Status **Active** PolicyStat ID **16378836**

Beaumont

Origination	7/14/2020
Last Approved	9/27/2024
Effective	9/27/2024
Last Revised	9/27/2024
Next Review	9/27/2026

Document Contact	Michele Sedlak: Lab Quality Coord
Area	Laboratory-Quality
Applicability	All Beaumont Hospitals
Key Words	GEN.20374

Laboratory Policy for Compliance with Applicable Federal, State and Local Laws and Regulations

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. The purpose of this policy is to guide laboratory personnel to recognize the necessity of complying with all applicable regulations that may affect laboratory operations.

B. The Corporate Compliance department of Beaumont Health has defined *compliance* as "conducting... business in a l**egal** and **ethical** manner." It is expected that *every* laboratory employee will responsibly comply with federal, state and local regulations that may impact this corporation.

II. POLICY STATEMENT:

It is the policy of this laboratory that *every* employee is to comply with all applicable local, state and federal laws and regulations. This policy is supported by the written Corewell Health East Laboratory Compliance Plan. The laboratory may obtain further information on applicable state and local laws and regulations from multiple additional sources including, the corporate management policies, state medical societies, the Michigan Department of Community Health, and through federal agencies.

III. DEFINITIONS:

A. **CMS – Centers for Medicare and Medicaid Services**: This federal agency defines and administers the rules and regulations of Medicare and Medicaid.

B. **CLIA-Clinical Laboratory Improvement Amendments:** Federal standards applicable to all U.S.

facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease

C. **OIG – Office of the Inspector General**: Provides objective oversight to promote the economy, efficiency, effectiveness, and integrity of Department of Health and Human Service programs.

D. **FDA/CBER - US Food & Drug Administration, Center for Biologics Evaluation and Research:** FDA/CBER is responsible for regulatory oversight of the U.S. blood supply. FDA promulgates and enforces standards for blood collection and for the manufacturing of blood products, including both transfusable components of whole blood, pharmaceuticals derived from blood cells or plasma, and related medical devices. FDA also inspects blood establishments and monitors reports of errors, accidents and adverse clinical events. CBER works closely with other parts of the Public Health Service to establish blood standards and to identify and respond to potential threats to blood safety or supply. (https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/regulation-blood-supply)

E. **OSHA – Occupational Safety and Health Administration:** OSHA's mission is to prevent injuries and protect America's workers by ensuring that the workplace is safe and healthy.

F. **MIOSHA – Michigan Occupational Safety and Health Administration**

G. **JC – Joint Commission:** The mission of the Joint Commission is to continuously improve the safety and quality of health care in the United States and in the international community through the provision of education, publications, consultation, and evaluation services.

H. **CAP – College of American Pathologists:** This organization operates voluntary programs in proficiency testing and quality monitors, as well as a complex, well-defined peer-based laboratory accreditation program.

I. **AABB:** An international association representing individuals and institutions involved in activities related to transfusion and cellular therapies, including transplantation medicine. This organization supports the highest standards of medical, technical and administrative performance, scientific investigation, and clinical application through standard setting, accreditation, education, advocacy and other activities

J. **ASHI – American Society of Histocompatibility and Immunogenetics:** This professional society is involved in histocompatibility, immunogenetics and transplantation. ASHI is dedicated to advancing the science and application of histocompatibility and immunogenetics, providing a forum for the exchange of information, and advocating the highest standards of laboratory testing in the interest of optimal patient care.

IV. CAP IDENTIFIED AREAS OF COMPLIANCE:

NOTE: Applicable federal, state and local requirements are NOT limited to the items listed in this table.

Identified Area	**For Compliance, Refer to**:
Handling Radioactive Materials	Laboratory Safety Documents
Shipping Infectious and/or Diagnostic Materials	Laboratory Procedure Documents
Reporting Infectious Disease Testing Results	Laboratory Procedure Documents
Personnel Qualifications	CLIA Regulations, CAP Accreditation Standards;

	Clinical Pathology Personnel Policy (job description)
Retention of Specimens and Records	CLIA Regulations; CAP Accreditation Standards
Hazardous Waste Disposal	Laboratory Safety Documents; Corporate Safety Documents
Fire Codes	Laboratory Safety Documents; Corporate Safety Documents
Medical Examiner or Coroner Jurisdiction	Michigan Dept. of Community Health (MDCH) or Oakland County Health Dept
Legal Testing	*Not performed in this laboratory.*
Acceptance of Specimens Only from Authorized Personnel	42 CFR Part 493.1241 Laboratory Regulations CAP Accreditation Standards
Handling Controlled Substances	Corewell Health East Toxicology Laboratory Security Standards Lab Compliance policy
Patient Consent for Testing	In Office Phlebotomy (IOP)/Patient Service Center (PSC) Consent for Laboratory Services Current version of Consent for Service and Financial Responsibility
Confidentiality of Test Results	Corewell Health East Laboratory: Confidentiality, Privacy and Information Security Guidelines: Laboratory Compliance Education Maintaining Patient Confidentiality and Privacy in Corewell Health East Laboratory: Lab Compliance policy
Donation of Blood: Blood is regulated as both a biologic and a drug and is subject to federal and state regulations. Tissue products are now subject to federal regulations.	FDA: CFR Title 21 Parts: 211, 600, 606, 610,630, 640, 660, and 820; CMS: CFR Title 42 Parts:482, 493; FDA: Tissue: CFR Title 21 Parts: 1270,1271, Michigan State Legislature: Public Health Code, Act 368, sections 331, 333

V. REFERENCES:

Refer to above table.

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	9/27/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	9/26/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	9/26/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	9/23/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/16/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	9/16/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	9/16/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	9/16/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	9/16/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	9/16/2024
	Sarah Britton: VP, Laboratory Svcs	9/9/2024
Operations Directors	Joan Wehby: Dir, Lab Services	9/3/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	8/14/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	8/9/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	8/9/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Services	8/8/2024
	Michele Sedlak: Lab Quality Coord	8/8/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne