Policy Title: Delegation of CLIA Waived Testing Responsibilities

Policy Number: [Insert Policy Number]

Effective Date: [Insert Effective Date]

Policy Statement:

This policy outlines the procedures for the delegation of Clinical Laboratory Improvement Amendments (CLIA) waived testing responsibilities at [Surgery Center Name]. The Laboratory Medical Director may delegate certain tasks related to CLIA-waived tests to qualified staff members, ensuring compliance with all regulatory requirements and maintaining the highest standards of patient safety and care.

I. Purpose:

The purpose of this policy is to:

1. Define the process for delegation of CLIA-waived testing responsibilities within [Surgery Center Name].

2. Ensure that all delegated tasks are performed competently and safely.

3. Outline the education, training, and competency requirements for staff involved in CLIA-waived testing.

II. Scope:

This policy applies to all staff members involved in CLIA-waived testing within [Surgery Center Name], including but not limited to laboratory personnel, nursing staff, and other qualified healthcare professionals.

III. Definitions:

1. CLIA Waived Test: A laboratory test classified as waived under the Clinical Laboratory Improvement Amendments (CLIA) and exempt from routine regulatory oversight.

IV. Delegation of CLIA Waived Testing Responsibilities:

1. The Laboratory Medical Director may delegate specific CLIA-waived testing responsibilities to qualified staff members who meet the following criteria:

a. Possess the appropriate educational background and credentials to perform CLIA-waived tests.

b. Have completed the required training and demonstrated competency in the specific waived test procedures.

c. Maintain a thorough understanding of the manufacturer's instructions and limitations for each CLIA waived test.

d. Adhere to all applicable policies and procedures related to CLIA waived testing.

2. Delegated CLIA waived testing responsibilities may include, but are not limited to:

a. Test specimen collection.

b. Test procedure performance.

c. Quality control and proficiency testing.

d. Documentation and record-keeping.

3. The Laboratory Medical Director shall maintain a record of all staff members authorized to perform delegated CLIA waived testing responsibilities.

V. Education, Training, and Competency:

1. Staff members seeking delegation of CLIA waived testing responsibilities shall complete the following requirements:

a. Participate in formal education and training programs related to the specific waived test(s).

b. Demonstrate competency in performing the waived test(s) under the supervision of qualified laboratory personnel.

c. Successfully complete any required competency assessments.

2. Ongoing education and training shall be provided to staff members to ensure the maintenance of competency in CLIA waived testing.

VI. Monitoring and Compliance:

1. The Laboratory Medical Director shall regularly monitor and evaluate the performance of staff members with delegated CLIA waived testing responsibilities to ensure compliance with regulatory requirements and internal policies.

VII. Documentation:

1. Records of education, training, competency assessments, and delegations of CLIA waived testing responsibilities shall be maintained in the employee's personnel file and in the laboratory's records.

VIII. Review and Revision:

1. This policy and its associated procedures shall be reviewed and revised as necessary to ensure compliance with changing regulatory requirements and the evolving needs of [Surgery Center Name].

IX. References:

[Include any relevant references to CLIA regulations, state regulations, or industry standards.]

X. Approval:

This policy has been approved by [Name and Title of Approving Authority], and it is effective as of [Effective Date]. All staff members are responsible for adhering to the procedures outlined herein.

XI. Distribution:

This policy shall be made readily available to all staff members involved in CLIA waived testing within [Surgery Center Name].