Specimen Management in Molecular Biology

PURPOSE

To maximize patient safety, all specimens must be properly identified through the entire accessing and testing processes. Proper specimen management is critical in order to provide test results that are accurate, significant and clinically relevant. It supports both good medicine and good laboratory practice.

POLICY

A. Refer to the Laboratory Services web page for test specific patient preparation and sample collection information.
B. All specimens must be collected in appropriate sterile containers and correctly labeled.

Procedure A: Follow the activity below for proper identification of samples and requisition information

Sample Identification and Labeling

Activity	Step	Action	Related Doc
Specimen container	1	All specimens must have accurate and legible patient identification on the specimen container and on the requisition (computer generated)	Organizational policy 630.00 MB 1.02 Specimen Rejection Criteria
	2	The identification on the specimen must include two of the following approved patient identifiers: ▪ The patient's full first and last name ▪ Medical record number ▪ Patient's date of birth	
	3	If two patient identifiers are not included, reject specimen according to policy	
Test Requisition	4	The test requisition should also include: ▪ Date and time of specimen collection ▪ Laboratory test requested ▪ Specimen source/site ▪ Requesting physician/provider ▪ Identification of person collecting the sample ***Note**: If any of the above information is missing, notify patient's caregiver and obtain necessary information*	
	5	Additional useful information ▪ Gender ▪ Diagnosis	
Laboratory Information System (LIS) records	6	A unique laboratory accession number with associated electronic worksheet is assigned to each specimen. LIS information includes: ▪ The patient's full first and last name ▪ Medical record number ▪ Patient's date of birth ▪ Date and time of specimen collection ▪ Laboratory test requested ▪ Specimen source/site ▪ Requesting physician/provider ▪ Date and time of receipt ▪ Documentation of laboratory personnel performing procedures	

Activity	Step	Action	Related Doc
Accession label	7	Generate a LIS accession label and affix to primary sample with matching patient identification and any secondary containers that may be required for aliquots	Refer to assay specific procedures for additional information

Procedure B: Follow the activity below for processing samples in the laboratory

Preparation and Handling of Sample Aliquots

Activity	Step	Action	Related Doc
Identification of secondary container	1	Sample identification of all aliquots must be traceable to the primary sample	
	2	Confirm the name and accession number on the aliquot label is the same as on the primary container	
	3	Affix LIS aliquot label with corresponding accession number on secondary container	
Avoiding cross contamination	4	Handle samples to avoid cross contamination of primary and sample aliquots as follows: Step a: Deliver primary samples unopened to the molecular laboratory when possible or perform the following steps Step b: Properly label secondary container with patient aliquot label Step c: Verify name on primary and secondary container before transfer Step d: Use sterile pipettes and technique when transferring samples Step e: Aliquot one sample at a time with only one tube open at a time Step f: Never return the aliquot to the original container	Refer to assay specific procedures for additional information
High risk pathogens	5	Handle specimens from patients suspected to have high risk pathogens such as avian influenza (H5, H7, H9, etc), SARS coronavirus, MERS coronavirus or similar emerging pathogens as follows: Step a: Process clinical specimens in a class II BSC wearing gloves, gown, N95 mask and eye protection Step b: For additional information refer to: ▪ MB 2.02 Biohazardous Containment ▪ Infection Prevention and Control page on StarNet for travel associated infectious disease information and resources with links to MDH and CDC ▪ Hospital policy 1201.12 Special Airborne (Transmission-Based) Precautions ▪ CDC MERS Information for Laboratories: http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html	

Procedure C: Follow the activity below to maintain sample integrity

Specimen Transport and Storage

Activity	Step	Action	Related Doc
Sample integrity	1	Transport primary samples within the specified time after collection	Refer to tables 1 and 2
	2	Use appropriate container for transport	
	3	Store samples at conditions that ensure stability of sample integrity	

Table 1: Abbreviation

A = ambient 18 – 28° C room temperature (RT)	h = hours	m = months
R = refrigerator 2 – 8° C	d = days	w = weeks
F = freezer –20° C or colder		
Br = bronch	MRSA = methicillin resistant *S. aureus*	TE = Tris EDTA buffer
NP = nasopharynx	RSV = respiratory syncytial virus	UTM = universal transport media

Table 2: Transport and Storage Requirements

Order Code	Transport Container	Specimen requirements	Storage/Stability				Notes
			Ambient	Refrigerate	Frozen	Shipping <1day	
BORDP Bordetella PCR	▪ Sterile container ▪ BBL Mini-tip CultureSwab®Liquid Stuart's, green ▪ BBL Mini-tip CultureSwab® Amies Charcoal, green	▪ 1 Posterior nasopharyngeal swab ▪ 1.0 ml (0.5 ml minimum) respiratory wash/aspirate or bronch	5 d 4 h: Br	5 d	1 y	A, R R: Br	▪ Excess blood or mucus may interfere with testing ▪ Calcium alginate swabs are unacceptable
GASDN Group A strep PCR	BBL CultureSwab® white or red	1 Throat swab	24 h	5 d	3 m in TE	R	▪ Excess blood or mucus may interfere with testing
MRSP/SMRSP MRSA PCR	BBL CultureSwab®, white	1 Anterior nares swab	48 h	5 d		R	▪ Excess blood or mucus may interfere with testing
RIP Flu A,B & RSV PCR	▪ UTM ▪ Sterile container ▪ BBL Mini-tip CultureSwab®, green	▪ 2 Posterior nasopharyngeal swabs ▪ 1.0 ml (0.5 ml minimum) respiratory wash/aspirate	1 h	72 h in UTM	1 y in UTM	R	▪ Excess blood or mucus may interfere with testing
CDT **C. difficile PCR**	Clean Stool Container	▪ Soft or liquid stool, stool aspirate	48 h	5 d	1 – 3 m	R	▪ If frozen, samples can be thawed up to 1 X
RVP Resp. Viral Panel	▪ UTM ▪ Sterile container ▪ BBL Mini-tip CultureSwab®, green	▪ 2 Posterior nasopharyngeal swabs ▪ 1.0 ml (0.5 ml minimum) respiratory wash/aspirate or bronch	1 h	7 d in UTM	1 y in UTM	R	▪ If frozen, samples can be thawed up to 2 X

Procedure D: Follow the activity below for rejection of primary samples

Rejection Criteria

Activity	Step	Action	Related Doc
Rejection conditions	1	Criteria have been developed for acceptance or rejection of primary samples	MB 1.02 Specimen Rejection Criteria for Molecular Diagnostics Organizational policy 630.00 Laboratory Specimen Labeling
	2	Testing will not be performed if the condition of the sample does not meet criteria established for: ▪ Sample labeling ▪ Test requested ▪ Transport ▪ Storage/stability conditions	
Notification and documentation	3	Notify caregiver if sample is rejected for testing	
	4	All actions regarding sample rejection must be documented: ▪ Reason for rejection ▪ Person notified, date and time of notification	

REFERENCES

1. Andrea J. Linscott, Section editor, *Specimen Collection, Transport, and Acceptability,* 2.1. In Lynne S. Garcia (ed) *Clinical Microbiology Procedures Handbook,* Third edition 2010, American Society for Microbiology, Washington, D.C.
2. J. Michael Miller, A guide to *Specimen Management in Clinical Microbiology*, 1999, ASM Press, 1325 Massachusetts Ave NW, Washington, DC

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1.0	P. Ackerman	12.19.99	Initial Version
1.1	P. Ackerman	09.13.01	
1.2	P. Ackerman	08.28.03	
1.3	P. Ackerman	06.28.04	
1.4	P. Ackerman	07.29.05	
1.5	P. Ackerman	06.27.07	Aliquot specimens must be appropriately labeled for specimen tracking. Never return to original container
1.6	P. Ackerman	06.25.09	Revised dept. title to “Molecular Diagnostics”; reformatted, modified content to fit Molecular specifically; added hyperlinks to supporting documents. Added Specimen transport and Storage table
1.7	P. Ackerman	10.09.10	Added CT/GC, RIPST and MPVP specimen transport and collection information to table
8	P. Ackerman	09.09.11	Reformatted procedure, Changed version designation to whole number
9	P. Ackerman	09.19.12	Remove CT/GC information from Table 1, added CDT information
10	P. Ackerman	09.19.14	Removed EVNA information; Added GASD storage/transport information
11	P. Ackerman	06.29.15	Added RVP storage/transport information
12	P. Ackerman	09.11.15	Added new director review
13	P. Ackerman	01.12.16	Added Bordetella PCR assay, BORP
14	P. Ackerman	05.01.16	Added High Risk Pathogens, Proc. B 5, Uploaded to CMS
15	P. Ackerman	01.24.16	Updated RSV/Flu A, B PCR information from RIPST to RIP