 5.1 of this Agreement at the sole discretion of NSH and/or IWK.

2.1.2. The Supplier shall follow all direction provided by NSH/IWK and standardize mandatory equipment, processes, and procedures, as per subsection 1.2 herein.

2.2. *Specimen Collection & Labeling*

2.2.1. The Supplier shall only collect venous and/or capillary blood and obtain urine Specimens under this Agreement. No other specimen collection or handling is authorized under this Agreement (e.g. stool sample, arterial blood).

2.2.2. The Supplier shall ensure collection of each Specimen meets accepted industry standards for specimen collection as per the applicable CLSI Standards.

2.2.3. The Supplier shall comply with all NSH and IWK policies and procedures relating to the collection of the Specimens.

2.2.4. The Supplier shall label all Specimens in accordance with NSH and IWK policies and ensure that Client information on the label and Requisition (as defined in subsection 2.5.1 herein) matches.

2.2.5. The Supplier shall ensure each Specimen is labeled with:

i. The Client's legal name (as defined in NSH/IWK policy),
ii. The Client's date of birth,
iii. An additional person-specific patient identifier (see subsection 2.2.6),
iv. The date and time of collection (recorded at that time),
v. All additional information that may be required by NSH/IWK policies and Testing Site, as defined herein, registration procedures (e.g. witness and Collector initials for blood transfusion protocol).

2.2.6. The Client's provincial health card number is the preferred additional person-specific patient identifier. An alternate piece of information is acceptable if it appears on the list of person-specific patient identifiers as defined in NSH/IWK policy, and is verifiable by the receiving location ("**Testing Site**") without the Client present, and also appears on the Requisition(s).

2.2.7. The Supplier will not perform pre-analytical processing (including centrifugation) on Specimens.

2.3. ***Specimen Storage, Packaging, Transport & Delivery***

2.3.1. The Supplier is responsible for ensuring Specimens are delivered to the appropriate Testing Site at either an NSH or IWK Laboratory as specified by the attached "Schedule A" and/or Laboratory policy and procedure.

2.3.1.1. Specimens delivered to an incorrect Testing Site will be rejected.

2.3.2. The Supplier must ensure Specimens are stored, packaged and transported to the Testing Site in accordance with all applicable requirements and standards, including but not limited to:

i. CLSI standards and guidelines;
ii. *Transportation of Dangerous Goods Act*, 1992 (1992, c.34) standards and requirements, and those set out in its associated regulations and procedures;
iii. NSH and IWK policies and procedures;
iv. Standardized and validated Specimen transport containers and packing schemes, as required by NSH/IWK; and

v. Ensuring Specimens and transport containers are not exposed to extreme temperatures.

2.3.3. Subject to the exception noted below, all Specimens must be delivered to the Testing Site within ninety (90) minutes of the time of collection.

2.3.3.1. The delivery time limit may be less than ninety (90) minutes depending on the time sensitivity, testing requirements, and priority of the test(s) requested. Such delivery time limits will be provided with the collection requirements of the specific test(s). The Website provides information on collection requirements.

2.3.3.2. Failure by the Supplier to meet the delivery time limit may result in rejection of the Specimen(s) and cancellation of tests/procedures.

2.3.4. The Supplier is solely responsible for knowing the hours of operation of the Testing Site (including any reduced or limited hours of operation for Testing Site acceptance of Specimens set out in this Agreement and Schedules) and must ensure that Specimens are delivered during these hours of operation.

2.3.5. The Supplier shall inform the courier/individual delivering Specimens of:

2.3.5.1. the specialized nature of the shipments (i.e. blood and urine for laboratory testing),

2.3.5.2. the responsibility to maintain Specimen integrity including the importance of meeting the delivery time requirements in clause 2.3.3 of this Agreement, and

2.3.5.3. the responsibility to complete a Delivery Confirmation Form (see Appendix B), and all documentation required at the Testing Site.

2.3.6. The Supplier is responsible for ensuring their Specimen transportation container(s) is/are picked up and removed from the Testing Site no later than the end of the business day following delivery of that/those same container(s).

2.4. ***Supplier Training and Competency Requirements***

2.4.1. The Supplier warrants that all employees or other persons involved in the collection of Specimens ("Collectors") are either:

- Medical Laboratory Technologists, holding current licensure with Nova Scotia College of Medical Laboratory Technologists ("**NSCMLT**"), or
- Another regulated health care professional, as exempted by section 42 of the *Medical Laboratory Technology Act* (Nova Scotia), and holding current licensure with their regulatory association/college, or
- Working under the direct supervision and control of a Medical Laboratory Technologist who holds current licensure with NSCMLT, in compliance with the *Medical Laboratory Technology Act* (Nova Scotia) and performing

only those activities permitted by the Medical Laboratory Technologists Registration Regulations, NS Reg 168/2003.

2.4.2. The Supplier warrants all Collectors have initial training and competency assessment, and ongoing assessment of competency to be performing phlebotomy and collection procedures on individuals. Such ongoing assessment of competency must be completed, at minimum, on an annual basis.

2.4.2.1. Initial training must be comparable to the training required of NSH and IWK employees engaged in similar work as the Supplier and its employees.

2.4.2.2. Initial competency assessments for each Collector regarding phlebotomy, urine collection, and Specimen handling/packaging must be performed at the time of establishing this Agreement, and on an annual basis (or more frequently if directed by NSH/IWK). These assessments must be documented and comparable to the assessments required of NSH and IWK employees engaged in similar work as the Supplier and its employees.

2.4.2.3. The Supplier must maintain documented proof of the training provided to Collectors related to phlebotomy, urine collection, and Specimen handling/packaging, and maintain accurate training and competency assessment records of all Collectors.

2.4.2.4. The Supplier will, on an annual basis, or at the request of NSH or IWK, provide proof of such training and assessment of competency and any other written confirmation as requested by NSH and/or IWK.

2.4.3. The Supplier warrants that all Collectors hold current emergency first aid certification or that immediate access is available at the collection location (see Schedule A) to a physician or paramedic licensed to practice in Nova Scotia.

2.4.4. The Supplier warrants that all Collectors, while performing duties within the scope of this Agreement, have access to a Nova Scotia Number 1 First Aid Kit.

2.4.5. The Supplier warrants that all Collectors hold current certification in Nonviolent Crisis Intervention (NVCI), or an equivalent certification, as determined by NSH/IWK.

2.4.6. The Supplier warrants that all Collectors are aware that collection must be performed in accordance with the CLSI Standards for collection of specimens, following NSH/IWK policy and procedure, and that failure to comply with these requirements may result in termination of this Agreement pursuant to subsection 5.1 herein.

2.4.7. The Supplier warrants it has access to the applicable CLSI Standards (as defined by NSH/IWK) and has read and understood those Standards. The Supplier warrants that all its Collectors have read and understand the aforementioned CLSI Standards.

2.4.8. The Supplier will ensure that all employees, contractors or agents who may be involved in the packaging, transportation and delivery of Specimens have received the training required by *Transportation of Dangerous Goods Act*, S.C. 1992, c.34 and its associated regulations and procedures prior to packaging, transporting or delivering Specimens.

2.4.9. The Supplier warrants that all Collectors will be made aware on an ongoing basis of changes or updates to all applicable CLSI Standards and guidelines and NSH and IWK policies and procedures.

2.4.10. The Supplier warrants that all errors and incidents of non-compliance with this Agreement are reviewed with employees and persons involved with Specimen collection, packaging, transportation and delivery.

2.4.10.1. The Supplier will keep a written record of their actions in response to errors and incidents of non-compliance with this Agreement and all related follow-up, and agrees to make these written records available to NSH/IWK upon request.

2.5. ***Requisition Requirements & Additional Forms***

2.5.1. Subject only to subsection 2.5.3 herein, Suppliers will ensure each Specimen is accompanied by a complete, approved, legible and unaltered diagnostic Requisition ("Requisition"). Requisitions must be issued by an Authorized Prescriber/Requestor, as defined in applicable NSH and IWK policies.

2.5.1.1. The Supplier may submit a reproduction (e.g. photocopy) of the original Requisition for Standing Order requests (i.e. those diagnostic test requests that are repeated on a regular basis and for which the Authorized Prescriber/Requestor issues only a single Requisition). All other Specimens are to be submitted with the **original** Requisition.

2.5.1.2. The Supplier is responsible to make exact reproductions (e.g. photocopies) of Requisitions as required, and is not permitted to manually transcribe Requisitions.

2.5.1.3. Requisitions expire one (1) year after the date of issue by the Authorized Prescriber/Requestor. Specimens submitted with an expired Requisition will result in rejection of the Specimen(s) and cancellation of tests/procedures.

2.5.2. A Requisition must contain all the following information to be considered valid and complete by the Testing Site:

i. The Client's full legal name and date of birth,

ii. Another person-specific patient identifier as defined by NSH/IWK policy (provincial health card number preferred), which also appears on each specimen label,

iii. The Authorized Prescriber/Requestor's name and required information as defined by the Testing Site's registration procedures (may include telephone number, mailing address, Provincial Medical Board (PMB) number, or Physician Registration Number (PRN)),

iv. Collection date and time (accurate collection information is required and must be recorded by the Collector at the time of collection),

v. A valid telephone number where the Client can be reached during a twelve (12) hour period after Specimen delivery,

vi. The full mailing address associated with any third-party billing,

vii. Collector ID or Facility ID, as assigned by NSH/IWK (see attached Schedule "A"),

viii. Collector's full and legible signature,

ix. Client information relevant to testing (e.g. fasting, anticoagulant therapy, drugs),

x. All additional information that may be required by NSH/IWK policies and Testing Site registration procedures (e.g. witness signature for blood transfusion protocol).

2.5.3. Notwithstanding subsection 2.5.1 herein**,** the Supplier is permitted to add to the Requisition any required information listed in clause 2.5.2 that is missing to ensure the Requisition is complete before delivery of the Specimen(s) to the Testing Site, and the Supplier is permitted to add a verbal test request under the direction of the Authorized Prescriber/Requestor. Verbal requests must be documented on the Requisition (date, time, test and name of Authorized Prescriber/Requestor) and initialed by the Collector.

2.5.4. Supplier shall not materially change the original Requisition. A "material change" for the purposes of this subsection includes any change whatsoever not specifically permitted or authorized pursuant to subsection 2.5.3 of this Agreement. Consequences to a Supplier for making a material change to the Requisition may include immediate termination of this Agreement at the option of NSH and/or IWK in accordance with section 5.1 herein.

2.5.5. A Delivery Confirmation Form (see Appendix B) must be completed by the Supplier and the courier. The completed form must accompany each delivery of Specimens by the Supplier or one of its contractors/agents.

2.5.6. Mandatory forms regarding specific laboratory tests that accompany the Requisition must be completed by the Supplier and submitted with the Requisition and Specimen(s).

2.5.7. Original Requisitions requesting Standing Orders must be returned to the Client, not retained on file by the Supplier.

2.6. ***Mandatory Information Supplier to provide NSH and IWK***

2.6.1. Upon request of NSH and/or IWK, the Supplier will confirm compliance with section 2.0 of this Agreement.

2.6.2. The Supplier must submit to NSH and IWK proof of its ability to access relevant CLSI Standards and guidelines (as defined by NSH and IWK), including updates to CLSI Standards and guidelines applicable to the collection, labeling, storage, packaging and transportation of laboratory specimens.

2.6.3. For each Collector, the Supplier must submit to NSH/IWK:

- Proof of MLT licensure with NSCMLT, or
- Proof of licensure with the applicable regulating association/college for Collectors exempted by the Medical Laboratory Technology Act (Nova Scotia), or
- A fully signed and completed Appendix C, and proof of MLT licensure with NSCMLT, for the MLT providing direct supervision and control of all work being performed under this Agreement by Collectors who are not licensed MLTs and not exempted under section 42 of the *Medical Laboratory Technology Act* (Nova Scotia) (see Appendix C).
- Proof of current certification in emergency first aid and CPR (or proof of immediate access to a physician or paramedic licensed to practice in Nova Scotia), and
- Proof of current certification in Nonviolent Crisis Intervention (NVCI) or an equivalent certification, as determined by NSH/IWK.

2.6.3.1. Proof of the aforementioned certifications and licensure must be provided at the time of establishing this Agreement, at the time of Agreement renewal, and upon request by NSH/IWK.

2.6.4. The Supplier must submit to NSH/IWK documented proof of the initial competency assessment (as described in section 2.4.2 of this Agreement) of each Collector, and that assessment must utilize the NSH & IWK approved Independent Phlebotomy Competency Assessment Form, provided on the Website. Assessment of a Collector's competency must be performed by an individual who is themselves competent (the "Assessor"), documented proof of which must be provided to NSH/IWK, upon request.

2.6.4.1. The Supplier must submit to NSH/IWK documented proof of the ongoing annual competency assessments of each Collector at the time of Agreement

renewal, or more frequently, upon request by NSH/IWK. Such assessments must utilize the NSH & IWK approved Independent Phlebotomy Competency Assessment Form, provided on the Website. Assessment of a Collector's competency must be performed by an individual Assessor (defined in section 2.6.4), documented proof of which must be provided to NSH/IWK, upon request.

2.6.4.2. An Assessor's competency cannot be evaluated by another Assessor whose initial or annual competency was evaluated and documented or can be traced back to the Assessor being evaluated. For greater clarity, and as an example of what is prohibited by this section; three Collectors are working for the Supplier: Collector 1 acts as the Assessor for Collector 2, who assesses Collector 3, who assesses Collector 1.

2.6.5. The Supplier must provide NSH and IWK with an active and monitored email address where the Supplier can receive information, such as notifications and audit reports.

2.6.5.1. Pursuant to section 3, the Supplier is responsible for reviewing all material and information sent to the provided email address, and will notify NSH and IWK immediately if the email address changes.

2.6.5.2. When requested, the Supplier shall acknowledge receipt of email notices that are in relation to the Agreement by return email within three (3) business days.

2.6.6. The Supplier must provide NSH and IWK with its current business operations and employee information ("Business Information") to complete the form attached hereto as Schedule "A". This requires that the Supplier provide a complete list of all current Business Information, including legal business name as registered with the Registry of Joint Stock Companies, hours of operation and location, and a complete list of employees, contractors or agents who may be involved in the collection, storage and/or transportation of Specimens.

2.6.7. The Supplier must provide a contact number where the Supplier can be reached up to six (6) hours from the time of each Specimen delivery.

2.6.8. During the Initial Term and any Renewal Term(s) of this Agreement, unless otherwise terminated in accordance with this Agreement, the Supplier agrees to update NSH and IWK with respect to any changes to its business information, being any of the information provided on Schedule "A" attached hereto ("Business Information"). The Supplier understands that such changes amount to a proposed amendment to the Agreement, requiring written approval and acceptance by NSH and IWK.

2.6.8.1. The Supplier agrees to request changes to its Business Information by submitting the required Form (see Appendix D). All requests are subject to NSH and IWK written approval and will be assessed with consideration for Testing Site operational requirements/limitations, applicable NSH and/or IWK policies, and CLSI Standards and guidelines.

2.7. ***Collector Identification and Location Identification***

2.7.1. The Supplier must obtain a Location Identifier ("Location ID") for each of the Supplier's collection location addresses, subject to the exception noted below. Location IDs are supplied by NSH and IWK during the application process.

2.7.1.1. Suppliers collecting Specimens in Clients' homes, workplaces, etc., are to identify "Mobile Collections" as the "location" to be used any time a collection is performed at such a location.

2.7.2. Subject to the exception noted below, the Supplier must obtain an individual Collector identifier ("Collector ID") for each of the Supplier's individual Collectors, prior to any collection by the individual Collector. Collector IDs are not transferable between Collectors, and must be assigned and approved by NSH and IWK.

2.7.2.1. Suppliers who are identified as employing more than six (6) licensed nurse Collectors at a single location may be issued a common Collector ID ("Facility ID"), which will be shared by all Collectors employed at that location.

2.8. ***Non-compliance and Adverse Event Reporting***

2.8.1. The Supplier will immediately notify the appropriate contact at the Testing Site if the Supplier becomes aware of any patient safety and/or privacy incident information related to the collection, packaging or transporting of Specimens. Contact information for such notifications will be available on the Website.

2.8.2. The Supplier will immediately notify NSH and IWK in writing if it becomes aware of any incidence of non-compliance or breach of the terms and conditions of this Agreement, and that awareness is not the result of notification from NSH/IWK.

3. NOTICES

3.1. Any notices required to be given pursuant to this Agreement will be given by email or facsimile as permitted below:

Notices will be sent to:

Josh MacDonald,
Provincial Client & Support Services Program Manager

Nova Scotia Health
Josh.macdonald@nshealth.ca

Independent Phlebotomy Office
Nova Scotia Health
IPOffice@nshealth.ca

Leota Dickey,
Director of Laboratory Operations
Pathology and Laboratory Medicine,
IWK Health Centre
Leota.Dickey@iwk.nshealth.ca

SIGNING AUTHORITY,
Title
BUSINESSNAME
EMAIL ADDRESS

4. TERM

4.1. This Agreement shall be effective from the date of last signature to this Agreement, until April 1, 2024 ("Initial Term").

4.2. This Agreement may be renewed upon mutual written consent of the parties for up to two (2) additional terms of one (1) year each ("Renewal Term(s)"), with the renewal date commencing on April 1st of the given year.

4.2.1. To initiate renewal of the Agreement for an additional one (1) year term, the Supplier must submit a complete Request for Renewal Form, attached hereto as Schedule "B", at least thirty (30) days before the end of the then-term.

5. TERMINATION

5.1. NSH and/or IWK may choose to immediately terminate this Agreement, written notice of which will be delivered to the Supplier, upon the happening of one or more of the following events:

5.1.1. NSH and/or IWK has determined in its sole discretion that the Supplier has failed to act in accordance with the specifications and/or procedures for the collection, labeling, storage, packaging, transport and/or delivery of Specimens as set out in this Agreement. Without limiting the generality of the foregoing events warranting immediate termination at the option of NSH and/or IWK include:

5.1.1.1. Failure to meet established delivery time requirements, whether the standard ninety (90) minute time-limit, or a reduced delivery time-limit as described more fully in subsection 2.3.3 herein;

5.1.1.2. Supplier performing pre-analytical processing (including centrifugation) on Specimens;

5.1.1.3. Failure by the Supplier or its employees (including without limitation Collectors) to adhere to applicable CLSI collection standards, and NSH/IWK policies and procedures related to specimen collection;

5.1.1.4. Failure of the Supplier to ensure and submit proof of required NVCI and emergency first aid/CPR certifications as described in subsection 2.6.3 herein;

5.1.1.5. Failure of the Supplier to perform and submit proof of competency assessments as described in subsection 2.6.4 herein;

5.1.1.6. Failure of the Supplier to provide proof of appropriate licensure, as described more fully in subsection 2.6.3 herein;

5.1.1.7. Failure of the Supplier and/or its agents to act in compliance with the CSMLS Code of Ethics, or, for employees/agents who are regulated healthcare professionals, the code for their applicable licensure (e.g. for nurses, the Canadian Nurses Association's Code of Ethics).

5.1.1.8. Failure by the Supplier to obtain prior approval from NSH and IWK of any changes to its Business Information or other business or operational changes relevant to this Agreement;

5.1.1.9. Supplier makes a material change to the original Requisition including but not limited to changes in:

i. Priority level;
ii. Adding to or changing the specific test(s) requested by the Authorized Prescriber/Requestor;
iii. Changing the Authorized Prescriber/Requestor; or
iv. Adding additional physicians or care providers.

5.2. Either party shall be at liberty to terminate this Agreement for convenience at any time before the expiry of the Initial Term or a Renewal Term upon the giving of thirty (30) days written Notice to the other party.

5.3. Failure of the Supplier to submit a Request for Renewal Form pursuant to subsection 4.2.1 herein **shall result in automatic termination** of this Agreement at the end of the then-term.

5.4. For greater clarity, and notwithstanding anything to the contrary, where NSH and/or IWK reasonably suspect(s) the Supplier of non-compliance with one or more terms or conditions of this Agreement, such as if the Supplier provides NSH and/or IWK with false information relating to the Supplier or its business operations and/or employees, Specimen collection times, or otherwise, NSH and/or IWK may, in its sole discretion, upon giving written notice to the Supplier, terminate for cause the whole or any part of this Agreement, either immediately, or at the expiration of a cure period (the duration of which shall be specified in the Notice), if the Supplier has not cured the non-compliance to the satisfaction of NSH and/or IWK within that cure period.

6. PRIVACY AND CONFIDENTIALITY

6.1. The Supplier shall keep private, treat as confidential, and not make public or divulge during as well as after the Initial Term and any Renewal Term(s) of this Agreement, any information or material to which the Supplier, its directors, officers, employees, independent suppliers, subcontractors, members, partners, volunteers, agents, and assigns become privy as a result of acting under this Agreement, without the prior written consent of NSH and IWK.

6.2. All personal health information collected, used, disclosed, retained and destroyed under this Agreement shall be done in accordance with the requirements of all provincial and federal legislation including, but not limited to, the *Personal Health Information Act,* 2010 (Nova Scotia), c.41 and the *Freedom of Information and Protection of Privacy Act* (Nova Scotia). 1993, c.5, as such apply to the collection, use, disclosure, storage, retention and transfer of personal health information.

6.3. The Supplier agrees to promptly notify NSH and IWK in writing upon becoming aware of a breach of either the Supplier's security standards and procedures or NSH's or IWK's security policies, or any unauthorized disclosure of personal health information that the Supplier is required to keep confidential under applicable law. The Supplier shall take immediate steps to mitigate any breach or unauthorized disclosure described in this Section 6.

7. TEST RESULTS AND RECORDS

7.1. Specimen test results generated as a result of the services provided under this Agreement are under the custody and control of NSH and IWK (as applicable), and will be communicated directly to the requesting Authorized Prescriber/Requestor noted on the Requisition (or to the Client where appropriate) in keeping with NSH and IWK policies and practices and the terms of this Agreement, and shall not be disclosed to the Supplier. All Specimens, Requisitions and associated forms received from the Supplier become the sole property of NSH and/or IWK.

8. INSURANCE

8.1. The Supplier shall, without limiting its obligations or liabilities herein and at its own expense, provide and maintain the following insurances with insurers licensed in Nova Scotia and in forms and amounts acceptable to NSH and IWK:

8.1.1. Professional Liability, where applicable, with policy limits not less than $5,000,000.00 per occurrence for this Agreement (for each firm) insuring its liability for errors and omissions in the performance of professional services including all consultants. The policy coverage shall also extend to include personal injury, bodily injury, and property damage from the performance of professional service;

8.1.2. Comprehensive General Liability with policy limits not less than $5,000,000.00 per occurrence covering against bodily injury, personal injury, death, and property damage including loss of use thereof. Such insurance shall include, but not be limited to non-owned automobile liability and employees as additional insureds;

8.1.3. Automobile Liability on all vehicles owned, operated, or licensed in the name of the Supplier with policy limits not less than $2,000,000.00;

8.1.4. "All-Risks" Valuable Papers and records Insurance on all such items pertaining to the Services under this Agreement in an amount adequate to enable their reconstruction.

8.2. All insurance policies shall name NSH and IWK as additional insureds, and the Supplier will provide NSH and IWK with no fewer than 30 (thirty) days' notice prior to cancellation or material change to the above policies.

8.3. Upon request, the Supplier agrees to provide NSH and/or IWK with a Certificate of Insurance.

9. INDEMNIFICATION & LIABILITY

9.1. The Supplier shall indemnify and save harmless NSH and IWK, their employees, servants and agents from and against all damages, costs, loss, expenses (including legal fees), claims, actions, suits of other proceedings of any kind or nature, which they, or any of them, may at any time incur or sustain as a result of or arising out of an Event of Default, or any act, omission or negligence of the Supplier, or any of its employees, servants, agents, or subcontractors, in the performance of this Agreement, including without limitation, any injury or death to persons, or loss of or damage to property. Notwithstanding the foregoing, the Supplier shall not be liable for any indirect or consequential damages sustained by NSH or IWK unless such damages result from the negligence or willful default of the Supplier, its servants, agents or subcontractors.

9.2. NSH and/or IWK shall not be liable for any damages or injury (including death) to any person or to any property of the Supplier as a result of or arising out of this Agreement or the provision of Services by the Supplier under this Agreement, unless such damages are direct damages, and are caused solely and directly by or as a result of the negligence of NSH/IWK. In no event shall NSH and/or IWK be liable for any indirect or consequential damages that are sustained by the Supplier, howsoever caused, as a result of or arising out of this Agreement or the provision by the Supplier of any Services hereunder.

10. INDEPENDENT CONTRACTOR RELATIONSHIP

10.1. NSH and IWK and the Supplier are each independent parties and nothing in this Agreement constitutes any party as the employer, principal, agent, or partner of any other party. The Supplier does not have any authority to assume or create any obligation or liability, either expressed or implied, on behalf of NSH or IWK. No employee, agent or contractor of the Supplier shall be considered an employee of NSH or IWK.

10.2. The Supplier will ensure all employees and agents engaged in the collection and/or transportation and/or in any other way with the Specimens in connection with this Agreement are at all times clearly identified as employees of Supplier, both at the Supplier's collection site and at the Testing Site at the time of delivery.

11. MISCELLANEOUS

11.1. The Supplier warrants that all employees and agents of the Supplier have reviewed and understand the terms of this Agreement and will comply with this Agreement.

11.2. The following documents form part of and constitute this Agreement:

11.2.1. This Agreement; and

11.2.2. The Schedules and Appendices:

- 11.2.2.1. Schedule A
- 11.2.2.2. Schedule B
- 11.2.2.3. Appendix A
- 11.2.2.4. Appendix B
- 11.2.2.5. Appendix C
- 11.2.2.6. Appendix D

11.3. NSH and IWK may change, restrict or limit their laboratory hours and Testing Sites available to receive and process Specimens for operational requirement reasons, including but not limited to workforce disruptions, workload, and laboratory capacity issues or concerns. Notification of such changes, restrictions or limitations will be promptly communicated to the Supplier per the Notice requirements of this Agreement.

11.4. NSH and IWK reserve the right to verify collection information and/or Client information by contacting the Client directly and reserve the right to investigate suspected Supplier non-compliance with this Agreement, including contacting Clients as they in their sole discretion deem appropriate.

11.5. NSH and IWK will directly respond to and follow-up on any Client concerns or complaints, or any adverse event information or any complaint they receive regarding the Supplier's collection of Specimens or operations generally. NSH and IWK will notify the Supplier if either party is in receipt of such Client complaint, or receives a report of an adverse event.

11.6. This Agreement, and the Schedules attached hereto, form the entire agreement between the parties pertaining to the subject matter hereof.

11.7. This Agreement shall be governed by and interpreted in accordance with the laws of Nova Scotia.

11.8. Neither Party may sell, assign, encumber, licence or otherwise transfer any of its rights, duties or obligations under this Agreement without the prior written consent of the other Party.

11.9. This Agreement binds and ensures to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns.

11.10. The signatories to this Agreement hereby warrant that their respective principals and that the person signing this Agreement on behalf of each Party has been properly authorized and empowered.

11.11. This Agreement may be executed in several counterparts, each of which when so executed shall be deemed to be an original, and such counterparts together shall constitute one and the same instrument, which shall be sufficiently evidenced by any such original counterpart. A copy of a signed counterpart may be delivered by fax, PDF email or other electronic means which shows a reproduction of the signature and such shall be considered complete delivery and shall be deemed to be a signed original.

IN WITNESS WHEREOF the Parties agree to be bound by the terms of this Agreement.

SUPPLIER BUSINESS NAME

Signing Authority	Date

NOVA SCOTIA HEALTH AUTHORITY

Vickie Sullivan, VP Operations Central Zone	Date

IZAAK WALTON KILLAM HEALTH CENTRE

Celine d'Entremont, Director of Lab Operations Pathology and Laboratory Medicine	Date
Dr. Anette Elliott Rose, VP Clinical Care and CNE Pathology and Laboratory Medicine	Date

SCHEDULE "A"

Agreement for Acceptance of Specimens for Laboratory Testing

I. SUPPLIER INFORMATION

Name of Supplier:
Supplier Contact Number:
Signing Authority(s):
Full Mailing Address:

II. SUPPLIER Location and Hours of Operation

Location			**Location ID**
Address			
Contact Person			
Contact's phone number			
Contact's email address			
Supplier: Days of Collection			
Supplier: Hours of Collection			
TESTING SITE Drop Off: Location specimens accepted			
Drop off: Days specimens accepted			
Drop off: Hours specimens accepted			

Supplier warrants the business name, location and days of collection information provided above is/are accurate and complete. In accordance with section 2.3 of the Agreement, Supplier acknowledges and understands the ability of NSH and/or IWK to continue to accept Specimens at the Supplier's approved days, hours and Testing Sites is dependent on the relevant Testing Site's operational requirements (e.g. holidays are excluded) and is subject to change.

Supplier signature: _____ Date: _____

III. SUPPLIER'S Employee/Contractor/Agent Information

The following is a complete list of employees, contractors or agents of the Supplier, working at the above business location, who may be involved in the collection, storage, and/or transportation of Specimens as required by the Agreement.

The signature of each employee, contractor or agent is acknowledgment that the person has read, understood and agrees to be bound by the terms of the Agreement.

By signing this form, each employee, contractor or agent consents to the collection of the information contained in this form by NSH and/or the IWK for the purpose of ensuring the integrity of Specimens processed by NSH and the IWK, and expressly consents to the use and disclosure of that information by NSH and the IWK in any manner deemed reasonable by NSH and/or the IWK.

The assigned Collector ID(s) **must be provided on the laboratory Requisition** (to be entered into the laboratory information system). Collector IDs are unique to each location and each individual Collector working with the Supplier at that location as further described in this Agreement.

Supplier Employees involved in Collection and Packaging:

Name	Signature	Collector ID (provided by PLM)

Contractors/Agents involved in Transportation

Supplier hereby acknowledge that listed above is a complete list of employees/contractors/agents involved in transportation of laboratory samples. Supplier warrants *Transportation of Dangerous Goods Act,* S.C. 1992, c.34 training completed for all employees, contractors or agents involved with specimen packaging and/or transportation (as defined in subsection 2.4.8).

Supplier signature: _____ Date: _____

Supplier to attach:

- **proof of purchase (receipt) of CLSI standards/guidelines**
- **proof of training and initial competency assessment for each Collector,**
- **proof of current emergency first aid/CPR certification for each Collector, or proof of immediate access to a physician or paramedic licensed to practice in Nova Scotia,**
- **proof of current NVCI certification for each Collector.**
- **Completed Independent Phlebotomy Competency Assessment Form for each Collector.**

SCHEDULE "B"
Renewal of Agreement

Renewal Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing by Pathology and Laboratory Medicine
(the "Renewal Agreement")

Between:

Nova Scotia Health Authority ("NSH")

- And –

Izaak Walton Killam Health Centre ("IWK")

- And –

BUSINESS NAME (**the** "**Supplier**")

WHEREAS NSH, IWK and the Supplier entered into the Agreement dated [DATE] for the acceptance by NSH and IWK of specimens collected by the Supplier for laboratory testing; and

WHEREAS the Supplier wishes to continue to have blood and urine specimens which it collects privately processed and analyzed and resulted by the Laboratories that comprise Pathology and Laboratory Medicine within NSH and the IWK.

WHEREAS NSH and IWK are agreeable to the extension of the Agreement in accordance with the terms and conditions of this Renewal Agreement;

WITNESSETH that in consideration of the mutual covenants contained in this Renewal Agreement and in consideration of the sum of $1.00, receipt of which is hereby acknowledged, the parties hereto agree as follows:

1. The Term of the Agreement is hereby extended from (insert your new start date for the renewal) to (insert your new expiry date).
2. The Agreement as amended hereby shall, in all other respects continue in full force and effect.
3. This Renewal Agreement may be executed in several counterparts, each of which when so executed shall be deemed to be an original, and such counterparts together shall constitute one and the same instrument, which shall be sufficiently evidenced by any such original counterpart. A copy of a signed counterpart may be delivered by fax, PDF email or other electronic means which shows a reproduction of the signature and such shall be considered complete delivery and shall be deemed to be a signed original.
4. This Renewal Agreement shall be governed by and interpreted in accordance with the laws of Nova Scotia and the laws of Canada applicable therein. Employee and NSH hereby irrevocably and unconditionally attorn to the exclusive jurisdiction of the courts of the Province of Nova Scotia and all courts competent to hear appeals therefrom.

IN WITNESS WHEREOF NSH and the Employee have caused this Agreement to be signed by their duly authorized representatives on the dates set forth below.

SUPPLIER BUSINESS NAME

Signing Authority	Date

NOVA SCOTIA HEALTH AUTHORITY

Eileen MacGibbon, VP Operations Central Zone	Date

IZAAK WALTON KILLAM HEALTH CENTRE

Celine d'Entremont, Director of Lab Operations Pathology and Laboratory Medicine	Date
Dr. Anette Elliott Rose, VP Clinical Care and CNE Pathology and Laboratory Medicine	Date

Supplier to attach:

- **proof of annual competency assessment for each Collector, using the Independent Phlebotomy Competency Assessment Form, and**
- **proof of current emergency first aid/CPR certification for each collector, or proof of immediate access to a physician or paramedic licensed to practice in Nova Scotia.**

Appendix A: Required CLSI Documents

The following provides the list of CLSI standards/guidelines that are required by all Suppliers to ensure compliance with section 2.6.2 of ***the Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing at NSH or IWK.***

2.6.2 The Supplier must submit to NSH and IWK proof of its ability to access relevant CLSI Standards and guidelines (as defined by NSH and IWK), including updates to CLSI Standards and guidelines applicable to the collection, labeling, storage, packaging and transportation of laboratory specimens.

- GP44 A4:2010 - Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition.
- GP41-ED7:2017 - Collection of Diagnostic Venous Blood Specimens - Seventh Edition
- H21 A5:2008 - Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Homeostasis Assays; Approved Guideline – Fifth Edition.
- GP16 A3:2009 - Urinalysis; Approved Guideline – Third Edition

<u>These two documents are required when performing capillary or newborn screening collections:</u>

- GP42 A6:2008 - Procedures and Devices for Collection of Diagnostic Capillary Blood Specimens; Approved Standard – Sixth Edition
- NBS01 A6:2013 Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard – Sixth Edition

Proof of access must be demonstrated by providing a copy of your receipt after purchasing the standards/guidelines.

Referenced to: Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing by Pathology and Laboratory Medicine

Appendix B: Pathology and Laboratory Medicine Delivery Confirmation Form

AUDIT RESULTS	TIME STAMP
LAB USE ONLY	LAB USE ONLY

Mandatory field for courier
Signature

Mandatory fields for Independent Phlebotomist		
Location or Facility ID Number	First sample collected (hh:mm)	Last sample collected (hh:mm)
Signature	**Date of delivery**	

Referenced to: Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing by Pathology and Laboratory Medicine

Appendix C: MLT Supervision & Control of Independent Phlebotomy

Between:

BUSINESS NAME (**the** "**Supplier**")

- And -

MLT NAME (the "MLT")

WHEREAS the Supplier has entered, or wishes to enter, into an Agreement for Acceptance of Specimens Collected by Independent Phlebotomists for Laboratory Testing by Pathology and Laboratory Medicine ("Agreement");

AND WHEREAS the Supplier is, or employs, one or more unlicensed healthcare professionals to perform the task of Specimen collection within the Agreement;

AND WHEREAS the Nova Scotia College of Medical Laboratory Technologists (NSCMLT) is the regulatory body responsible for the licensure of Medical Laboratory Technologists (MLT) within Nova Scotia;

AND WHEREAS the Medical Laboratory Technology Act ("Act") prohibits the performance of medical laboratory technology tasks by an unlicensed healthcare professional, except where it is carried out under the supervision and control of a Medical Laboratory Technologist, as set out in the regulations;

NOW THEREFORE the parties hereto covenant and agree with each other as follows:

1.0 MLT RESPONSIBILITIES:

1.1. The MLT must ensure unlicensed healthcare professionals employed by the Supplier and/or acting within the scope of the Supplier's Agreement are limited to performing those medical laboratory technology tasks which involve:

- Data entry and procurement/receipt;
- Performance of pre-analytical procedures that do not involve any analysis or use of scientific knowledge;

1.2. The MLT must ensure unlicensed healthcare professionals employed by the Supplier and/or acting within the scope of the Supplier's Agreement follow quality assurance policies and procedures, in accordance with established laboratory standards and procedures as set out in the Act and the Agreement.

1.3. The MLT must ensure an adequate level of supervision and control is provided to unlicensed healthcare professionals employed by the Supplier and/or acting within the scope of the Supplier's Agreement, and at minimum, must:

- ensure work assigned to unlicensed healthcare professionals acting within the Agreement is only the work outlined in NSCMLT regulations 11a and 11b, and within the Agreement;
- allow the unlicensed healthcare professional(s) to perform tasks only to support and assist the MLT;
- ensure a mechanism is in place to determine ongoing competence of the unlicensed healthcare professional(s) acting within the Agreement, and that documentation of competence is provided to NSH/IWK as required by the Agreement;
- direct the task(s) of the unlicensed healthcare professional(s);
- monitor the performance of the unlicensed healthcare professional(s), including direct observation when deemed necessary by the MLT or NSH/IWK;
- be readily accessible in case of difficulty or need of intervention;
- remain aware of tasks being performed by the unlicensed healthcare professional(s);
- intervene when there is a concern about the unlicensed healthcare professional's performance;
- act as the Contact Person (see Agreement Schedule A) for all locations where unlicensed healthcare professional(s) are working;
- ensure all non-compliance reports provided by NSH/IWK are reviewed with the unlicensed healthcare professional(s) involved, acted upon as appropriate, and follow up actions are documented; and
- remove work from any unlicensed healthcare professional(s) who the MLT determines is not competent to perform the work.

1.4. The MLT assumes responsibility for the quality and accuracy of all laboratory tasks performed by unlicensed healthcare professionals acting within the Agreement.

2.0 SUPPLIER RESPONSIBILITIES:

2.1 The Supplier warrants that the MLT holds current licensure with NSCMLT, and must submit proof of that licensure when requested by NSH/IWK, as per subsection 2.6.3 of the Agreement.

2.2 The Supplier warrants that all Collectors have read this Appendix C, understand the limitations applied to their practice, and acknowledge the conditions herein under which they are required to work.

SUPPLIER BUSINESS NAME

Signing Authority _____ Date _____

MLT NAME

MLT _____ Date _____

Appendix D: Independent Phlebotomy - Changes to Information Form

A. Supplier information	
Name of Supplier	*(As on original Agreement)*
NSH/IWK Assigned location ID	*(As on original Agreement)*
Contact Name	
Email address	

B. Complete sections that have changed.				
Change in Business Name	*<As registered with Registry of Joint Stock Companies>*			
Supplier Phone #		**Business Fax #**		
Contact Name				
Contact Phone #		**Contact Fax #**		
Email address				
Days of collection	*<Indicate days of collection (no expansion to previously approved days) >*			
Hours of collection	*<Indicate hours of collection (no expansion to previously approved times)>*			
Change in staffing: Staff name	**Remove**	**New**	**Initials F/M/L**	**Collector ID (provided by PLM)**

Change in Couriers :	Remove	New

Application Submitted By:	
Name:	Date:
Approved/Completed by	
Name:	Date:

Save completed form and email to IPOffice@nshealth.ca
Help? Contact IPOffice@nshealth.ca