

TECHNICAL MANUAL

SEVENTEENTH
EDITION

JOHN D. ROBACK

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Advancing Transfusion and
Cellular Therapies Worldwide

Technical Manual



17TH EDITION

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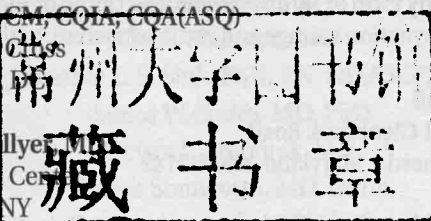
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Glossary of Abbreviations

AATB	American Association of Tissue Banks	CCI	corrected count increment
ACD	acid-citrate-dextrose	CD	clusters of differentiation
ACE	angiotensin-converting enzyme	CDC	Centers for Disease Control and Prevention
ACOG	American College of Obstetricians and Gynecologists	cDNA	complementary deoxyribonucleic acid
ADP	adenosine diphosphate	CDRH	Center for Devices and Radiological Health
AET	2-aminoethylisothiuronium	CFR	Code of Federal Regulations
AHF	antihemophilic factor	CFU	colony-forming unit
AHG	antihuman globulin	CGD	chronic granulomatous disease
AHTR	acute hemolytic transfusion reaction	cGMP	current good manufacturing practice
AIDS	acquired immune deficiency syndrome	cGTP	current good tissue practice
AIHA	autoimmune hemolytic anemia	cGy	centiGray
ALDH	aldehyde dehydrogenase	CI	confidence interval
ALT	alanine aminotransferase	CIDP	chronic inflammatory demyelinating polyneuropathy
AML	acute myelogenous leukemia	CJD	Creutzfeldt-Jakob disease
AMR	antibody-mediated rejection	CLIA	Clinical Laboratory Improvement Amendments
ANH	acute normovolemic hemodilution	CLSI	Clinical and Laboratory Standards Institute
AORN	Association of periOperative Registered Nurses	CML	chronic myelogenous leukemia
APC	antigen-presenting cell	CMS	Centers for Medicare and Medicaid Services
aPTT	activated partial thromboplastin time	CMV	cytomegalovirus
ARDP	American Rare Donor Program	CNS	central nervous system
AS	additive solution	CP2D	citrate-phosphate-dextrose-dextrose
ASFA	American Society for Apheresis	CPD	citrate-phosphate-dextrose
ASHI	American Society for Histocompatibility and Immunogenetics	CPDA-1	citrate-phosphate-dextrose-adenine-1
ATP	adenosine triphosphate	CR	complement receptor
BCR	B-cell receptor	CREG	cross-reactive group
BLA	biologics license application	CRYO	cryoprecipitate (Cryoprecipitated AHF)
BPD	biological product deviation	C/T	crossmatch/transfusion
BSA	bovine serum albumin or body surface area	CV	coefficient of variation
BSC	biological safety cabinet	DAF	decay-accelerating factor
BSL-1	Biosafety Level 1	DAT	direct antiglobulin test
CAP	College of American Pathologists	DDAVP	deamino-D-arginine vasopressin
CAS	cold agglutinin syndrome	DHQ	donor history questionnaire
CBER	Center for Biologics Evaluation and Research	DHTR	delayed hemolytic transfusion reaction

DIC	disseminated intravascular coagulation	HBsAg	hepatitis B surface antigen
DMSO	dimethylsulfoxide	HBV	hepatitis B virus
DNA	deoxyribonucleic acid	Hct	hematocrit
DOT	(US) Department of Transportation	HCT/PS	human cells, tissues, and cellular and tissue-based products
2,3-DPG	2,3-diphosphoglycerate	HCV	hepatitis C virus
DRG	diagnosis-related group	HDFN	hemolytic disease of the fetus and newborn
DSTR	delayed serologic transfusion reaction	HES	hydroxyethyl starch
DTT	dithiothreitol	HHS	(US) Department of Health and Human Services
EACA	epsilon aminocaproic acid	HIT	heparin-induced thrombocytopenia
EBAA	Eye Bank Association of America	HIV	human immunodeficiency virus
ECMO	extracorporeal membrane oxygenation	HNA	human neutrophil antigen
ECV	extracorporeal volume	HPA	human platelet antigen
EDTA	ethylenediaminetetraacetic acid	HPC	hematopoietic progenitor cell
EIA	enzyme immunoassay	HPC(A)	HPCs from apheresis (HPC, Apheresis)
ELBW	extremely low birthweight	HPC(C)	HPCs from cord blood (HPC, Cord Blood)
ELISA	enzyme-linked immunosorbent assay	HPC(M)	HPCs from marrow (HPC, Marrow)
EMAs	emergency management agencies	HSC	hematopoietic stem cell
EPO	erythropoietin	HSCT	hematopoietic stem cell transplantation
FACT	Foundation for the Accreditation of Cellular Therapy	HTLV-I	human T-cell lymphotropic virus, type I
FcR	Fc gamma receptor	HTR	hemolytic transfusion reaction
FDA	Food and Drug Administration	HUS	hemolytic uremic syndrome
FFP	Fresh Frozen Plasma	IAT	indirect antiglobulin test
FMH	fetomaternal hemorrhage	IATA	International Air Transport Association
FNAIT	fetal/neonatal alloimmune thrombocytopenia	ICAM-1	intercellular adhesion molecule-1
FNHTR	febrile nonhemolytic transfusion reaction	ID	identification or individual donation
FTA-ABS	fluorescent treponemal antibody absorption test	Ig	immunoglobulin
G-CSF	granulocyte colony-stimulating factor	IL-1 α	interleukin-1 alpha
GalNAc	N-acetylgalactosamine	IL-1 β	interleukin-1 beta
GM-CSF	granulocyte-macrophage colony-stimulating factor	IL-2	interleukin-2
GMP	good manufacturing practice	IM	intramuscular
GPIa	glycoprotein Ia	IND	investigational new drug
GPA	glycophorin A	INR	international normalized ratio
GPB	glycophorin B	IRL	immunohematology reference laboratory
GPC	glycophorin C	IS	immediate spin
GPD	glycophorin D	ISBT	International Society of Blood Transfusion
GTP	good tissue practice	ISO	International Organization for Standardization
GVHD	graft-vs-host disease	ITP	immune thrombocytopenia
Gy	Gray	IU	international unit
HAV	hepatitis A virus	IV	intravenous
HAZMAT	hazardous material	IVIG	intravenous immune globulin
Hb	hemoglobin	LDH	lactate dehydrogenase
HBc	hepatitis B core antigen		

LDL	low-density lipoprotein	QC	quality control
LISS	low-ionic-strength saline	QSE	Quality System Essential
LN ₂	liquid nitrogen	RBCs	Red Blood Cells (blood donor unit)
LR	leukocyte-reduced	RFLP	restriction fragment length polymorphism
MAC	membrane attack complex	rFVIIa	recombinant Factor VIIa
2-ME	2-mercaptoethanol	Rh	Rhesus factor
MF	mixed field	RHAG	Rh-associated glycoprotein
MHC	major histocompatibility complex	RhIG	Rh Immune Globulin
MNC	mononuclear cell	RIBA	recombinant immunoblot assay
MoAb	monoclonal antibody	RIPA	radioimmunoprecipitation assay
MPHA	mixed passive hemagglutination assay	RNA	ribonucleic acid
mRNA	messenger ribonucleic acid	RPR	rapid plasma reagin (serologic test for syphilis)
MSDS	material safety data sheet	RT	room temperature or reverse transcriptase
MSM	males who have sex with other males	SCF	stem cell factor
NAIT	neonatal alloimmune thrombocytopenia	SD	standard deviation or solvent/detergent
NAN	neonatal alloimmune neutropenia	SNP	single nucleotide polymorphism
NAT	nucleic acid testing	SOP	standard operating procedure
NHLBI	National Heart, Lung, and Blood Institute	SPRCA	solid-phase red cell adherence
NIH	National Institutes of Health	TA	transfusion-associated
NIPA	nonimmunologic protein adsorption	TACO	transfusion-associated circulatory overload
NK	natural killer	TCR	T-cell receptor
NMDP	National Marrow Donor Program	TMA	transcription-mediated amplification
NRC	Nuclear Regulatory Commission	TNCs	total nucleated cells
NRF	National Response Framework	TNF- α	tumor necrosis factor alpha
OSHA	Occupational Safety and Health Administration	TPE	therapeutic plasma exchange
p	probability	TPO	thrombopoietin
PAD	preoperative autologous (blood) donation	TRALI	transfusion-related acute lung injury
PBS	phosphate-buffered saline	TSE	transmissible spongiform encephalopathy
PCH	paroxysmal cold hemoglobinuria	TTP	thrombotic thrombocytopenic purpura
PCR	polymerase chain reaction	UCB	umbilical cord blood
PEG	polyethylene glycol	UDP	uridine diphosphate
PF24	Plasma Frozen Within 24 Hours After Phlebotomy	UNOS	United Network for Organ Sharing
PPE	personal protective equipment	USC	United States Code
PRA	panel-reactive antibody	vCJD	variant Creutzfeldt-Jakob disease
PRCA	pure red cell aplasia	VLBW	very low birthweight
PRP	platelet-rich plasma	vWD	von Willebrand disease
PRT	pathogen reduction technology	vWF	von Willebrand factor
PT	prothrombin time or proficiency testing	WAIHA	warm autoimmune hemolytic anemia
PTP	posttransfusion purpura	WB	whole blood or Western blot
PTT	partial thromboplastin time	WBC	white blood cell
PVC	polyvinyl chloride	WHO	World Health Organization
QA	quality assessment or quality assurance	WNV	West Nile virus

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Preface

Acknowledgments

THE 17TH EDITION OF the *Technical Manual* was the work of many dedicated individuals. In addition to the chapter authors, I would like to thank my three associate editors: Brenda Grossman, Teresa Harris, and Chris Hillyer. Their efforts and long hours in revising and rewriting chapters during the review process made my job immeasurably easier. Teresa, in particular, took the lead in revising the methods sections, a job she is eminently more qualified to undertake than I. If you enjoy the content of the 17th edition, all credit should go to the associate editors and the authors. Laurie Munk, Jennifer Boyer, Jay Pennington, and their colleagues are an unmatched publication resource. Their knowledge of transfusion medicine is encyclopedic, matched only by their grammatical acumen. If the text reads well, it is due to their efforts. Should you find problems with the 17th edition, however, the blame resides with me.

We would also like to acknowledge the members of the following committees and program units for their expert review of chapters, methods, and appendices for the 17th edition of the *Technical Manual*.

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Finally, we would like to thank the editors, authors, and program unit members of the 16th and earlier editions of the *Technical Manual* for selected tables, figures, methods, and written sections of the chapters that could not be improved upon, and thus were used again in the 17th edition.

John D. Roback, MD, PhD
Chief Editor

Preface

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THE EDITORS ARE pleased to present the 17th edition of the *Technical Manual*. This is the second edition to use the revised format, which includes listing authorship for each chapter. In preparing the 17th edition, we carefully considered the comments received after publication of the 16th edition, both from readers and from authors. Many believed that the new format was successful in bringing the necessary levels of expertise to the preparation of each chapter. However, they also suggested a number of changes that have now been incorporated into the present edition. For example, Chapter 10 was expanded through the addition of several pages of basic and applied immunology as a primer for later immunohematology chapters. A section on hemovigilance was added to Chapter 27 in keeping with AABB's expanding commitment to this important quality and safety activity. Another significant change was the inclusion of several "Key Points" at the end of each chapter, which should be useful for both students and experienced readers alike.

We believe that with the revised format a modest amount of author rotation is beneficial. Thus, for the 17th edition we recruited new authors for three chapters; additional authorship changes were also made for five other chapters. These changes should help to keep the text of the 17th edition fresh while also maintaining continuity with earlier editions.

One aspect of the *Technical Manual* that has not changed is the commitment of the AABB and the editors to extensive, multi-layered technical review. Each chapter was reviewed and revised at least twice by an editor. The chapters were also submitted to sub-

ject matter-appropriate committees for detailed content review (see list in Acknowledgments). All chapters were then subjected to additional regulatory, AABB standards, legal, and editorial review prior to publication. Finally, as noted above, many highly knowledgeable readers functioned as an ad hoc "post-publication" review committee for the 16th edition by bringing errors and omissions to the editors' notice. We have carefully considered each of the issues that was raised and where appropriate included revised text in the 17th edition. Because the field of blood banking, transfusion medicine, and cellular therapy is complex, detail-oriented, and continues to evolve, we once again invite all readers to contact us if they should find omissions, errors, and inconsistencies in the 17th edition, or if they would like to suggest ways to improve the next edition of the *Technical Manual*. We value your opinions and look to the readership for assistance in keeping this valuable resource up to date with our dynamically evolving field.

It is important for readers to realize that, in the opinions of the chapter authors and the editors, the methods chosen for inclusion in the 17th edition represent best technical practices. However, these methods are not the only approaches that fulfill the requirements of *AABB Standards*; readers may choose to use other approaches. Furthermore, should you find that any method or statement in the *Technical Manual* is in conflict with the *Standards*, the authority of the *Standards* supersedes that of the *Technical Manual*.

John D. Roback, MD, PhD
Chief Editor

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