



The 2020 Certified Tissue Bank Specialist Examination Reference Guide

Published May 1, 2020

American Association of Tissue Banks
820 Greensboro Drive, Suite 320
McLean, VA 22102

About the Exam

The AATB Certified Tissue Bank Specialist (CTBS) Examination is comprised of 120 multiple-choice test items intended to assess the comprehensive knowledge, understanding and application of the Standards for Tissue Banking, regulations, and best practices associated with tissue banking. The exam is not limited to memorization of facts alone; rather, it is meant to assess the ability of the candidate to apply the subject materials and concepts. Study materials are not only limited to the current Standards; rather, additional study materials will be necessary to adequately prepare for the exam.

The CTBS exam does **not** include any questions related to reproductive tissue or the NADO standards.

About This Reference Guide:

The guide has been developed to direct examinees to areas of study and review of relevant documents including AATB Standards for Tissue Banking and applicable regulations, such as FDA regulations. Presentations surrounding anatomy and clinical application are not detailed throughout this document.

This guide is developed to align with the AATB 2020 CTBS Prep Course. It is recommended that examinees study all materials including, but not limited to:

- 2020 AATB CTBS Prep Course Presentations
- AATB 14th Edition Standards for Tissue Banking
- AATB Guidance Documents and Appendices
- FDA Regulations
- Relevant Anatomy

Example Question:

Authorization is obtained for musculoskeletal tissues and you are assigned to the case on April 27th at 1400. The time of death was 2300 on April 26th. The potential donor arrived to the hospital morgue and was placed in cooling at 1000 on April 27th and was removed from cooling from 1100 through 1300 for autopsy. According to AATB Standards for Tissue Banking you should:

- a. Defer tissue due to being post-autopsy.
- b. Defer tissue due to greater than 12 hours out of cooling.
- c. Defer tissue due to intermittent warm ischemic time being greater than 12 hours.
- d. Recover tissue as the current warm ischemic time is less than 15 hours.

The correct answer is **D**. Deferrals for specific conditions, such as being post-autopsy, may be processor, bank or tissue establishment specific but may not be a requirement of AATB or FDA.

Table of Contents:

- 1. Donor Eligibility**
 - a. DRAI & Core Elements of Risk Assessment
 - b. Medical Record Review
 - c. Physical Assessment
 - d. The Basics of Serology & NAT Testing
 - e. Travel, Endemic Areas & Automatic Deferrals
 - f. Plasma & Donor Cooling Criteria
 - 2. Recovery & Acquisition**
 - a. Authorization & Consent
 - b. Aseptic Technique
 - c. Donor Preparation & Recovery Site Assessment
 - d. Surgical Recovery: Skin
 - e. Surgical Recovery: Cardiac % Vascular
 - f. Surgical Recovery: MS
 - 3. Quality Assurance & Quality Systems**
 - a. AATB Accreditation
 - b. Quality System Requirements
 - c. Labeling & Storage Validation
 - 4. Tissue Processing**
 - a. Lyophilization, Cryopreservation & Processing 101
 - 5. Tissue Distribution**
 - a. Distribution
 - 6. Birth Tissue**
 - a. Overview of Birth Tissue & Relevant AATB Standards
-

Module 1: Donor Eligibility

Review the presentation “**DRAI & Core Elements of Risk Assessment,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D4.000 Donor Screening and Testing

D4.100 Donor Screening

D4.110 Age Criteria

D4.120 Physical Assessment

D4.130 Physical Examination

D4.140 Donor Risk Assessment Interview (DRAI)

D4.141 Family History and Genetic Background

D4.150 Relevant Medical Records Review

F1.000 Tissue Release

F1.100 Donor Eligibility Review

F1.110 Records for Review

F1.111 Absence of Third-Party Records

F1.112 Autopsy Report

F1.120 Infectious Disease Risk Review

F1.130 Other Medical Conditions

F1.140 Interpretation of Infectious Disease Test Results

Appendix II: Criteria for Preventing Transmission of RCDADs (Relevant Communicable Disease Agents and Diseases).

FDA Guidance for Industry

<https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Eligibility-Determination-for-Donors-of-Human-Cells--Tissues--and-Cellular-and-Tissue-Based-Products--Guidance-for-Industry.pdf>

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.50, § 1271.75

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation “**Medical Record Review & Screening,**” and reference the following standards & guidances:

AATB 14th Edition Standards for Tissue Banking

C1.000 Records Management

C1.100 General

- C1.110 Required Processing Documentation
- C1.120 Electronic Records
- C1.200 Availability for Inspection
- C1.300 Retention
- C1.400 Traceability
- C1.500 Revisions
 - D4.150 Relevant Medical Records Review
 - D5.710 Recovery Records
- F1.000 Tissue Release
 - F1.100 Donor Eligibility Review
 - F1.110 Records for Review
 - F1.111 Absence of Third-Party Records
 - F1.112 Autopsy Report
 - F1.120 Infectious Disease Risk Review
 - F1.130 Other Medical Conditions
 - F1.140 Interpretation of Infectious Disease Test Results

AATB Standards for Tissue Banking 14th Edition

Appendix II: Criteria for Preventing Transmission of RCDADs (Relevant Communicable Disease Agents and Diseases)

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.50, § 1271.75

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation, “**Plasmadilution & Donor Cooling Criteria,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D4.200 Donor Testing

D4.211 Plasma Dilution

D5.400 Time Limits for Postmortem Tissue Recovery

AATB Guidance Document No. 7. Evaluation of Body Cooling at Standard D5.400

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.80, § 1271.145, § 1271.150

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review presentation “**Physical Assessment,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D4.000 Donor Screening and Testing

D4.100 Donor Screening

D4.120 Physical Assessment

D5.700 Records

Appendix III: Tissue Donor Physical Assessment Form Requirements

AATB Guidance Document No. 1. Tissue Donor Physical Assessment Form

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.145, § 1271.150, § 1271.215

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation, “**The Basics of NAT & Serology Testing,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D4.000 Donor Screening & Testing

D4.200 Donor Testing

D4.210 Blood Specimens

D4.220 Infectious Disease Testing

D4.230 Required Infectious Disease Tests

D4.232 Disclosure and Availability of Positive Infectious Disease Test Results

D4.240 Archived Samples

D4.300 Information Sharing

AATB Guidance Document No. 3. Current Good Tissue Practices, Section III

FDA Regulations

Testing HCT/P Donors for Relevant Communicable Disease Agents and Diseases

<https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm095440.htm>

Testing Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

(HCT/P): Specific Requirements

<https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm151757.htm>

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.75, § 1271.80, § 1271.85

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation, “**Travel, Endemic Areas, & Automatic Deferrals,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D4.140 Donor Risk Assessment Interview (DRAI)

D4.220 Infectious Disease Testing

D4.240 Archived Samples

F1.120 Infectious Disease Risk Review

F1.130 Other Medical Conditions

F1.140 Interpretation of Infectious Disease Test Results

Appendix II: Criteria For Preventing Transmission of RCDADs (Relevant Communicable Disease Agents and Diseases).

FDA Guidance for Industry, Section 4

<https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Eligibility-Determination-for-Donors-of-Human-Cells--Tissues--and-Cellular-and-Tissue-Based-Products--Guidance-for-Industry.pdf>

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.145, § 1271.150

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Center for Disease Control (CDC)

<http://www.cdc.gov>

Module 2: Recovery & Acquisition

Review the presentation, “**Authorization & Consent,**” and reference the following standards, documents & guidances:

AATB Standards for Tissue Banking 14th Edition

D2.000 Authorization

D2.100 Requirements

D2.200 Conditions

D2.300 Signatures and Documentation

D2.310 Documentation of Gift

D2.320 Documentation of Authorization

D2.330 Methods of Obtaining Authorization

D2.400 Core Elements for Authorization

D2.500 Notification of Gift

D2.600 Services to Donor Families

D3.000 Informed Consent

D3.100 Requirements

D3.200 Conditions

D3.300 Signatures and Documentation

D3.310 Methods of Obtaining Informed Consent

D3.400 Core Elements for Informed Consent

D3.500 Services Involving Living Donors

AATB Guidance Document No. 3. Current Good Tissue Practices, Section II. Recovery

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.215

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation, “**Aseptic Technique,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D5.300 Tissue Recovery, Collection, and Acquisition

D5.310 Recovery

D5.500 Recovery Environment

D5.520 Recovery Cleansing and Preparation

D5.530 Recovery Technique

D5.531 Cultures Obtained at Recovery

D5.810 Post-Recovery Packaging and Labeling

D5.900 Reconstruction of a Deceased Donor’s Body

AATB Guidance Document No.2. Prevention of Contamination and Cross Contamination at Recovery: Practices and Culture Results

AATB Aseptic Technique Training Guide

Review the presentation “**Donor Preparation & Site Assessment,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

D5.000 Recovery, Collection & Acquisition

D5.200 Donor Identification

D5.210 Verification Procedures

D5.310 Recovery

D5.500 Recovery Environment

D5.510 Recovery Site Suitability Parameters

D5.520 Recovery Cleansing and Preparation

AATB Guidance Document No.2. Prevention of Contamination and Cross Contamination at Recovery: Practices and Culture Results

AATB Guidance Document No. 3. Current Good Tissue Practices, Section IV

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.215

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the Surgical Recovery of CV, MS and Skin presentations and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

- D5.000 Recovery, Collection & Acquisition
 - D5.300 Tissue Recovery, Collection, and Acquisition
 - D5.310 Recovery
 - D5.340 Pooling
 - D5.530 Recovery Technique
 - D5.531 Cultures Obtained at Recovery
 - D5.710 Recovery Records
 - D5.800 Packaging, Labeling, and Transport
 - D5.810 Post Recovery Packaging and Labeling
 - D5.900 Reconstruction of a Deceased Donor's Body

Module 3: Quality Assurance & Quality Systems

In review of the presentation, “**AATB Accreditation,**” and reference the following standards:

AATB Standards for Tissue Banking 14th Edition

- A1.000 Accreditation
 - A1.100 Failure to Comply with Standards
 - A1.200 Requesting a Variance to Standards

Review the presentation, “**Quality Systems Requirements,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

- B2.110 Quality Policy
- B2.150 Quality Assurance Program
- B2.400 Quality Assurance Program
- C1.000 Records Management
 - C1.100 General
 - C1.300 Retention
 - C1.400 Traceability
 - C1.500 Revisions
- F1.300 Quality Review
- F3.200 Technical or Quality Assurance Assessments
- K1.000 Quality Assurance Program
 - K1.100 Basic Elements
 - K1.200 Qualification, Verification, and Validation Requirements

AATB Guidance Document No. 3. Current Good Tissue Practices

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.160

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Review the presentation “**Labeling & Storage Validation,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

- K1.000 Quality Assurance Program
 - K1.200 Qualification, Verification, and Validation Requirements
 - K1.210 Validation Methods
 - K1.220 Packaging Qualification and Transport/Shipping Validation
 - K1.230 Verification Methods
 - E2.210 Environmental Control and Monitoring
 - E2.423 Storage
 - E2.424 Integrity and Sterility
 - E2.425 Visual Inspection
- E3.100 Quarantine
 - E3.110 Quarantine Areas
 - E3.120 Situations Requiring Quarantine
 - E3.130 Labeling Quarantined Tissue
 - E3.140 Quarantine Records
- E3.300 Storage Temperatures

AATB Guidance Document No. 3. Current Good Tissue Practices, Section IV, V & VIII

Current FDA Regulations: Code of Federal Regulations Title 21

§ 1271.195, § 1271.225, § 1271.250

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Module 4: Tissue Processing

AATB Standards for Tissue Banking 14th Edition

- C1.100 General
 - C1.110 Required Processing Documentation
- E1.000 Receipt of Tissue at Processing/Storage Facility
 - E1.100 Tissue Identification
 - E1.200 Pooling
- E2.00 Processing
 - E2.100 Tissue Evaluation
 - E2.200 Processing Environment
- E2.300 Tissue Contamination
- E2.400 Reagents, Supplies, Materials and Equipment
 - E2.410 Stock Rotation
 - E2.420 Containers
 - E2.421 Physical Properties
 - E2.422 Receipt of New Shipments
 - E2.510 Temperature Limits
 - E2.520 Time Limits for Pre-processing, Processing and Preservation Phases
 - E2.530 Prevention of Matrix Deterioration
 - E2.540 Additives
 - E2.610 Tolerance Limits of Processed Tissue
 - E2.612 Calcium Residuals: Demineralized Bone
 - E2.710 Lyophilization

- E2.720 Dehydration/Desiccation
- E2.730 Freezing Tissue
- E2.740 Cryopreservation
- E2.750 Chemical Preservation
- E2.810 Non-Terminal Irradiation
- E.820 Terminal Sterilization by Irradiation
- E2.830 Sterilization by Other Methods
- E2.840 Disinfection by Chemical Agents
- E2.850 Other Disinfection Agents
- E3.200 Segregation of Tissue
- K2.100 Laboratory Proficiency Testing
- K2.200 Laboratory Quality Assurance Program
- K2.300 Microbiological Tissue Cultures
 - K2.310 Pre-Sterilization/Pre-Disinfection Cultures
 - K2.320 Final/Pre-Packaging Cultures
- K2.400 Testing for Residues
- K2.500 Other Quality Control Procedures
 - K2.510 Lyophilized/Dehydrated/Desiccated Tissue
 - K2.520 Annual Calibrations
- K3.000 Microbiological Testing
 - K3.100 Microbiologic Subcultures

AATB Guidance Document No. 3. Current Good Tissue Practices, Section VII

Module 5: Tissue Distribution

Review the presentation “**Distribution,**” and reference the following standards & guidances:

AATB Standards for Tissue Banking 14th Edition

- E3.400 Expiration Date/Storage Period
- F4.000 Tissue Transfer
- H1.000 Distribution (dispensing does not apply to this exam)
- L3.000 Dispensing, Further Distribution and Disposal
- M4.000 Distribution
 - M9.200 Distribution Records

AATB Guidance Document No. 3. Current Good Tissue Practices, Section VI

Current FDA Regulations: Code of Federal Regulations Title 21

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271>

Module 6: Birth Tissue

Review the presentation “**Overview of Birth Tissue & Relevant AATB Standards**” and reference the following standards & guidances:

AATB Standards For Tissue Banking 14th Edition

A2.00 Definitions Of Terms

B1.500 Written Agreements/Contracts

D3.500 Services Involving Living Donors

D4.100 Donor Screening

D4.110 Age Criteria

D4. 130 Physical Examination

D4.140 Donor Risk Assessment Interview (DRAI)

D4.141 Family History And Genetic Background

D5.300 Tissue Recovery, Collection, And Acquisition D5.310 Recovery

D5.330 Acquisition

D5.600 Delivery Environment And Cultures Obtained Prior To Acquisition

D5.610 Delivery Environment

D5.620 Cultures Obtained Prior To Acquisition

D5.820 Post-Delivery Packaging And Labeling