

Milford Regional Physician Group, Inc.

Effective Date: 2/1/2018
Distribution: All Urgent Care Facilities

Manual: Urgent Care

Originating Dept. Operations

Committee: Director of Operations

Senior Management:

Urgent Care Physician
Director

Medical Director

Signature:


Nancy Jolicœur

Signature:


Michael Connors, MD

Signature:


Elizabeth Siraco, MD

☒ **New**

☐ **Supersedes:**

CLIA Waived Testing
(Policy Name)

2/1/2018
(Effective
Date)

2016
(Origination
Date)

Subject: CLIA waived testing.

Purpose: It is the purpose of this policy to establish guidelines for the training, usage, and quality control for all CLIA waived tests approved for use at Milford Regional Physician Group, Inc.'s Urgent Care facilities.

Policy: It is the policy of Milford Regional Physician Group Inc.'s Urgent Care facilities to document the CLIA Waived tests approved for use at its facilities and ensure the safe and accurate performance and results of those tests in accordance with law and regulation.

Procedure:

A. Training

1. During orientation, clinical staff will receive training for each CLIA Waived test used at Milford Regional Physician Group Inc.'s Urgent Care Facilities (as well as for each piece of equipment used to run such tests). This training will be documented.

2. CLIA Waived tests will only be performed by physicians and clinical staff with appropriate training.
3. Milford Regional Physician Group, Inc.'s physicians are permitted to perform any non-instrument based CLIA Waived test without the requirement of further training.
4. Clinical training will include all the following:
 - a. The requirement to review manufacturer instructions for each CLIA Waived test.
 - b. A review of all CLIA waived tests approved by Milford Regional Physician Group Inc.'s Urgent Care facilities.
 - c. Training on properly performing the tests and their controls.
 - d. The proper use and maintenance of instruments used to run approved CLIA Waived tests.
5. The Clinical staff will also be required to pass one observed CLIA Waived test before they are allowed to perform that test without supervision.
6. Competency testing will be assessed at the time of orientation and annually thereafter by the Clinical Resource Nurse.
7. A written record will be kept listing the individual who is leadership-approved to perform CLIA training for Milford Regional Physician Group Inc.'s Urgent Care staff.

B. Approved CLIA Waived Tests

1. Each CLIA Waived test will be approved by leadership before it is approved for use. Each test will be re-approved by leadership every 3 years. If a test is not re-approved, then it will not be approved for use.
2. Any CLIA Waived test that undergoes changes of manufacturer or procedural instructions will again need to be approved by Milford Regional Physician Group Inc.'s leadership before it will be used for testing.
3. Milford Regional Physician Group Inc.'s leadership has approved the following CLIA Waived tests:

Test	Machine
Urinalysis Test	Multistix 10 SG
Glucometer Test	Quintet AC
hCG Urine Cassette Pregnancy Test	McKesson Consult
Strep A Test	OSOM
Hemoccult (Fecal Occult Blood Test)	Beckman Coulter
Influenza A & B Test	Sofia

C. Controls

1. Controls will be performed and documented for each CLIA Waived test in accordance with its manufacturer's recommendations. Control records will be kept for at least two (2) years.
2. A control log will be kept for each of the approved CLIA Waived tests listed above.
3. Controls will be performed for all instrument-based tests on approved list above with each new lot.
4. Control for Hemocult tests will be recorded each time the test is performed (using the test's internal controls) as instructed by the manufacturer.
5. Urinalysis QC will be run based on the Urinalysis QC Process.

D. Documentation of Results

1. Every patient who has a CLIA Waived test performed will have their results documented in their record and signed and dated by the person taking the test.

E. Manufacturers Instructions

1. The instructions and procedures for each Milford Regional Physician Group, Inc. approved CLIA Waived test will be kept in the lab area of each facility.
2. The procedures outlined for each test in the manufacturer's instructions will be approved by leadership before they are used and will be re-approved at least every three (3) years afterward.

F. Confirmatory Testing

1. Confirmatory testing will be done for each test at the discretion of Milford Regional Physician Group Inc.'s physicians.

Quality Control Log for Quintet Blood Glucose Meter

Run a new QC for each Test Strip box opened

Facility _____

Date Collected	Time Collected	Consult Control Solution Lot #	Exp. Date	Normal Control	High Control	Staff Initials

Quality Control Log for Strep A & B

Run a new QC for each box opened

Facility:

[illegible]

Facility-

Run a new QC for each box opened

[illegible]

Facility-

Run a new QC for each box opened

[illegible]

Quality Control Log for Sofia Influenza A+B Kit

Run a new QC for each box opened

Facility _____

Date Collected	Qty of boxes with same Lot #	Kit Lot #	Exp. Date	Positive A Control	Positive B Control	Negative Control	Staff Initials