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Platelet Function Testing by Aggregometry; Approved Guideline

This document provides concrete, standard procedures for using aggregometry to assess platelet function in patient specimens with the intent to achieve greater uniformity of results.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Platelet Function Testing by Aggregometry; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document H58-A—*Platelet Function Testing by Aggregometry; Approved Guideline* provides concrete, standard procedures for using aggregometry to assess platelet function in patient specimens and samples, with the intent to achieve greater uniformity of results by laboratories following these guidelines. Descriptions of light transmission aggregometry, whole blood impedance aggregometry, and shear-flow technologies are provided so both long-time and new users may establish consistent, reproducible platelet function testing programs in their laboratories.

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Foreword

Platelets play a vital role in hemorrhagic, thrombotic, and vascular ischemic disorders. Antiplatelet therapy (APT) is regarded as "the cornerstone of treatment" for various coronary conditions,[1] giving dramatic rise to the introduction of new antiplatelet drugs. This in turn has increased the interest among clinicians and laboratorians to use various tests of platelet function. One such method is platelet aggregometry, a common technology that has been part of clinical laboratory practice for over 40 years. Yet, surprisingly, platelet aggregometry has largely been performed without globally accepted performance standards. Consequently, customized procedures and reagents are frequently used, often making it difficult to obtain consistent results.

This guideline provides concrete, standard procedures for using aggregometry to assess platelet function in patient specimens and samples with the intent to achieve greater uniformity of results by laboratories following these guidelines. Descriptions of light transmission aggregometry (LTA), whole blood impedance aggregometry, and shear-flow technologies are provided so both long-time and new users may establish consistent, reproducible platelet function testing programs in their laboratories. Laboratories are advised to consult the instrument manufacturer regarding country-specific registration and/or clearance, eg, US Food and Drug Administration 510(k) clearance, CE mark.

Key Words

Antiplatelet therapy (APT), impedance aggregometry, light transmission aggregometry (LTA), low and high shear, platelet activation, platelet aggregation, platelet function testing

Platelet Function Testing by Aggregometry; Approved Guideline

1 Scope

This guideline specifies requirements/recommendations for specimen collection, preexamination considerations, patient preparation, sample processing, testing, result analysis, and quality control (QC) in relation to platelet function testing by aggregometry using light transmission aggregometry (LTA), whole blood impedance aggregometry as well as low and high shear technologies. It covers anticoagulants, specimen storage and transport temperatures, sample selection for various methodologies, establishment of reference intervals, result reporting, result analysis, assay validation, and troubleshooting. The intended users of this guideline are clinicians, hospital and reference laboratorians, manufacturers, and regulatory agencies. This guideline is not intended for use with global hemostasis, platelet counting, flow cytometry, home testing, point-of-care, or research systems. This guideline does not address therapeutic guidance or interpretive guidelines.

2 Introduction

Platelet function testing has been a part of clinical laboratory practice since early in the 20th century. Hundreds of publications have defined healthy and pathologic platelet activity using numerous methodologies, such as the *in vivo* bleeding time, platelet aggregometry techniques, measurement of granular content and release, assessment of membrane surface markers, evaluation of signaling pathways, and *in vivo* platelet survival. Yet, despite this vast wealth of information, no clear direction exists to guide setting minimum performance standards among laboratories performing platelet function testing. Establishing such a path is critical, given the role of platelets in both hemorrhagic and thrombotic conditions and the rising significance of antiplatelet therapy (APT) in controlling platelet function across a broad spectrum of vascular disorders. The goal of this guideline is to set minimum requirements for the performance of platelet function testing when using LTA, whole blood impedance aggregometry, and shear-flow technologies.

3 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.[2] For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to CLSI document M29.[3]

4 Terminology

4.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all challenges to harmonization. In light of this,

Related CLSI Reference Materials*

C28-A3 **Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (2008).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.

GP29-A2 **Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition (2008).** This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

H01-A5 **Tubes and Additives for Venous Blood Specimen Collection; Approved Standard—Fifth Edition (2003).** This document contains requirements for venous blood collection tubes and additives, including technical descriptions of ethylenediaminetetraacetic acid (EDTA), sodium citrate, and heparin compounds used in blood collection devices.

H03-A6 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition (2007).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

H18-A3 **Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition (2004).** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

H21-A5 **Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition (2008).** This document provides procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and general recommendations for performing the tests.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

NOTES

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Memorial Regional Hospital (FL)
Mercy Hospital (ME)
Methodist Dallas Medical Center (TX)
Methodist Hospital (Houston, TX)
Methodist Hospital (San Antonio, TX)
Methodist Hospital Pathology (NE)
MetroHealth Medical Center (OH)
Metropolitan Hospital Center (NY)
Metropolitan Medical Laboratory, PLC (IA)
The Michener Inst. for Applied Health Sciences (Canada)
Mid Michigan Medical Center – Midland (MI)
Middelheim General Hospital (Belgium)
Mike O'Callaghan Federal Hospital (NV)
Mississippi Baptist Medical Center (MS)
Mississippi Public Health Lab (MS)
Monongalia General Hospital (WV)
Montreal General Hospital (Quebec, Canada)
Mt. Sinai Hospital - New York (NY)
MuirLab (CA)
National Cancer Center (S. Korea)
National Healthcare Group (Singapore)
National Institutes of Health, Clinical Center (MD)
National Naval Medical Center (MD)
National University Hospital Department of Laboratory Medicine (Singapore)
Nationwide Children's Hospital (OH)
Naval Hospital Great Lakes (IL)
Naval Hospital Oak Harbor (WA)
Naval Medical Center Portsmouth (VA)
NB Department of Health (Canada)
The Nebraska Medical Center (NE)
New England Baptist Hospital (MA)
New England Fertility Institute (CT)
New Lexington Clinic (KY)
New York Presbyterian Hospital (NY)
New York University Medical Center (NY)
Newark Beth Israel Medical Center (NJ)
Newton Memorial Hospital (NJ)
North Carolina Baptist Hospital (NC)
North Coast Clinical Laboratory, Inc. (OH)
North District Hospital (Hong Kong, China)
North Mississippi Medical Center (MS)
North Shore Hospital Laboratory (New Zealand)
North Shore-Long Island Jewish Health System Laboratories (NY)
Northridge Hospital Medical Center (CA)
Northside Hospital (GA)
Northwest Texas Hospital (TX)
Northwestern Memorial Hospital (IL)
Norton Healthcare (KY)
Ochsner Clinic Foundation (LA)
Ohio State University Hospitals (OH)
Onze Lieve Vrouw Ziekenhuis (Belgium)
Ordre Professionel des Technologistes Medicaux du Quebec (Quebec, Canada)
Orebro University Hospital (Sweden)
Orlando Regional Healthcare System (FL)
Ospedale Casa Sollievo Della Sofferenza – IRCCS (Italy)

The Ottawa Hospital (Canada)
Our Lady of Lourdes Medical Center (NJ)
Our Lady of Lourdes Reg. Medical Ctr. (LA)
Our Lady's Hospital for Sick Children (Ireland)
Palmetto Health Baptist Laboratory (SC)
Pathlab (IA)
Pathology and Cytology Laboratories, Inc. (KY)
Pathology Associates Medical Laboratories (WA)
Pathology Associates of Boone (NC)
Penn State Hershey Medical Center (PA)
Pennsylvania Hospital (PA)
The Permanente Medical Group (CA)
Peterborough Regional Health Centre (Canada)
Piedmont Hospital (GA)
Pitt County Memorial Hospital (NC)
Prairie Lakes Hospital (SD)
Presbyterian Hospital – Laboratory (NC)
Presbyterian Hospital of Dallas (TX)
Presbyterian/St. Luke's Medical Center (CO)
Prince County Hospital (Canada)
Providence Alaska Medical Center (AK)
Providence Health Care (Canada)
Provincial Health Services Authority (Vancouver, BC, Canada)
Provincial Laboratory for Public Health (Edmonton, AB, Canada)
Queen Elizabeth Hospital (Canada)
Queen Elizabeth Hospital (China)
Queensland Health Pathology Services (Australia)
Quest Diagnostics, Inc
Quest Diagnostics Laboratories (WA)
Quincy Hospital (MA)
Rady Children's Hospital San Diego (CA)
Redington-Fairview General Hospital (ME)
Regional Health Authority Four (RHA4) (Canada)
Regions Hospital (MN)
Reid Hospital & Health Care Services (IN)
Renown Regional Medical Center (NV)
Research Medical Center (MO)
Riverside Regional Medical Center (CA)
Riyadh Armed Forces Hospital, Sulaymainia (Saudi Arabia)
Robert Wood Johnson University Hospital (NJ)
Rockford Memorial Hospital (IL)
Roxborough Memorial Hospital (PA)
Royal Victoria Hospital (Canada)
Rush North Shore Medical Center (IL)
SAAD Specialist Hospital (Saudi Arabia)
Sacred Heart Hospital (FL)
Sacred Heart Hospital (WI)
Sahlgrenska Universitetssjukhuset (Sweden)
Saint Francis Hospital & Medical Center (CT)
Saint Mary's Regional Medical Center (NV)
Saints Memorial Medical Center (MA)
St. Anthony Hospital (OK)
St. Anthony's Hospital (FL)
St. Barnabas Medical Center (NJ)
St. Elizabeth Community Hospital (CA)
St. Eustache Hospital (Canada)
St. Francis Hospital (SC)
St. John Hospital and Medical Center (MI)
St. John's Hospital (IL)
St. John's Hospital & Health Ctr. (CA)
St. John's Mercy Medical Center (MO)
St. John's Regional Health Center (MO)
St. Joseph Health Center (MO)
St. Joseph Mercy Hospital (MI)
St. Joseph's Medical Center (CA)
St. Joseph's Regional Medical Center (NJ)
St. Jude Children's Research Hospital (TN)
St. Louis University Hospital (MO)
St. Luke's Hospital (IA)
St. Luke's Hospital (PA)
St. Martha's Regional Hospital (Canada)
St. Mary Medical Center (CA)
St. Mary's Hospital (WI)
St. Tammany Parish Hospital (LA)
Sampson Regional Medical Center (NC)
Samsung Medical Center (Korea)
San Francisco General Hospital-University of California San Francisco (CA)
San Juan Regional Medical Group (NM)
Sanford USP Medical Center (SD)
Santa Clara Valley Medical Center (CA)
Saudi Aramco Medical (Saudi Arabia)
Schneck Medical Center (IN)
Scott & White Memorial Hospital (TX)
Scott Air Force Base (IL)
Seoul National University Hospital (Korea)
Seton Medical Center (CA)
Sheik Kalifa Medical City (UAE)
Shore Memorial Hospital (NJ)
Shriners Hospitals for Children (SC)
Singapore General Hospital (Singapore)
SJRMC Plymouth Laboratory (IN)
Sky Lakes Medical Center (OR)
South Bend Medical Foundation (IN)
South Miami Hospital (FL)
Southern Health Care Network (Australia)
Southern Maine Medical Center (ME)
Speare Memorial Hospital (NH)
Spectrum Health - Blodgett Campus (MI)
Stanford Hospital and Clinics (CA)
State of Connecticut Department of Public Health (CT)
State of Hawaii Department of Health (HI)
State of Washington-Public Health Labs (WA)
Stillwater Medical Center (OK)
Stony Brook University Hospital (NY)
Sudbury Regional Hospital (Canada)
Suncoast Medical Clinic (FL)
Sunnybrook Health Science Center (ON, Canada)
Sunrise Hospital and Medical Center (NV)
Sydney South West Pathology Service Liverpool Hospital (Australia)
T.J. Samson Community Hospital (KY)
Taipei Veterans General Hospital (Taiwan)
Taiwan Society of Laboratory Medicine (Taiwan)
Tallaght Hospital (Ireland)
Tartu University Clinics (Estonia)
Texas Children's Hospital (TX)
Texas Department of State Health Services (TX)
Thomason Hospital (TX)
Timmins and District Hospital (Canada)
The Toledo Hospital (OH)
Touro Infirmary (LA)
Tri-Cities Laboratory (WA)
Trident Medical Center (SC)
Trinity Medical Center (AL)
Tripler Army Medical Center (HI)
Tufts New England Medical Center Hospital (MA)
Tulane Medical Center Hospital & Clinic (LA)
Turku University Central Hospital (Finland)
UC Davis Health System (CA)
UCI Medical Center (CA)
UCLA Medical Center Clinical Laboratories (CA)
UCSD Medical Center (CA)
UCSF Medical Center China Basin (CA)
UMass Memorial Medical Center (MA)
UMC of Southern Nevada (NV)
UNC Hospitals (NC)
Union Clinical Laboratory (Taiwan)
United Christian Hospital (Hong Kong)
United Clinical Laboratories (IA)
Unity HealthCare (IA)
Universita Campus Bio-Medico (Italy)
University College Hospital (Ireland)
University Hospital Center Sherbrooke (CHUS) (Canada)
University Medical Center at Princeton (NJ)
University of Alabama Hospital Lab (AL)
University of Arkansas for Medical Sci. (AR)
University of Chicago Hospitals (IL)
University of Colorado Health Sciences Center (CO)
University of Colorado Hospital (CO)
University of Iowa Hospitals and Clinics (IA)
University of Kentucky Med. Ctr. (KY)
University of Maryland Medical System (MD)
University of Miami (FL)
University of MN Medical Center - Fairview (MN)
University of MS Medical Center (MS)
University Pittsburgh Med. Ctr. (PA)
University of So. Alabama Children's and Women's Hospital (AL)
University of Texas Health Center (TX)
The University of Texas Medical Branch (TX)
University of the Ryukyus (Japan)
University of Virginia Medical Center (VA)
University of Washington (WA)
UPMC Bedford Memorial (PA)
U.S. Naval Hospital (FPO AP)
US Naval Hospital Naples (FPO)
U.S.A. Meddac (Pathology Division) (MO)
UW Hospital (WI)
UZ-KUL Medical Center (Belgium)
VA (Asheville) Medical Center (NC)
VA (Bay Pines) Medical Center (FL)
VA (Biloxi) Medical Center (MS)
VA (Chillicothe) Medical Center (OH)
VA (Cincinnati) Medical Center (OH)
VA (Dayton) Medical Center (OH)
VA (Decatur) Medical Center (GA)
VA (Indianapolis) Medical Center (IN)
VA (Long Beach) Medical Center (CA)
VA (Miami) Medical Center (FL)
VA New Jersey Health Care System (NJ)
VA Outpatient Clinic (OH)
VA (San Diego) Medical Center (CA)
VA (Seattle) Medical Center (WA)
VA (Sheridan) Medical Center (WY)
Valley Health (VA)
Vancouver Coastal Health Regional Laboratory (BC, Canada)
Vancouver Island Health Authority (SI) (Canada)
Vanderbilt University Medical Center (TN)
Via Christi Regional Medical Center (KS)
Virga Jessezieukenhuis (Belgium)
Virtua - West Jersey Hospital (NJ)
WakeMed (NC)
Walter Reed Army Medical Center (DC)
Warren Hospital (NJ)
Washington Hospital Center (DC)
Waterbury Hospital (CT)
Waterford Regional Hospital (Ireland)
Wayne Memorial Hospital (NC)
Weirton Medical Center (WV)
West China Second University Hospital, Sichuan University (P.R. China)
West Valley Medical Center Laboratory (ID)
Western Baptist Hospital (KY)
Western Healthcare Corporation (Canada)
Wheaton Franciscan & Midwest Clinical Laboratories (WI)
Wheeling Hospital (WV)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
William Osler Health Centre (Canada)
Winchester Hospital (MA)
Winn Army Community Hospital (GA)
Wisconsin State Laboratory of Hygiene (WI)
Wishard Health Sciences (IN)
Womack Army Medical Center (NC)
Woodlawn Hospital (IN)
York Hospital (PA)

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