

DATE:	24 June 2024
TO:	Community Clinicians- Edmonton and North Sector
FROM:	EDM Base Lab Cytology Department
RE:	Gyne PAP Sample Submission

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Message

- To remain in accordance with legislative, accreditation, legal and regulatory requirements, as well as recognized laboratory practice, all PAP test sample vials must be labeled with the patient's first and last name, and a minimum of one, preferably two, of the following unique identifiers (in order of priority):
 - ULI (Unique Lifetime Identifier)
 - PHN (Personal Health Number)
 - Government issued identification number (Federal, Military, RCMP, Refugee, Immigration, Passport, Driver's License)
 - Medical Record Number (Hospital number, Clinic number, Unit number, Account number., Accession number)
- Please note that patient date of birth (DOB) is not considered a **unique** identifier and cannot be used as the minimum requirement on the sample vial. After September 1st, samples without the minimum unique identifier labeling requirements will be rejected, and testing will not proceed. The submitting location will be notified with the reason of the rejected sample.

Background

- The Cytology laboratory has previously been accepting sample vials labeled with only a name and date of birth. This is not in compliance with legislative requirements. After September 1st PAP vials without the minimum labeling requirements will be rejected and testing will not proceed.

How this will impact you

- After September 1, 2024, samples without the minimum labeling requirement of unique identifiers will be rejected, and testing will not proceed.

Action Required

- Please review attachments for further details.

Effective **September 1st, 2024**

Questions/Concerns

- Rebecca Nawaz, Manager, Anatomic Pathology and Cytopathology, EDM Base Lab
Rebecca.nawaz@albertaprecisionlabs.ca

Approved by

- Lorelei Bigelow, Executive Director, Hub Laboratory Services & Discipline Councils
- Dr. Erene Farag, Associate Medical Director Hub Lab North

Effective September 1, 2023, APL has become the sole provider of all public lab services in Alberta. As a result, community lab services formally provided by DynaLIFE Medical Labs will become the responsibility of Alberta Precision Labs (APL). This change impacts all zones.

TEST REQUEST MINIMUM REQUIREMENTS

SAMPLE TYPE	MAJOR REQUIREMENTS			MINOR	ADDITIONAL PREFERRED INFORMATION
				OTHER REQUIRED INFORMATION	
CLINICAL	NAME IDENTIFIER	UNIQUE IDENTIFIER	SAMPLE SPECIFIC		
General Laboratory	Patient's full first and last name (or coded name for confidential / research patients or study name or temporary ID for unknown patients).	At least one (preferably two) of the following assigned identifiers: (in order of priority): 1. ULI (Unique Lifetime Identifier) 2. Personal Health Number# (e.g. PHN) 3. Government Issued Identification Number (e.g. Federal, Military, RCMP, Refugee, Immigration, Passport, Driver's License, etc) 4. Medical Record Number (e.g. Hospital # / Clinic # / Unit # / Account # / Accession # / Research # / Subject ID/initials)	- Body site/sample type (if applicable)* - Relevant clinical history (if applicable)* - Reason for request (for qualitative toxicology testing)*	- Date of Birth (DOB) - Gender - **Collection date and time - Patient location(for patients in care facilities) - Patient phone number for non-inpatients only - Test(s) /procedure(s) ordered - Full first and last name of requester - Report location or full address of requester - Full first and last name of recipient, "copy to" recipient(s) and/or program name(s) - Location / full address of recipient, "copy to" recipient(s) and/or program - EI Number (if applicable in outbreak situations)* ♦ <u>Notifiable communicable diseases as per Public Health Act</u> -Infected persons full name, personal health number, date of birth, age, gender, full address and telephone number -The name of the disease of infecting agent -The name of the physician who ordered the laboratory test -The name of the reporting laboratory	- Priority status if other than routine - Collector ID - Phone/ fax number of requester and recipient - Physician identification number (e.g. practitioner ID) - Referral laboratory's accession number (if available) <u>Therapeutic Drug Monitoring (TDM) Samples:</u> - Time of last dose - Time of next dose - Length of time on current dosing regimen
Pathology, Cytology, Microbiology, Genetics			- Exact site (e.g. laterality, lobes, quadrants, etc), organ of origin and procedure type - Relevant clinical history ** Time tissue removed & time tissue in fixative **Collection date and time, if applicable		
Transfusion Medicine			- Transfusion Service Identification Number (TSIN) when testing is for the purpose of transfusing must be recorded on the request or collection information and must correlate with sample TSIN - ♥Collector name, initials or computer identification code must be documented when testing is for the purpose of transfusing the patient - Special requirements and relevant clinical history		<u>Transfusion Medicine</u> - Identifier (witness) ID be documented when testing is for the purposes of transfusing a patient - Required blood component / product and volume/ dosage - Date and time of request - Date and time of intended transfusion

* Refer to www.albertahealthservices.ca/lab and choose **Lab Test Directory** for additional information.

♥Documentation of the identity of the collector on the requisition, collection slip, collection tube or electronically is acceptable.

♦ Refer to the Public Health Act for additional information.

** Must appear on the sample and/or test request/requisition. When information appears on both the information must correlate.

Minor test request discrepancies may be corrected if correct information can be confirmed at the point of service with patient/healthcare card.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 1 of 10

TEST REQUEST MINIMUM REQUIREMENTS CONTINUED

SAMPLE TYPE	MAJOR REQUIREMENTS			MINOR OTHER REQUIRED INFORMATION	ADDITIONAL PREFERRED INFORMATION
	NAME IDENTIFIER	UNIQUE IDENTIFIER	SAMPLE SPECIFIC		
CLINICAL					
Newborn Metabolic Screening & Biochemical Genetics First Trimester Prenatal Screening	In addition to identifiers above AND Sonographer's full first and last name	In addition to identifiers above, AND Sonographer's operator code (indicating a valid in-date license)			
Newborn Metabolic Screening	Use name identity at time of sample collection	If ULI pending (i.e. adoption, home birth) use date of birth.	- Date and time of birth - Date and time of collection		

(continued on next page)

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 2 of 10

TEST REQUEST MINIMUM REQUIREMENTS

SAMPLE TYPE	MAJOR REQUIREMENTS			MINOR	ADDITIONAL PREFERRED INFORMATION
	NAME IDENTIFIER	UNIQUE IDENTIFIER	SAMPLE SPECIFIC	OTHER REQUIRED INFORMATION	
NON CLINICAL					
Foods and animal testing	Foods: Sample Source – e.g. Restaurant name, name of family (if from private family) Animals: Name of animal owner	Type of food (e.g. chicken, pizza) Type of animal Sample source: e.g. feces	Lot number, if applicable Expiry date, if applicable Brand, if applicable	<ul style="list-style-type: none"> - Collection date and time - Tests /procedure ordered - Full first and last name of requester - Location/full address of requester - Full first and last name of recipient, “copy to” recipient(s) and/or program name(s) - Location / full address of recipient, “copy to” recipient(s) and/or program - *EI Number (if applicable in outbreak situations) - Sample storage details (e.g. refrigerated, frozen) 	<ul style="list-style-type: none"> - Priority status if other than routine - Phone/ fax number of requester and recipient
Infection Control, Pharmaceutical , etc.	Name of submitter (e.g.: name of agency/ business)	Sample source / type (e.g. drug name)	*Relevant history (if applicable)	<ul style="list-style-type: none"> - Collection date and time - Tests /procedure ordered - Full first and last name of requester - Location/full address of requester - Full first and last name of recipient, “copy to” recipient(s) and/or program name(s) - Location / full address of recipient, “copy to” recipient(s) and/or program - *EI Number (if applicable in outbreak situations) 	<ul style="list-style-type: none"> - Priority status if other than routine - Phone/ fax number of requester and recipient - Physician identification number (e.g. practitioner ID) Referral laboratory's accession number (if available)

* Refer to www.albertahealthservices.ca/lab and choose **Test Directory** for additional information.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 3 of 10

TEST REQUEST MINIMUM REQUIREMENTS con't

SAMPLE TYPE	MAJOR REQUIREMENTS		MINOR	ADDITIONAL PREFERRED INFORMATION
	UNIQUE IDENTIFIER	SAMPLE SPECIFIC	OTHER REQUIRED INFORMATION	
ENVIRONMENTAL Water, Ice or Biological Indicator	Identification number for water or ice; Access number for Biological Indicators.	As required based on type of sample submitted; refer to www.albertahealthservices.ca/provlab and choose "Guide to Services".	As required based on type of sample submitted; refer to www.albertahealthservices.ca/provlab and choose "Guide to Services".	

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 4 of 10

SAMPLE LABELLING MINIMUM REQUIREMENTS

SAMPLE TYPE		MAJOR REQUIREMENTS		
CLINICAL	NAME IDENTIFIER	UNIQUE IDENTIFIER	OTHER REQUIRED INFORMATION	SAMPLE SPECIFIC
General Laboratory	Patient's full first and last name (or coded name for confidential / research patients or Study name or temporary ID for unknown patients).	At least one (preferably two) of the following assigned identifiers (in order of priority): 1. ULI (Unique Lifetime Identifier) 2. Personal Health Number # (e.g. PHN) 3. Government Issued Identification Number (e.g. Federal, Military, RCMP, Refugee, Immigration, Passport etc) 4. Medical Record Number (e.g. Hospital # / Clinic #/ Unit # / Account # / Accession # / Research #/ Subject ID/initials)	- **Collection date and time - *EI Number (if applicable in outbreak situations)	- Body Site/Sample Type (If Applicable) * - Collector ID (if Applicable)* -Patient's full first and last name with unique second identifier or two other unique identifiers on peripheral blood smears and parasite smears sent to an alternate site for testing or verification.
Pathology, Cytology, Microbiology, Genetics				-Exact site (e.g. laterality, lobes, quadrants, etc), organ of origin and procedure type indicated for each sample submitted (not abbreviated to just a corresponding number/letter). Note: When multiple samples are received this information must appear on both the test request and sample label and must correlate. -**tissue fixation time
Transfusion Medicine				*Transfusion Service Identification Number (TSIN) when testing is for the purpose of transfusing the patient.
Newborn Metabolic Screening				
NON-CLINICAL				
Foods and Animal Testing	Foods – sample source	Foods – type of food		
	Animals – name of owner	Animals – type of animal		
Infection Control, Pharmaceutical, etc.	Name of submitter (e.g.: name of agency/ business)	Collection date and time		
ENVIRONMENTAL		Identification number for water or ice; Access number for Biological Indicators		
Water, Ice or Biological Indicator				

*Refer to www.albertahealthservices.ca/lab and choose **Test Directory** for additional information.

** Must appear on the sample and/or test request. When information appears on both, information must correlate.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 5 of 10

SAMPLE ACCEPTANCE CRITERIA

SAMPLE TYPE	MAJOR	
	REQUIREMENTS	
	CRITERIA	SAMPLE SPECIFIC CRITERIA
General Laboratory	<ul style="list-style-type: none"> Sample accompanied by test request(s) submitted in a format approved for use by Laboratory Services Standard Requirements for test request and labelling met Test request is legible Test Request and sample labelling match Sample labeled on the primary collection container *Appropriate sample for test requested *Adequate sample quantity for test(s) requested *Proper collection (timed procedures, hemolysis, contamination, container, tube) *Proper fixation or preservation and neutralization *Proper, timely transportation (re-sealable plastic bag with external pocket, temperature, storage) Does not pose a safety risk to laboratory personnel (e.g. leaking, broken containers, sharps or sample bags not sealed) It is strongly recommended that each re-sealable, plastic bag with external pocket contain only one patient's samples. 	
Transfusion Medicine		<ul style="list-style-type: none"> Intraosseous blood samples are acceptable for ABO blood grouping only.
Pathology, Cytology, Microbiology		<ul style="list-style-type: none"> Slides must be labeled using lead pencil or insoluble ink
Genetics		<ul style="list-style-type: none"> Completed documentation for samples requiring pre-consultation / pre-counselling
Non-Clinical (Infection Control, Pharmaceutical, Animal, etc)		<ul style="list-style-type: none"> Tissue samples exempt from submission – Refer to the Exempt Tissue List (Operation of Approved Hospitals Regulation AR 247/90 s23).
Environmental (Water, Ice, Biological indicator)		

* Refer to www.albertahealthservices.ca/lab and choose **Test Directory** for additional information.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 6 of 10

MAJOR/MINOR DEFICIENCY DEFINITIONS

NOTE: Discrepancies/deficiencies of any type in standard requirements are not accepted when testing is for the purpose of transfusing a patient

TYPE	NAME IDENTIFIER	UNIQUE IDENTIFIER	OTHER
MAJOR	<ul style="list-style-type: none"> Identifier missing (unlabelled) Incomplete name (e.g. first or last name missing, initials only) First or last name completely different between sample and test request/requisition Significant misspelling where more than 2 letters are transposed or missing/added letters that changes the interpretation of the name. i.e. Olliver vs. Over 	<ul style="list-style-type: none"> Identifier missing Identifier on test request/requisition and sample do not match Numbers incorrect or missing from identifier 	<ul style="list-style-type: none"> “Standard Requirements” defined for test request/requisition and sample labelling and/or acceptance criteria not met Test request/requisition received without a corresponding sample or sample received and no test request/requisition is available
MINOR	<ul style="list-style-type: none"> Use of recognized nicknames, abbreviations, derivative names, middle name Insignificant spelling where there is a simple transposition of letters, one letter added or missing that does not change the interpretation of the name. i.e. Michael vs. Micheal Spelling is correct, but order of names is inconsistent Apostrophe or space discrepancy (Obrien vs. O'Brien or Saddleback vs. Saddle Back) Maiden vs. married last name as long as names can be reconciled Temporary baby name changed to permanent name 		<ul style="list-style-type: none"> “Other Requested Information” defined for test request/requisition not met (e.g. requester location not provided, gender incorrect etc) or discrepant between the test request/requisition and sample or between the test request/requisition and LIS Time of collection missing on sample and deemed necessary for accurate test reporting

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 7 of 10

SAMPLE EXCEPTIONS

The following exceptions may be made by laboratory personnel without medical/scientific personnel approval and in accordance with any zone or program procedures:

- Samples from invasive procedures including but not limited to:
 - Sterile body fluids/effusions and washes (amniocentesis, ascites, CSF, pericardial, peritoneal, pleural, synovial, aspirates, effusions and washes)
 - Stem cell harvests
 - Bronchoscopy samples
 - Urine obtained by Cystoscopy or Suprapubic Aspiration
 - Deep wound
 - Chorionic villus sampling (CVS) & amniotic fluid sampling
 - Samples from the Operating Room
 - Bone marrow
 - Samples collected from clinical trials or research patients where recollection may affect enrollment or treatment or may result in a lab protocol deviation
- Non re-collectable samples:
 - Anatomic Pathology samples (surgical, bone marrow, fine needle aspirates, biopsies. NOTE: does not include pap tests)
 - Parasite identification samples, excluding stool samples for microscopic ova and parasite examination
 - Entire toenail or fingernail for fungus
 - Kidney stones / renal calculi
 - Food samples
 - Medical devices for microbiological culture (e.g.: vascular catheter tips, intra-uterine devices)
 - Cases sent by the Medical Office of Health or EI for Outbreak Investigation
 - Life threatening
 - First Trimester Prenatal Screening
 - Timed samples for clinical trials or research patients where lab visits are defined by the protocol (e.g. PK collections)
- Transplant donor samples
- Cadaver or autopsy samples

Exceptions Requiring Approval Before Acceptance

The following additional exceptions may be made *in consultation with the Pathologist/Medical Lead and/or Requester*:

- Samples obtained before an intervention that might alter the result such as:
 - Timed collections (e.g. timed urines, 24 hour urines, urea breath test, sequential timed collections- tolerances, therapeutic drug monitoring, 72 hour fecal fats)
 - Blood cultures
 - Drug levels
 - Stimulation tests

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 8 of 10

- Pre-dialysis samples
- Cord blood samples from stillborns
- Cord blood samples for blood gases
- Neonatal and pediatric samples (excludes testing for the purpose of transfusing a patient)
- Tests where medication levels will be adjusted based on the test results (e.g. PT)
- Tests where the time of collection can be critical to patient care or patient management (e.g. fasting patients, fasting tests)
- Sexual assault samples collected for clinical purposes
- Samples where recollection would cause the patient undue hardship or affect continuity of care such as:
 - Samples from critically ill patients
 - Exceptional home care patient samples
 - Neonatal or pediatric samples
 - Patients with physical or mental disabilities or impairments that would make a return to the laboratory difficult
 - Recovery room, trauma, and Code Blue patients
 - Extremely difficult collections

DEFINITIONS

Access Number means a unique identifier assigned by the Environmental Laboratory linked to a particular sampling location or supply (water or ice) or a sterilizing device.

Blinded sample sometimes called a coded sample, is a sample submitted to the laboratory from clinical trials, research or clinical areas where patient confidentiality is considered very sensitive (e.g. sexual health). These samples have unique identifiers such as an alphanumeric code assigned known only to the submitters and will have no individually identifiable information. The identifying information on the test request submitted with the samples must match the sample labelling.

Clinical sample means a patient or client sample submitted to the laboratory for analysis or examination where a patient result report is generated and the result report is used for the purposes of diagnosis, treatment or monitoring.

Coded name see Blinded Sample above.

DOB means Date of Birth

Environmental sample means water, ice or biological indicator

Exposure Investigation (EI) Number means a number assigned by the Provincial Laboratory for Public Health for the purpose of tracking laboratory specimens associated to a specific event (e.g. a potential outbreak) at a specific location and time.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 9 of 10

Hazardous sample means a sample that poses a safety risk to laboratory personnel such as:

- broken or leaking containers or contaminated by breakage or leakage of other samples
- samples received in inappropriate containers (e.g. fluids in bags)
- samples in syringes with needle attached

LIS means Laboratory Information System

Non-clinical sample means a sample derived from sources other than human beings such as animal or pharmaceutical, exclusive of environmental samples

Preferred Information means information that is beneficial but is not required for sample or test request/requisition acceptance.

Primary Collection Container means the body of the innermost container received by the laboratory that actually holds the sample.

Recipient means the physician/ health care provider and/or program or individual authorized to receive results.

Requester for clinical and non-clinical samples means the individuals authorized by CPSA to request laboratory testing; for environmental samples means the authorized submitting individual / agency utilizing environmental laboratory services.

Requirement means information that must be provided and criteria that must be met before the Laboratory will accept, collect or test a sample.

Research sample means a sample obtained for the purpose of investigation or experimentation aimed at the discovery of new information, the advancement of scientific theories and development of practical applications. A patient result report is not generated and included in the patient's medical record.

Test Request means a request for testing of a laboratory sample made in either electronic (e.g. order/entry) or paper format (e.g. Laboratory requisition, physician office requisition) that is legible with clear orders (no undefined mnemonics or phone orders).

Transfusion Service Identification Number (TSIN) –an assigned number used for identification of patient and blood component as this number is utilized throughout the transfusion process, from collection to transfusion. It is displayed on the patient armband, requisition, collected samples and blood components to be transfused. This number is referred to differently dependent upon the blood services provider, e.g. RTSIS (Regional Transfusion Service Identification System), BBIN (Blood Bank Identification Number), TMID (Transfusion Medicine Identification).

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 10 of 10

Acceptance of Laboratory Samples and Test Requests Policy

Applicability	This document applies to all personnel of AHS Laboratories, the Lamont Health Centre, laboratories administered by Covenant Health, DynaLIFE Medical Labs and Canadian Blood Services Diagnostic Services Laboratory which will be referred to collectively as “Laboratory Services” or the Laboratory”.
Purpose	This policy outlines the minimum sample and test request acceptance requirements required by Laboratory Services and the follow-up actions required when clinical, non-clinical and environmental samples and tests requests do not meet these minimum requirements.
Background	Quality and accuracy of laboratory results can only be assured when samples and requests meet specific acceptability criteria. Proper sample identification and preparation, complete and legible test request information along with proper sample collection, handling and labeling are essential for client safety and valid laboratory results.
Policy	<p>Laboratory Services accepts samples and test requests and performs testing in accordance with all legislative, accreditation, legal and regulatory requirements, and recognized standards of laboratory practice. All samples and test requests received in the laboratory must be accessioned and a report issued.</p> <p>Samples delivered to the Laboratory must meet all sample labelling minimum requirements and sample acceptance criteria in order to be accepted, processed and tested (as outlined in <i>Appendix A</i>). Clinical trials, research, and certain clinical patient samples where confidentiality is considered very sensitive must meet the same acceptance criteria as other clinical samples. Blinded or coded samples must be submitted with test request identifier(s) matching the sample. Of special note, only ABO blood grouping can be performed on intraosseous blood sample. These samples are not acceptable for chemistry and hematology analysis.</p> <p>Tests requests must meet all test request minimum requirements in a format approved for use by Laboratory Services (either paper or LIS-generated electronic format) prior to sample acceptance and/or collection (as outlined in <i>Appendix A</i>). Non-standard abbreviations which could lead to errors in test or examination results, such as those used in the sample description, or on the sample label should be written out in full.</p> <p>All major sample and/or test request deficiencies are documented on a Laboratory Deficiency Resolution Request Form (AHS Form 18025 or 18026) and are recorded as a non-conforming event.</p>
Rejection	Samples with known significant personnel safety risks and health hazards are rejected unless an approved exception applies. Testing is not performed if there is any concern about patient safety as a result of unsatisfactory or sub-optimal, mislabeled or unlabeled samples or tests requisitions are received. It is strongly recommended samples and test requests for only one patient are included in each re-sealable, plastic bag with external pocket.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 1 of 6

Samples exempt from submission to the laboratory such as those on the *Exempt Tissue List* (Operation of approved Hospitals Regulation AR247/90 s23) are not required to be tested or examined.

Exceptions

Cases with minor discrepancies or deficiencies may be accepted if the test request and sample have a minimum of two acceptable identifiers that match exactly. Note: environmental samples require only one identifier on both the sample and test request.

Cases with major discrepancies or deficiencies are rejected unless an approved exception applies (refer to Acceptance of Laboratory Samples and Test Requests Policy -*Appendix A*).

Samples received with truncated names on the labels will be accepted as long as two other identifiers are present that match the requisitions exactly **except for Transfusion Medicine samples**.

Samples and/or test requests with discrepancies or deficiencies of any type are not accepted when testing is for the purpose of transfusing a patient.

Deficiency Resolution

Where an approved exception applies, corrections to information on samples or accompanying test requests are documented using the appropriate "Laboratory Deficiency Resolution Request Form" (AHS Form 18025 or 18026). Note: The policy statements related to approved exceptions and the use of the Laboratory Deficiency Resolution Form (Non-Clinical) is not applicable to environmental samples.

All exceptions authorized by the requester must receive Laboratory approval.

All original information submitted on the sample and/or test request is legibly retained. If changes are required, the original information is marked with a strike through and includes the date and initials of the person making the change.

Whenever possible, sample and original test requests are maintained in the Laboratory during deficiency resolution. The Laboratory takes measures to maintain sample integrity during problem resolution. This includes retention, possible "off line" testing and appropriate storage in the laboratory.

Samples and test requests, as well as any documentation including the "Laboratory Deficiency Resolution Request Form" will be retained following the appropriate retention schedules and guidelines.

Laboratory Reports

A report is sent to the requester and "copy to" recipient(s) where appropriate for all samples and test requests or requisitions that do not meet acceptance criteria, which includes a statement that identifies the problem and action taken.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 2 of 6

Whenever possible, the laboratory will contact the requester or patient when samples are rejected or not tested and recollection may be required.

Documentation All occurrences where samples or test requests did not meet acceptance criteria are documented using the appropriate mechanism. Adverse events resulting from deficiencies related to sample and/or test request acceptance are reported in compliance with all AHS policies.

Initial Acceptance When samples have undergone acceptance at the initial laboratory and have laboratory labels applied, and then are referred to another laboratory, these samples are not required to be reassessed for acceptance and rejection criteria by the subsequent receiving laboratory. Note: If changes are required on the reference laboratory requisition, the original information is marked with a strike through and includes the date and initials of the person making the change or a copy of the Laboratory Deficiency Resolution Request Form will be submitted.

Tracking of Acceptance Data Tracking and analysis of sample and test request acceptance indicator data is performed. Trends identified through tracking and analysis will be used to identify and prioritize opportunities for improvement.

Responsibility The requester (or designate) is responsible for:

- Ensuring the sample has met all acceptance criteria before submission to the Laboratory, and
- Authorizing correction of information for all samples where a major deficiency or discrepancy has been identified and an approved exception applies.

Medical, Scientific or Professional personnel (or designate) are responsible for approval of sample and test request or requisition exceptions when unusual circumstances not defined in this policy are identified.

Laboratory Personnel are responsible for:

- Accepting samples and tests requests only when defined criteria are met,
- Approval of sample and test requests exceptions when defined criteria are met,
- Contacting requesters and/or patients when samples and test requests are not acceptable and advising of next steps,
- Bringing concerns or unusual circumstances not identified in this policy to the attention of Medical, Scientific or Professional personnel for direction, and

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 3 of 6

- Documenting any sample acceptance nonconformances according to laboratory procedures.

Definitions

Approved exception means a sample that does not meet acceptance criteria upon arrival at the Laboratory but falls within the exception criteria defined by this policy or has been approved for processing by clinical/medical/scientific staff.

Blinded or Coded Sample is a sample submitted to the laboratory from clinical trials, research or clinical areas where patient confidentiality is considered very sensitive (e.g. sexual health) or unknown patient identity. These samples have unique identifiers such as an alphanumeric codes assigned known only to the submitters and will have no individually identifiable information. The identifying information on the test request submitted with the samples must match the sample labelling.

Client means individuals, agencies, organizations or groups who receive or have requested laboratory services. The term patient or resident may be used interchangeably for clinical clients dependent on the AHS setting.

Clinical sample means a patient or client sample submitted to the laboratory for analysis or examination where a patient result report is generated and the result report is used for the purposes of diagnosis, treatment or monitoring.

Environmental sample means water, ice or biological indicator.

Hazardous sample packaging means a sample that arrives in a way that poses a safety risk to laboratory personnel such as:

- broken or leaking containers or contaminated by breakage or leakage of other samples
- samples received in inappropriate containers (e.g. fluids in bags), or
- samples in syringes with needle attached.

Laboratory approval means acceptance of corrected sample label and/or test request/requisition information provided and authorization for testing to continue:

- For situations that meet defined criteria this means front line personnel, or
- For situations where unusual circumstances exist this means Medical, Scientific or Professional personnel or designate.

Major Discrepancy or Deficiency means samples or test requests with deficiencies or discrepancies in defined acceptance criteria:

- Name and unique identifier missing (e.g. sample unlabeled),
- Name identifier incomplete (e.g. first or last name missing, initials only),
- Name or unique identifier completely different between sample and test request,

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 4 of 6

- Significant misspelling where more than 2 letters are transposed or missing/added, letters that changes the interpretation of the name. i.e. Olliver vs. Over,
- Numbers incorrect or missing from the unique identifier,
- Identifier Information on sample and test request do not match
- Test request received without a corresponding sample or vice versa, or
- "Standard Requirements" defined for test request and sample labelling and/or acceptance criteria not met.

Minor Discrepancy or Deficiency means samples or test requests where deficiencies or discrepancies are considered not significant and information provided adequately identifies the sample or test request/requisition:

- Use of recognized nicknames, abbreviations, derivative names, middle name,
- Insignificant spelling where there is a simple transposition of letters, one letter added or missing that does not change the interpretation of the name. i.e. Michael vs. Micheal,
- Spelling is correct, but order of names is inconsistent,
- Apostrophe or space discrepancy (e.g. Obrien vs. O'Brien or Saddleback vs. Saddle Back),
- Maiden vs. married last name as long as names can be reconciled,
- "Other Requested Information" defined for test request not met (e.g. requester location not provided, gender incorrect etc.) or discrepant between test request and sample or between test request/requisition and LIS,
- Temporary baby name or identifier changed to permanent name, or
- Time of collection missing on sample and not deemed necessary for accurate test reporting.

Non-clinical sample means a sample derived from sources other than human beings such as animal or pharmaceutical, exclusive of environmental samples.

Off-line testing means testing that is performed but orders are not entered into the LIS and/or results are not released.

Personnel means all individuals who are employed or contracted within Laboratory Services.

Recipient means the physician or health care provider and/or program or individual authorized to receive results.

Requester for clinical and non-clinical samples means the individuals authorized by CPSA to request laboratory testing; for environmental samples means the authorized submitting individual or agency utilizing environmental laboratory services.

Research sample means a sample obtained for the purpose of investigation or experimentation aimed at the discovery of new information, the advancement of scientific theories and development of practical applications. A patient result report is not generated and included in the patient's medical record.

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 5 of 6

Test Request means a request for testing of a laboratory sample made in either electronic (e.g. order/entry) or paper format (e.g. Laboratory requisition, physician office requisition) that is legible with clear orders (no undefined mnemonics or phone orders).

Transfusion Service Identification Number (TSIN) – assigned number used for identification of patient and blood component as this number is utilized throughout the transfusion process, from collection to transfusion. It is displayed on the patient armband, requisition, collected samples and blood components to be transfused. This number is referred to differently dependent upon the blood services provider, e.g., RTSIS (Regional Transfusion Service Identification System), BBIN (Blood Bank Identification Number), TMID (Transfusion Medicine Identification).

Reference AHS Patient Identity Policy, current version on Insite at
<http://insite.albertahealthservices.ca/6495.asp>

Related Documents Current versions available in the Laboratory Quality Manual/ QSE Process Management/ Acceptance of Laboratory Samples & Test Requests at
<http://insite.albertahealthservices.ca/7415.asp> :

- Acceptance of Laboratory Samples and Test Requests Policy – Appendix A - PQMPMJ00004A
- Acceptance of Laboratory Samples and Test Requests Process- PQMPMX00004A

Printed copies are UNCONTROLLED unless signed by an authorized lab personnel below.

(Authorized individuals are: lab personnel designated in their zone/program or provincial role to produce print copies)

Initials:

Site:

Date Printed:

Page 6 of 6