

This document has been prepared and approved by members of the EBAA Exam Committee. It is intended to be used as a guide for candidates taking the Certified Eye Bank Technician Exam. The information contained in this document follows the format of the current exam content outline and is designed to highlight resources that may be used to study for the exam.

General study resources include, but are not limited to:

- EBAA Medical Standards
 - o Including appendices and glossary of terms
 - The current edition is available at <u>www.restoresight.org</u>.
- EBAA Technical Procedures Manual
 - Including glossary of terms
 - o The current edition is available at www.restoresight.org.
- Food and Drug Administration CFR 1271
 - o FDA Final Guidance for Industry: Current Good Tissue Practice (cGTP)
 - o FDA Final Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- Introduction to Eye Banking, A Handbook and Atlas, Rosenwasser and Nicholson
- Corneal Surgery and Technique, Brightbill, McDonnell, McGhee, Farjo, Serdarevic
- Berry and Kohn's Operating Room Technique, Phillips

Study Tips:

- When an EBAA Medical Standard (MS) and/or Procedure Manual (PM) section is referenced as '1.000', the entire section should be reviewed, as opposed to a specific sub-section.
- The MS and PM includes additional references for each section, which are good study resources.
- Use Tabers Medical Dictionary or an online resource to look up any unfamiliar words.
- Don't study from your eye bank's SOPs. Use original sources for practice such as CFRs or EBAA
 Medical Standards, or any source that is referenced, i.e. <u>Berry and Kohn's OR Technique</u>.



I. ANATOMY AND PHYSIOLOGY (12%)

- General Ophthalmology, Vaughn and Asbury, Lange Medical Publications, Los Altos, CA.
 Parts of the Eye, and Optics and Refraction
- Ophthalmic Assistant: A Guide to Ophthalmic Medical Personnel, Stein, Stein and Slatt, Anatomy
- Smolin and Thoft's The Cornea, Smolin, Gilbert and Thoft, Richard
- <u>Clinical Slit Lamp Biomicroscopy and Photo Slit Lamp Biomicrography</u>, Martonyi, Bahn and Meyer, Time One Ink
- Cornea Atlas, Krachmer and Palay. Elsiver Mosby: Normal Anatomy
- Ocular Surface Disease: Medical and Surgical Management, Holland and Mannis. Springer Verlag, New York. Anatomy and Physiology of the Ocular Surface.
- Internet searches, including images

a. Ocular

- i. General Characteristics As you learn the parts of the eye you should understand the following:
 - I. Location
 - 2. Anatomy / structure
 - 3. Function
 - 4. Healthy state vs. diseased state
 - 5. Age-related changes, as applicable
- ii. Parts of the Eye
 - I. Sclera
 - 2. Iris
 - 3. Ciliary body
 - 4. Choroid
 - 5. Retina
 - 6. Retinal Pigment Epithelium
 - 7. Lens
 - 8. Vitreous and Aqueous
 - 9. Conjunctiva
 - 10. Extraocular Muscles
 - 11. Optic Nerve
 - 12. Canal of Schlemm
 - 13. Pupil
 - 14. Anterior and Posterior Chambers
 - 15. Eyelid
 - 16. Glands
 - 17. Tenon's Capsule



- iii. Refractive Power of the Eye
 - I. Refractive Properties
 - a. Definition / how refraction works
 - b. Structures involved
 - 2. Refractive Errors
 - a. Myopia
 - b. Hyperopia
 - c. Presbyopia
 - d. Astigmatism
- iv. Accommodation
 - I. Theories
 - 2. Effects of age
- v. Other
- b. Cornea
 - i. General Characteristics
 - ii. Corneal Layers: Study function, relative location, thickness, etc.
 - I. Epithelium
 - 2. Bowman's Membrane
 - 3. Stroma
 - 4. Descemet Membrane
 - 5. Endothelium
 - iii. Metabolic Functions
 - iv. State of Hydration
 - v. Factors Affecting Transparency
 - I. Rejection
 - 2. Edema
 - 3. Other

II. SCIENTIFIC BASIS FOR PRACTICE (24%)

- a. Microbiology
 - i. Organisms
 - I. Gram-positive bacteria
 - 2. Gram-negative bacteria
 - 3. Optisol GS and other intermediate-preservation media coverage
 - ii. Cultures
 - EBAA PM: C3.200, G1.210
 - 1. Requirements
 - 2. Reporting
 - 3. Environmental control



- b. Quality Assurance and Control
 - i. EBAA Standardized Procedures
 - I. EBAA MS: G1.000, Appendix III
 - 2. EBAA PM: E1.110, G1.000, G1.100
 - ii. Sterilization
 - EBAA MS: C3.000, C3.300
 - EBAA PM: C3.200
 - ANSI/AAMI Standard 79:2010/A2:2011
 - I. Heat sterilization
 - a. 250 F (121 C) @ 15 psi x 30 min
 - b. 270 F (132 C) @ 30 psi x 6 min
 - 2. Chemical sterilization
 - a. Ethylene oxide
 - b. Hydrogen peroxide plasma
 - iii. Refrigeration and Temperature Recording
 - EBAA MS: C3.200
 - 2. EBAA PM: C3.100
 - 3. FDA 21 CFR 1271.200, 1271.260
 - iv. Instrument Inspection, Cleaning, and Handling
 - I. EBAA MS: C3.300
 - 2. EBAA PM: C3.300
 - 3. FDA 21 CFR: 1271.210
 - 4. ANSI/AAMI Standard 79:2010/A2:2011
 - v. Quality Assurance Monitoring
 - EBAA MS: G1.000, G1.100, M1.500
 - 2. EBAA PM: G1.000, G1.100
 - 3. EBAA PM: Guidance Document: Implementation Guidance Document, Donor Risk Assessment Interview Forms
 - 4. EBAA PM: Guidance Document: Effective Quality Assurance of the Donor Risk Assessment Interview
 - 5. FDA 21 CFR: 1271.150, 1271.160, 1271.180, 1271.320
 - 6. Elements of a QA program
 - 7. Audits
 - 8. Validation vs. Verification
 - vi. Record Keeping and Documentation
 - I. EBAA MS: C3.200, D1.300, L1.000, M1.000, M1.100, M1.400
 - 2. EBAA PM: M1.050
 - 3. FDA 21 CFR: 1271.55, 1271.190, 1271.270
 - vii. Professional Standards
 - I. Accreditation
 - a. EBAA MS: B1.000
 - b. EBAA PM: B1.000



- 2. Certification
 - a. EBAA MS: C2.000
 - b. EBAA PM: C2.000
- 3. Personnel
 - a. EBAA MS: C1.000
 - b. EBAA PM: C2.000
- 4. Reporting Requirements (change in governance, etc.)
 - a. EBAA MS: C1.400
 - b. EBAA PM: B1.000
- viii. Adverse Reaction Reports
 - EBAA MS: G1.000, M1.400, M1.500
 - 2. EBAA PM: M1.550
 - 3. EBAA PM Guidance Document Guidance Document for Investigating and Reporting Adverse Reactions to the EBAA
 - 4. FDA 21 CFR: 1271.350
- ix. Recalls and Withdrawals
 - EBAA MS: E1.300, G1.300
 - 2. EBAA PM: G1.300
 - 3. FDA 21 CFR: 1271.440
- x. Other
- c. Diseases and Epidemiology
 - i. Prevention of Disease Transmission
 - I. Aseptic Technique
 - a. EBAA MS: E1.000
 - b. EBAA PM: E1.110
 - c. FDA 21 CFR: 1271.210, 1271.215, 1271.220(a)
 - d. AORN Standards, Recommended Practices, and Guidelines
 - e. <u>Berry & Kohn's Operating Room Technique</u>: chapters vary with different editions
 - 2. Standard Precautions
 - a. EBAA MS: E1.100
 - b. EBAA PM: C3.000, E1.000
 - c. www.cdc.gov
 - 3. Laminar Flow Hood
 - a. EBAA MS: C3.200, E1.200
 - b. EBAA PM: C3.100, E1.200
 - 4. Communicable Diseases
 - a. EBAA MS: D1.000, G1.000, Appendix I
 - b. EBAA PM Guidance Documents Minimizing the Risk of Disease Transmission During Corneal Tissue Processing



- ii. Conditions of the Eye
 - I. EBAA MS: D1.100
 - 2. Common ocular pathologies, e.g. cataracts, glaucoma, etc.
- iii. Transmissible Spongiform Encephalopathies (TSE)
 - I. EBAA MS: D1.110, Appendix I
 - 2. FDA 21 CFR 1271 HCT/Ps
 - FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- iv. HIV
 - I. EBAA MS: D1.000, E1.000, G1.000, Appendix I, II, IV
 - EBAA PM: C3.600, D1.000, D1.210, E1.110, E1.140, G1.000, G1.220, G1.230, G1.280, H1.000, L2.000
 - 3. FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- v. Hepatitis
 - I. EBAA MS: D1.000, E1.000, G1.000, Appendix I, II, IV
 - 2. EBAA PM: C3.600, D1.000, D1.210, E1.110, E1.140, G1.000, G1.220, G1.240, G1.280, H1.000, L2.000
 - 3. FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- vi. Septicemia
 - I. EBAA MS Appendix I, II
 - 2. EBAA PM: D1.210
 - 3. FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- vii. Diseases of Unknown Etiology
 - I. EBAA MS: D1.110, E1.100, Appendix II
 - 2. FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- viii. Contraindications to Transplantation
 - I. EBAA MS: D1.100, Appendix I, II
 - 2. EBAA PM: D1.200
 - FDA Guidance for Industry: Eligibility Determination for Donors of HCT/Ps
- ix. Rabies
 - EBAA MS: D1.110, E1.100
- x. Retinoblastoma
 - I. EBAA MS: D1.110
- xi. Other



- III. DONOR-RELATED ISSUES (20%)
 - a. Authorization
 - i. Required Request Law (42 U.S.C.A. § 1320b-8)
 - ii. Uniform Anatomical Gift Act
 - I. www.uniformlaws.org
 - iii. Informed Authorization Procedures and Documentation
 - I. EBAA MS: D1.400
 - 2. EBAA PM: D1.300
 - b. Donor History, Screening, and Evaluation
 - i. Blood Drawing Procedures
 - I. EBAA PM: E1.140
 - ii. Serology
 - I. Tests
 - a. EBAA MS: D1.200, Appendix I, Appendix IV
 - b. EBAA PM: G1.200, G1.200
 - c. FDA 21 CFR 1271.3, 1271.80, 1271.85
 - 2. Plasma dilution
 - a. EBAA MS: D1.200, Appendix IV
 - b. FDA 21 CFR 1271.3, 1271.80, 1271.85
 - iii. Determination of Suitability
 - I. Donation
 - a. EBAA MS: E1.100
 - b. FDA 21 CFR 1271.50, 1271.75
 - 2. Transplant
 - a. EBAA MS: D1.000, Appendix I, II, III
 - b. EBAA PM Guidance Document: Effective Quality Assurance of the Donor Risk Assessment Interview
 - c. FDA 21 CFR 1271.50, 1271.75
 - iv. Legislation and Regulatory Requirements
 - I. FDA Registration
 - a. FDA 21 CFR 1271.21 1271.37
 - 2. FDA Donor Eligibility Rule
 - a. FDA 21 CFR 1271.45 1271.60, 1271.75
 - 3. FDA Good Tissue Practices
 - a. FDA 21 CFR 1271.145, 1271.150
 - 4. CMS Conditions of Participation (CoP)
 - a. FDA 42 CFR 482.45
 - 5. Other



- IV. TISSUE-RELATED PROCEDURES (20%)
 - a. Preservation of Tissue
 - i. Procedures and Methods
 - I. EBAA MS: E1.200 E1.400
 - 2. EBAA PM: E1.1.30, E1.210, E1.221
 - ii. Storage Solution
 - I. EBAA MS: E1.200 E1.400
 - 2. EBAA PM: E1.300 E1.400
 - b. Transport and Storage of Tissue
 - i. Packaging and Labeling
 - I. EBAA MS: JI.000, L2.000
 - 2. EBAA PM: JI.000, L2.000
 - 3. EBAA PM: Guidance Document: Implementation Guide, Use of ISBT 128 in North American Eye Banks
 - 4. FDA CFR 21 1271.250, 1271.370, 1271.265
 - 5. ISBT 128 ICCBBA ST-002
 - ii. Documentation Requirements
 - I. EBAA MS: L1.000, Appendix III
 - 2. EBAA PM: L1.000
 - 3. FDA CFR 1271.55, 1271.370
 - iii. Distribution of Tissue
 - I. EBAA MS: KI.000
 - 2. EBAA PM: K1.000
 - 3. FDA CFR 1271.265
 - iv. Storage
 - I. EBAA MS: II.000
 - 2. EBAA PM: 11.000
 - 3. FDA CFR 1271.260
 - c. Examination and Evaluation of Tissue
 - Introduction to Eye Banking, A Handbook and Atlas, Rosenwasser and Nicholson
 - i. Slit Lamp Biomicroscopy
 - I. EBAA MS: F1.100, F1.300
 - 2. EBAA PM: F1.100, F1.200
 - ii. Specular Microscopy
 - I. EBAA MS: F1.200
 - 2. EBAA PM: F1.300
 - iii. Other



- d. Surgical Procedures
 - YouTube is a great resource of surgical videos, just search for the type of procedure preceded by 'cornea'
 - Understand the relationship between tissue surgical suitability, i.e. endothelial cell
 density and slit lamp findings, surgical use of tissue and corresponding pre-operative
 diagnoses
 - Frederick Brightbill's Corneal Surgery and Technique
 - i. Penetrating Keratoplasty PKP
 - ii. Lamellar Keratoplasty
 - I. Anterior e.g. ALKP, DALKP, etc.
 - 2. Posterior e.g. EK, DSEK, DSAEK, DMEK, DMAEK, PDEK, etc.
 - iii. Epikeratoplasty
 - iv. Patch Graft tectonic, therapeutic
 - v. Refractive Keratoplasty
 - I. LASIK
 - 2. Photorefractive keratectomy, PRK
 - vi. Trabeculectomy
 - vii. Sclera
 - 1. How is sclera used in ocular surgery?
 - viii. Keratolimbal Allograft KLAL
 - ix. Other
- e. Use of Tissue in Education and Research
 - i. EBAA MS: H1.000
 - ii. EBAA PM: H1.000
 - iii. FDA CFR 1271.65

V. TECHNICAL PROCEDURES (24%)

- a. Whole Eye Enucleations
 - i. Preparation
 - I. EBAA MS: E1.100
 - 2. EBAA PM: E1.100, E1.110
 - ii. Equipment, Supplies, and Reagents
 - iii. Procedure
 - I. EBAA MS: E1.210
 - 2. EBAA PM: E1.120
- b. Corneal Excisions
 - i. Preparations
 - ii. Equipment, Supplies, and Reagents
 - iii. Procedure
 - I. EBAA MS: E1.220, E1.221
 - 2. EBAA PM: E1.130, E1.221



- c. Scleral Preservation
 - i. Preparations
 - ii. Equipment, Supplies, and Reagents
 - iii. Procedure
 - EBAA MS: E1.230
 EBAA PM: E1.230
- d. Tissue Processing
 - Be familiar with how eye banks process tissue after preservation, e.g. precut for DSAEK, peel for DMEK, laser processing, etc.
 - YouTube is a good source for videos on tissue preparation if your eye bank doesn't perform the procedure/s.
 - i. Preparations
 - ii. Equipment, Supplies, and Reagents
 - iii. Procedure
 - I. EBAA MS: E1.222, E1.223
 - 2. EBAA PM: E1.210, E1.222, E1.224, E1.225, E1.226
- e. Safety Issues
 - i. EBAA PM Guidance Document Minimizing the Risk of Disease Transmission During Corneal Tissue Processing
 - ii. Aseptic Technique
 - iii. Standard Precautions