**Agreement for Acceptance of Specimens Collected by External Agencies for Laboratory Testing**

**Between:**

**NL HEALTH SERVICES (NLHS)**

**-and-**

**_____ ("Specimen Collector")**

**WHEREAS** the Specimen Collector wishes to have the specimens which are collected privately by the Specimen Collector processed and analyzed by the Laboratories that comprise Pathology and Laboratory Medicine within NLHS;

**AND WHEREAS** the Specimen Collector is an individual or a business, or the employer of an individual, who engages in phlebotomy or obtains blood or urine specimens from individuals for the purpose of routine laboratory testing;

**AND WHEREAS** NL Health Services (NLHS) requires certain conditions be met in order to ensure the integrity of specimens they process and the accuracy of resultant patient data;

**AND WHEREAS** Canadian Standards Association ("CSA") establishes standards for primary sample collection facilities and medical laboratories, and the Clinical and Laboratory Standards Institute ("CLSI") establishes guidelines for the collection, storage and delivery, and processing of samples and specimens;

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

**TERMS & CONDITIONS:**

## 1 NL HEALTH SERVICES RESPONSIBILITIES

**1.0** NL Health Services Laboratories comprising their respective departments of Pathology and Laboratory Medicine, agree to accept samples and specimens from the Specimen Collector for processing and analyzing in accordance with, and only in compliance with, the terms of this Agreement.

**1.1** NL Health Services shall provide access to relevant policies, procedures, forms, test menus, collection instructions, and transport requirements by email distribution. It is the responsibility of the Specimen Collector to provide NLHS with an active email, for the purpose of information distribution.

**1.2** NL Health Services will notify the Specimen Collector of all information updates and changes to the test menu, collection, and handling instructions, and NLHS policies and procedures using the aforesaid email in a timely manner immediately upon release of the approved documents. Relevant documents will also be posted on the NLHS website.

**1.3** NL Health Services will post on the NLHS website or otherwise provide the Specimen Collector with a list of CLSI Guidelines applicable to this agreement.

**1.4** NL Health Services will maintain a website ("Website") accessible by the Specimen Collector for information purposes. NLHS does not warrant the completeness or correctness of the Website.

## 2 SPECIMEN COLLECTOR RESPONSIBILITIES

**2.0** ***Strict Compliance & Consequences of Breach***

**2.0.1** The Specimen Collector shall comply with NLHS policies and procedures relating to the collection, handling, and transport of laboratory specimens for processing.

**2.0.2** The Specimen Collector warrants it has access to the most up to date Guideline CLSI GP41 *Collection of Diagnostic Venous Blood Specimens* and the CSA Standard Z316.7 *Primary sample collection facilities and medical laboratories* and complies with the requirements therein.

**2.0.3** Specimen Collector shall be solely responsible for ensuring that they are knowledgeable and will follow all applicable NLHS policies, procedures, and forms once they have been provided to Specimen Collector; as well as Standards and Guidelines subject to subsections 1.1 to 1.3 herein.

**2.0.4** The specimen Collector shall collect, label, store, package, transport and deliver specimens in strict accordance with the specifications and procedures set out in section 2 "Specimen Collector Responsibilities" in this Agreement. Nonconformances on the part of the Specimen Collector of one or more of its

responsibilities in this Agreement may lead to the parties entering into discussions to remedy the issues. Where warranted, notice shall be given to the specimen collector to correct the nonconformities in accordance section 8.2 of this Agreement.

**2.0.5** The NLHS Laboratory reserves the right to audit for compliance all sections of this agreement. Any non-compliance documented as part of the auditing program will be communicated to the Specimen Collector and may lead to termination of this Agreement in accordance with section 8.2 of this Agreement.

**2.1 Requisition Requirements, Specimen Tracking Log, and other forms**

**2.1.1** Subject only to subsection 2.1.2 herein; the Specimen Collector will ensure each specimen is accompanied by a complete, legible, and unaltered requisition signed by an authorized prescriber/requestor in accordance with *NLHS Laboratory Requisition*s policy.

**2.1.2** The Specimen Collector must 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 provincial regulations or NLHS policies. For example, material changes to the requisition include, but not limited to, changing the priority level of the test, or changing the specific tests requested by the authorized prescriber. If a Specimen Collector makes a material change to a requisition, then the specimen may be rejected and repeated material changes to a requisition may result in immediate termination of this Agreement at the option NLHS in accordance with section 8.2.

**2.1.3** The Specimen Collector will ensure each batch of specimens is accompanied by a complete and legible *NLHS Specimen Tracking Log*.

**2.2 *Specimen Collection & Labeling***

**2.2.1** The Specimen Collector shall ensure collection of each specimen follows and meets accepted industry standards for specimen collection in accordance with the current CSA Z316.7 Standard and CLSI GP41Guideline.

**2.2.2** The Specimen Collector shall only collect those tests posted on the website in the *Test Menu and Transport – Externally Collected Specimens* document that can be delivered in appropriate timelines to ensure specimen stability and quality.

**2.2.3** The Specimen Collector will ensure each specimen is labeled with a minimum of two (2) unique pieces of identifying Client information including the Client's official first and last name and the health care number in accordance with NLHS policies and procedures. "Unique identifiers" must comply with NLHS Policy.

**2.2.4** The Specimen Collector shall ensure the date and time of collection and the collectors' name or NLHS assigned mnemonic are included and accurately recorded on the requisition and on the specimen label for each specimen collected.

**2.2.5** All specimens must be labelled in accordance with the laboratory quality requirements based on CLSI Guideline Auto12A such that the information written on the collection containers is fully legible to prevent error.

**2.2.6** Failure to meet aforementioned collection and labelling requirements may result in rejection of the specimen or cancellation of tests/procedures.

**2.2.7** The Specimen Collector shall be responsible to purchase all supplies, including but not limited to collection bottles, tubes, needles, and transport containers required to complete specimen collection services. NLHS is not responsible to provide supplies to Specimen Collectors.

**2.3 *Specimen Packaging Transport & Delivery***

**2.3.1** The Specimen Collector shall ensure all specimens are stored, packaged, and transported to the receiving location in accordance with all applicable regulations and standards, including but not limited to:

- *Transportation of Dangerous Goods Act,* S.C. 1992, c.34 standards and requirements, and those set out in its associated regulations and procedures ("TDG");

- NLHS policies and procedures for packaging and transport.

**2.3.2** Subject to the exceptions in 2.3.2.1 and 2.3.2.2, all specimens must be delivered to the Testing Site within the target collection-to-delivery timeframes as defined by NLHS. In most cases, the target collection-to-delivery time is three hours (180 minutes).

**2.3.2.1** The delivery time-limit may be less than three hours (180 minutes) depending on the time sensitivity, testing requirements and priority of the test requested. The delivery requirement will be provided with the collection requirements of the specific test.

**2.3.2.2** The Specimen Collector is solely responsible for knowing the hours of operation of the Testing Site (including any reduced or limited hours of operation) and must ensure that specimens are delivered during these hours of operation and only on regular working days, Monday to Friday. NLHS shall advise Specimen Collector of the hours of operation and/or where such information may be obtained to ensure up to date availability of the Testing Site.

**2.3.3** The Specimen Collector shall ensure specimens are delivered to the appropriate drop-off location as specified by the Specimen Collector on the application submitted to NLHS. Specimens delivered to a location not specified in the application may be rejected.

**2.3.4** NL Health Services will assess specimen delivery times at the time of drop off and those specimens that do not meet the stability or other quality criteria will not be accepted by NLHS for testing.

**2.3.5** Failure to meet established delivery time requirements or packaging requirements, may result in rejection of the specimen, cancellation of tests/procedures, and/or termination of this agreement by NLHS in accordance with section 8.2 of this Agreement.

**2.4** ***Specimen Collector Training and Competency***

**2.4.1** The Specimen Collector warrants that all persons involved in the collection of specimens have formal training in phlebotomy and other collection procedures and demonstrate ongoing competency which is comparable to the competencies required of NLHS employees engaged in similar work.

**2.4.2** The Specimen Collector must maintain records of in-house training and competencies relevant to scope of this Agreement of all persons involved in the collection, labelling, and packaging of specimens; and will, on the request of NLHS, provide proof of such training and competency during any audit undertaken as part of section 2.0.5 above.

**2.4.3** The Specimen Collector warrants that all persons involved in the collection of specimens are aware that collection must be performed in accordance with NLHS policies and procedures and in compliance with CSA Standard Z316.7 and CLSI Guideline GP41 and that failure to do so could result in termination of this Agreement pursuant to section 8.2.

**2.4.4** The Specimen Collector warrants that all of its individual Collectors have access to CLSI Guideline GP41.

**2.4.5** The Specimen Collector will ensure that employees, contractors, or agents who may be involved in the packaging, transportation and delivery of specimens have received the training required in accordance with the *Transportation of Dangerous Goods Act,* and its associated regulations and procedures.

## 2.5 *Mandatory Information and Communications*

**2.5.1** Communications under this Agreement will be accepted by e-mail by both Parties. Contact information for NLHS is as follows:

NL HEALTH SERVICES LABORATORY INFORMATION

Email to be used by NLHS for routine communications such as distribution of documents, information, and notifications, and information between NL Health Services and the Specimen Collector:

NLHS email address _____

Private patient information shall not be discussed through email.

Urgent patient safety concerns shall be communicated via the telephone numbers set out for such communications as posted on the NL Health Services laboratory website.

The contact information for the Specimen Collector shall be set out in the Application for Collectors Agreement and/or as submitted on the *External Collector Change to Information* form.

**2.5.2** The Specimen Collector must provide NL Health Services with an active e-mail address and phone number where the Specimen Collector can receive information, such as notifications and audits related to collections, packaging, transport, or adverse event reporting. Use of the e-mail address and phone number will be considered valid notice to the Specimen Collector and any changes to the e-mail address and/or phone number must be immediately communicated to the NLHS laboratory using the *External Collector Change to Information* form.

**2.5.3** The Specimen Collector is responsible for reviewing all material and information sent to the e-mail address provided and adhering to the policies and procedures thereof.

**2.5.4** When requested, the Specimen Collector is required to acknowledge receipt of e-mail notices that are in relation to non-compliances with the Agreement by return e-mail.

**2.5.5** During the term of this Agreement, the Specimen Collector agrees to update NLHS with respect to any changes to its business information or its contact information by submitting the *External Collector Change to Information* form to NLHS.

**2.5.6** The Specimen Collector will ensure that employees, contractors, or agents who may be involved in the packaging, transportation and delivery of specimens have received the training required in accordance with the *Transportation of Dangerous Goods Act,* S.C. 1992, c.34 and its associated regulations and procedures. A copy of each individual Collector's printed name and initials/signature that will be used on specimens and requisitions must be provided to the NLHS Laboratory.

**2.6** ***Noncompliance and Adverse Event Reporting***

**2.6.1** The Specimen Collector will immediately notify NLHS in writing if it becomes aware of any incidence of non-compliance or breach of the terms and conditions of this Agreement. Any such notice will be given by email.

**2.6.2** NL Health Services reserves the right to investigate non-compliance with this Agreement as per the audit provisions of this Agreement.

**2.6.3** The Specimen Collector will immediately notify by phone and email the appropriate contact at the Testing Site if the Specimen Collector becomes aware of any adverse event information related to the collection, packaging or transporting of specimens.

**2.6.4** The Specimen Collector warrants that all corrective actions related to errors and incidents of non-compliance with this Agreement are reviewed with employees and persons involved with specimen collection, packaging, transportation, and delivery.

## 3 INSURANCE

**3.0** The Specimen Collector hereby represents and warrants that it holds sufficient commercial general liability and professional liability insurance to cover its own acts and omissions and those of its employees and agents, as applicable.

**3.1** Upon signing this agreement, the Specimen Collector agrees to provide NL Health Services with a Certificate of Insurance.

## 4 INDEMNIFICATION & LIABILITY

**4.0** The Specimen Collector shall indemnify and save harmless NLHS and their affiliates, officers, employees, contractors, authorized prescribers, directors, and agents from and against all third-party claims, damages, actions, cause of actions, and expenses (including without limitation reasonable legal fees and disbursements) occasioned by, or attributable to, any act or omission of the Specimen Collector or its employee(s), agent(s), or contractor(s) in connection with this Agreement.

**4.1** NL Health Services shall indemnify and save harmless the Specimen Collector and their affiliates, officers, employees, contractors, authorized prescribers, directors, and agents from and against all third-party claims, damages, actions, cause of actions, and expenses (including without limitation reasonable legal fees and disbursements) occasioned by, or attributable to, any act or omission of NLHS or its employee(s), agent(s), or contractor(s) in connection with this Agreement.

**4.2** Except for each party's obligations of confidentiality neither party will be liable to the other party for any consequential, incidental, indirect, special, punitive,

exemplary or other similar damages, nor for any loss of revenue, income, profits, opportunity or reputation, nor for any business interruption, failure to realize expected savings or other similar damages arising out of or in connection with a breach or alleged breach of this agreement, whether based in contract, tort or any other legal theory.

**4.3** Under no circumstances will any employee, officer or director of a party have any liability to the other party for anything related to the subject matter of this agreement. Each party shall at all times remain liable for the actions of its employees, officers, and directors.

## 5 INDEPENDENT CONTRACTOR RELATIONSHIP

**5.0** NL Health Services and the Specimen Collector are each independent Parties and nothing in this Agreement constitutes any party as the employer, principal, agent, or partner of any other party. Neither party shall have any authority to assume or create any obligation or liability, either expressed or implied, on behalf of the other party. No employee, agent, or contractor of the other party shall be considered an employee of the other party.

## 6 PRIVACY AND CONFIDENTIALITY.

**6.0** The Specimen Collector, whether an individual or a company shall execute NL Health Services Privacy/Confidentiality Oath or Affirmation as provided by NLHS and as defined in the NLHS policy *Privacy and Confidentiality*.

**6.1** **"Confidential Information"** of a Party means any information provided by such Party to the other Party in connection with this Agreement and includes Intellectual Property of a Party and the terms of this Agreement and any ancillary document. The Party which receives Confidential Information from the other Party is the "Receiving Party." The Party which discloses confidential information to the other Party is the "Disclosing Party." The Receiving Party shall use the Confidential Information of the Disclosing Party only for the purpose of performing its obligations under this Agreement and shall take reasonable and prudent measures to maintain the confidentiality of Confidential Information it receives from the Disclosing Party, and such measures shall be at least as stringent as those it uses to protect its own confidential information of similar importance and sensitivity. The Receiving Party shall only disclose Confidential Information received from the Disclosing Party to those of its personnel who have a "need to know" and only for use as permitted under this Agreement or as otherwise required by Applicable Law.

**6.2** Notwithstanding the foregoing, Confidential Information shall not include: (i) information publicly disclosed by the Disclosing Party; (ii) information that is independently developed by the Receiving Party without reference to the Confidential

Information of the Disclosing Party; or (iii) information received from a third party not in breach of obligations of confidentiality.

**6.3** In the event the Receiving Party receives a subpoena, Court Order, or order from any regulator or Court of competent jurisdiction, then the Receiving Party shall, where permitted by Applicable Law, give prompt written notice to the Disclosing Party, to enable the Disclosing Party to seek a Court Order to limit the disclosure of the Disclosing Party's Confidential Information.

**6.4** The Receiving Party shall notify the Disclosing Party if the Receiving Party becomes aware of any likely or actual unauthorized use, disclosure, making available, or copying of the Disclosing Party's Confidential Information.

**6.5** The Receiving Party acknowledges that unauthorized use, disclosure, making available, or copying of the Disclosing Party's Confidential Information may cause irreparable harm to the Disclosing Party and acknowledges that the Disclosing Party may seek interim, interlocutory, or permanent injunctive relief to prevent such authorized activities.

**6.6** The Receiving Party shall at all times remain liable for any unauthorized use, disclosure, making available, or copying of the Disclosing Party's Confidential Information by any of the Receiving Party's personnel.

**6.7** The Parties shall be bound by the obligations of Confidentiality in this Section 6, for the Term of this Agreement and for five (5) years following its termination.

**6.8** Return Upon Termination. Upon expiration or termination of this Agreement for any reason each Party shall, at its option, require the other Party to either destroy or return to the Party all its Confidential Information other than a copy retained solely for legal, administrative and archiving purposes and such additional copies of, or any computer records or files containing, the Confidential Information of the Party that have been created by the other Party's standard automated electronic archiving and back-up procedures; provided, however, that (a) reasonable measures shall be taken to assure confidential treatment of such information during its retention; and (b) if requested, each Party shall certify to the other Party that it has complied with the foregoing.

## 7 MISCELLANEOUS

**7.0** The Specimen Collector is responsible to ensure that all of its employees or agents (if any) have been trained on the requirements of section 2 of this Agreement. The failure of any employee or agent of the Specimen Collector to comply with the terms of this Agreement may result in termination of this Agreement by NLHS in accordance with section 8.2 of this Agreement.

**7.1** NL Health Services may change, restrict, or limit its 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. Any such changes, restrictions or limits must be notified in advance where possible, to the Specimen Collector to ensure the Specimen Collector may adjust its deliveries as may be required.

**7.2** NL Health Services reserves the right to verify collection information and/or patient information by contacting the patient directly.

**7.3** NL Health Services will directly respond to and follow-up on any patient concerns or complaints, or any adverse event information they receive regarding the Specimen Collector's collection of specimens or operations generally.

**7.4** This Agreement shall be final and binding upon the Parties, their heirs, representatives, successors, and assigns.

**7.5** This Agreement constitutes all of the agreements between the Parties and supersedes all prior agreements, negotiations, or discussions, whether oral or written of the Parties to it.

**7.6** No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions, nor shall the waiver constitute a continuing waiver unless otherwise expressly provided.

**7.7** This Agreement may only be amended by written consent of both Parties.

**7.8** This Agreement shall be governed by and construed in accordance with the laws of the Province of Newfoundland and Labrador.

**7.9** Each Party acknowledges that it has read this Agreement, including the Schedules attached, and each party understands and agrees to be bound by its terms and conditions, and agrees that they are signing the Agreement voluntarily.

**7.10** This Agreement may be executed by facsimile or by scan and e-mail and the Parties shall recognize such execute as valid and binding.

**7.11** This Agreement may be executed in counterparts, each of which shall be deemed to be an original, and all of which together shall constitute the same Agreement.

**7.12** The signatories to this Agreement personally warrant that they have the full power and authority to enter into this Agreement and that the person signing this Agreement on behalf of each Party has been properly authorized and empowered.

## 8 TERM & TERMINATION

**8.0** This Agreement shall be effective from the date of last signature to this Agreement and shall be for a term of term of three (3) years (the "Term").

**8.1** This Agreement may be renewed upon mutual written consent of the parties for up to two (2) additional terms of three (3) years each and any renewals shall form part of the Term using the form set out in Schedule A.

**8.2** Notwithstanding anything else in this Agreement, the Specimen Collector acknowledges NL Health Services may terminate this Agreement if at its sole discretion NLHS reasonably suspects the Specimen Collector of gross negligence in relation to the terms of this Agreement, including, but not limited to, providing NLHS with false information about the Specimen Collector, its business operations, employees, or agents (if any), and specimen collection issues. NLHS will confirm termination using the *External Collector Privileges Revoked Form*.

**8.2.1** Where warranted, notice shall be given to the specimen collector to correct the nonconformities. Failing subsequent improvement, after a period of time no less than 10 days from notification, may lead to termination at the sole discretion of NLHS. Gross negligence, and failure to comply with accepted practices shall lead to termination of this Agreement. Any termination shall be documented by NLHS using the *External Collector Privileges Revoked* form.

## 9 REQUIRED DOCUMENTATION

**9.0** NL Health Services has provided the Specimen Collector with:

- Access to Relevant NLHS policies and procedures.
- Access to Test Menu for Specimen Collectors

**9.1** Specimen Collector has submitted to NL Health Services, the *Application for External Collector Permit* and attached proof of documentation as listed on the application form.

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The Parties agree to be bound by the terms of this Agreement.

**NL HEALTH SERVICES**

**Director of Pathology and Laboratory Medicine**

**Name (print):** _____

**Signature:** _____ **Date:** _____
**DD/MM/YYYY**

**SPECIMEN COLLECTOR**

**Title** _____

**Name (print):** _____

**Signature:** _____ **Date:** _____
**DD/MM/YYYY**

NL Health Services
Pathology and Laboratory Medicine

**SCHEDULE "A"**

**Request for Renewal of Agreement**

**Renewal Agreement for Acceptance of Specimens for Laboratory Testing at NL Health Services (the "Renewal Agreement)**

**Between:**

**NL HEALTH SERVICES (NLHS)**

**- and -**

_____ **("Specimen Collector")**

**WHEREAS** NL Health Services and the Specimen Collector entered into the Agreement described above, dated _____, for the acceptance by NLHS of specimens collected by the Specimen Collector, for laboratory testing; and

**WHEREAS** the Specimen Collector wishes to continue to have specimens which it collects privately processed and analyzed by the Laboratories that comprise Pathology and Laboratory Medicine within NLHS.

The Parties agree to continue to be bound by the terms of the Agreement for an additional three (3) year term commencing upon the last date of signatures affixed below:

**SPECIMEN COLLECTOR**

**Title** _____

**Name (print):** _____

**Signature:** _____ **Date:** _____
**DD/MM/YYYY**

**NL HEALTH SERVICES**

**Director of Pathology and Laboratory Medicine**

**Name (print):** _____

**Signature:** _____ **Date:** _____
**DD/MM/YYYY**