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Document Contact	Wendy Frizzo: Bone and Tissue Coordinator
Area	Laboratory-Blood Bank
Applicability	Farmington Hills, Royal Oak, Troy

Receipt of Tissue Products

Document Type: Procedure

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I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the Blood Bank staff with specific guidance for inspecting tissues received into the Blood Bank. Compliance to this procedure will promote the quality of the tissue provided by the Blood Bank.

II. CLINICAL SIGNIFICANCE:

Tissues will arrive at the Blood Bank in diverse packaging, at various temperature states, and from many tissue manufacturers and distributors. Transportation of tissue may affect the integrity and can compromise tissue. Incoming tissue shall be inspected and documentation of receipt must be recorded before the tissue is accepted into the Blood Bank inventory.

III. SPECIAL SAFETY PRECAUTIONS:

Tissues are bio-hazards. Any broken packaging or compromised tissues should be handled using standard precautions.

IV. PROCEDURE:

Action	Notes
1. Inspect the shipping container for damage, the presence or absence of coolant, and shipment expiration date and time if applicable.	A. Refrigerated or frozen tissues are often received in validated shipping containers with an expiration date and time. This often appears as a neon

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	sticker on the outside of the container. B. Shipments of frozen or refrigerated tissues received without a posted expiration should be investigated by inquiring about validated shipping practices of the concerned supplier or manufacturer. C. Document any shipment concerns using the on-line internal variance form. Refer to site specific Transfusion Medicine *Variance Reporting* policy for additional information. D. Damaged tissue or tissues shipped in expired packaging should be input into the Transfusion Medicine Laboratory Information Systems (LIS) and then quarantined. Refer to Transfusion Medicine policy, *Tissue Quarantine or Discard,* for additional information.
2. Record shipment expiration and time on the packing slip, if applicable. Print the UPS or FedEx tracking form of the shipment and attach the tracking form to the packing slip.	A. This is done so that shipments are received to the Blood Bank in a timely manner. The tracking form will show the date and time the package was received on the dock. Packages should not sit on the dock more than 4 hours. If there is a delay in processing tissues in the Blood Bank computer system, time stamp the packing slip recording the date and time the graft was delivered to the Blood Bank.
3. Remove the packing slip from the shipping container and verify the shipping address.	A. Careful inspection is required. Shipping and receiving departments have inadvertently shipped and received packages that have been addressed incorrectly.
4. Inspect the packing slip and match the slip to the contents of the shipping container. Compare the alphanumeric identification number and tissue description as recorded on the packing slip to the tissue.	A. Initial, date and time stamp the packing slip as evidence of review. B. Document discrepancies using the on-line Royal Oak Blood Bank Variance

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	form. Refer to Transfusion Medicine policy, *Variance Reporting*, for additional information.
5. Inspect each tissue for: A. Legible, affixed tissue ID label B. Tissue expiration C. Package insert D. Package Integrity	A. **Label:** Description of tissue matches the tissue within the package. If the package is sealed and the tissue is not visible, assume it matches. *Do not compromise sealed packaging.* B. Expiration of corneas often include an expiration time, as well as date that should be recorded. C. If the package is sealed, do not open the graft. It can be assumed that the package insert is available for the physician. D. **Integrity:** Inspection of the package included for the following: 1. *Frozen tissue:* • No evidence of thawing. • Dry ice or liquid nitrogen is present. • No evidence of the graft penetrating the packaging. • No evidence cracks or fractures in packaging. 2. *Refrigerated tissue:* • Wet ice or coolant pack is present. • No evidence of the graft penetrating the packaging. • Protective seal is intact (corneas and sclera).

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	• No evidence of cracks or fractures in packaging. 3. *Apligraft:* • No evidence cracks or fractures in packaging. • Protective seal is intact. • Check the pH of agarose gel using the affixed color-coded pH chart. 4. *Lyophilized tissue:* • No evidence cracks or fractures in packaging. • Note any discrepancies using a site-specific internal variance form and notify management.
6. Input all tissue into the Blood Bank computer system and label the tissue package with the appropriate product code label.	A. Refer to Blood Bank Tissue CDMs, Tissue Single Delivery, *Tissue Batch Delivery*. B. All tissue, regardless of acceptable or non-acceptable condition, should be input into the Blood Bank computer system. C. Quarantine any questionable tissue in the computer and place tissue in the designated quarantine storage area until resolved. Refer to Transfusion Medicine policy, *Tissue Quarantine or Discard*, for additional information. D. Refer to the Tissue Reference Book for

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	further assistance on inputting attributes and assigning the appropriate product code label.

NOTE: Tissue brought in by sales representatives will only be accepted if the sales representative is registered with the FDA as a distributor. Tissue should be received directly from the supplier or manufacturer.

V. REFERENCES:

A. Tissue package inserts: See Tissue Supplier Qualification and Reference Manual
B. American Association of Tissue Banks, Standards, current edition
C. AABB, Standards for Blood Banks and Transfusion Services, current edition.

Approval Signatures

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Step Description	Approver	Date
	Kristina Davis: Staff Physician	3/20/2023
	Ryan Johnson: OUWB Clinical Faculty	1/18/2023
	Vaishali Pansare: Chief, Pathology	1/17/2023
	John Pui: Chief, Pathology	1/11/2023
Policy and Forms Steering Committe (if needed)	Wendy Frizzo: Bone and Tissue Coordinator	1/11/2023
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	11/29/2022
	Rebecca Thompson: Medical Technologist Lead	11/29/2022
	Karrie Torgerson: Supv, Laboratory	11/22/2022
	Teresa Lovins: Supv, Laboratory	11/22/2022
	Wendy Frizzo: Bone and Tissue Coordinator	11/11/2022
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