

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

AABB Membership

- Must be an active Individual Member.

AND

- Must work at an AABB accredited facility.

Education Requirements

Donor, Transfusion Assessors

- Bachelors degree or equivalent in a related science

Cell Therapy Clinical Assessors

- MD, Physician's Assistant, Nurse Practitioner, BSN with patient care experience.

Cell Therapy Assessors (HPC, Cord Blood, Somatic Cell)

- Bachelors degree in a biological science

Immunoematology Reference Laboratory Assessors

- Bachelors degree or equivalent
- Must meet the requirements of a "supervisor" as defined in the current edition of *Standards for Immunoematology Reference Laboratories*

Molecular Testing Laboratory Assessors

- Bachelors degree or equivalent
- Must meet the requirements of a "laboratory supervisor" as defined in the current edition of *Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens*

Perioperative Assessors

- Minimum 2 year degree in related science

Relationship Testing Assessors

- BA/BS degree in biological science, with experience in Relationship Testing

Patient Blood Management Program Assessors

- Bachelors degree or equivalent in a related science with related experience (PBM program Medical Directorship, management, program coordinator, or program member)

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

Technical Training and Experience

Note: Direct work experience = actual experience performing technical/patient care duties

Donor Center and Transfusion Service Assessors

- Minimum **3 years** direct (hands on) work experience (a portion of which has occurred in the last 3 years).

OR

- Minimum 3 years direct work experience, which occurred over 3 years in the past AND current active involvement in a related field that allows an individual to keep informed of scientific, technical, and accrediting requirements of the activity. (Considered when applicant has had direct work experience in the past and now works in a capacity such as supervisor of operations or quality assurance)

Cellular Therapy Clinical Assessors

- Minimum of **3 years** of experience in an established clinical program (3 years of which have occurred in the last 5 years),

AND

- Program experience to include direct patient care. Program examples include, but not limited to: HPC, Cord Blood, Apheresis/Marrow Transplant Program, Pancreatic Islet Transplant Programs, other CT products,

AND

- Direct work experience with research protocols preferably as a principle investigator,

AND

- Working knowledge of investigational products desired (IND, BLA, and relevant international regulatory experience also helpful),

AND

- Maintain continuing education in the field current to the last year, i.e. specific to clinical transplant activities, patient care and research.

Cellular Therapy HPC Assessors (Procurement and Laboratory Processing)

- Minimum of **3 years** direct work experience related to HPC (Apheresis and Marrow) activities (3 years of which have occurred in the last 5 years)

AND

- Direct work experience to comprise of product procurement and/or product processing including storage and shipping requirements,

AND

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

- Maintain continuing education in the field current to the last year, i.e., specific to cellular product collection/processing activities.

Cellular Therapy Cord Blood Assessors (Procurement and Laboratory Processing)

- Minimum of **3 years** direct work experience related to Cord Blood activities (3 years of which have occurred in the last 5 years)

AND

- Direct work experience to comprise of product procurement and/or product processing including storage and shipping requirements,

AND

- Maintain continuing education in the field current to the last year, i.e., specific to cellular product collection/processing activities.

Cellular Therapy Somatic Cell Assessors (Procurement and Laboratory Processing)

- Minimum **2 years** direct work experience in a cGMP environment (a portion of which has occurred in the last 4 years),

AND

- Have IND experience and experience working with investigational products,

AND

- Maintain continuing education in the field in the last year, i.e., specific to that area

Immunoematology Reference Laboratory Assessors

- Minimum **3 years** direct work experience in an immunoematology reference laboratory (a portion of which has occurred in the last 3 years).

OR

- Active involvement in a related field that allows individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of IRL-AC).

Molecular Testing Assessors

- Minimum **2 years** direct work experience in a Molecular Testing laboratory (a portion of which has occurred in the last 2 years)

OR

- Active involvement in a related field that allows individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of MT-AC)

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

Perioperative Assessors

- Minimum **3 years** direct work experience (a portion of which has occurred in the last 3 years).

Patient Blood Management Program Assessors

- Minimum **3 years** direct work experience in a Patient Blood Management program (a portion of which has occurred in the last 3 years).

OR

- Active involvement in PBM activities that allows the individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of PBM-AC).

Relationship Testing Assessors

- Minimum **3 years** direct (hands on) work experience (a portion of which has occurred in the last 3 years).

OR

- Minimum 3 years direct work experience, which occurred over 3 years in the past AND current active involvement in a related field that allows an individual to keep informed of scientific, technical, and accrediting requirements of the activity. (Considered when applicant has had direct work experience in the past and now works in a capacity such as supervisor of operations or quality assurance)

All Assessors:

- Understanding of quality programs (Quality System Essentials), audit practices or other quality practices either through actual experience or training.

AND

- Active participation (through either a managerial or technical position) in managing a quality program, performing assessments, or having responsibilities for quality systems, process control or other quality-related practices that include cGMP related functions.

AND

- Successful completion of AABB Accreditation Program's New Assessor Training.

AND

- Successful completion of assigned trainee assessment(s) under the guidance of an approved assessor during the onsite trainee assessment.

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

Continuing Education Requirements

Must successfully recertify as an assessor by participating in the Assessor Continuing Education Program biennially.

Profile Update

Maintaining current demographic information on file with AABB through submission of the profile update biennially .

Competence Requirements

Competence will be assessed by input from the following:

- Facility feedback on assessment (Post-Assessment Questionnaire)
- Validation assessment conducted by AABB
- CMS validation results if performed within 60 days of AABB assessment (when available)
- Assessor(s) feedback on assessment (Evaluation in the Assessor Portal in APEX)
- Adherence to timeframes, completeness/clarity of assessment reports
- Biennial submission of continuing education
- Completion of Assessor Training annually

Commitment

- Must be fully vaccinated against SARS-COV2 (excluding booster shot).
- Participate in at least 2 facility assessments per year, when requested
 - Note: Some assessments may last more than 1 day and may involve travel outside of your local area
- Participate in Assessor Continuing Education Program biennially
- Completion of Profile Update biennially
- Abide by Code of Conduct for Assessors
- Abide by Confidentiality Agreement

Definition of Assessor Roles

Trainee I	Assessor who must complete first trainee assignment
Trainee II	Assessor who must complete second trainee assignment
Trainee III	Assessor who must complete trainee assignment for new activity
Team member	Assessor who participates as a member of an assessment team.
Sole	Assessor who performs assessments as the sole representative of the AABB.
Lead	Assessor who is the leader of a team of assessors.

ASSESSOR QUALIFICATIONS/REQUIREMENTS/RESPONSIBILITIES

Responsibilities While on Assignment

All assessors:

- Abide by time frames set by the accreditation program
- Review pre-assessment materials to prepare for assessment
- Perform assessment

Lead/sole assessor:

- Serves as the contact person to the facility
- Communicate and coordinate the assessment with team members (if applicable)
- Prepare and finalize the assessment summary report

Trainee

- Observes experienced assessors as they perform all aspects of the assessment
- Assists experienced assessors by applying the information obtained from new assessor training workshops to assessment process (trainees are not to work independently)
- Works with experienced assessors to complete training checklist and evaluation
- Prepares of the summary report with contribution from team members (if any)