# CLIA-Waived Tests: Types, Requirements, and How to Choose the Right Test Kits

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## Meta Tags

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## Blog Content

# H1: CLIA-Waived Tests: Types, Requirements, and How to Choose the Right Test Kits

CLIA “waived” tests are one of the backbones of physicians’ offices, urgent care centers, clinics, and other point-of-care settings. They are designed to be so simple to administer and read that, when performed per the manufacturer's instructions, they don't require a lab setting to produce accurate results.

When choosing a CLIA-waived test, understanding the requirements can help you make quicker decisions in the clinic, improve patient pathways, and reduce the number of samples you need to send to labs. However, regulations still apply to waived tests. Understanding your facility's requirements is important. Choosing the right CLIA-waived test kits depends on the tests you perform, the patients you see, and your staff's skill level and scope of practice.

**Click the section to read:**


- What Are CLIA-Waived Tests?
- CLIA-Waived Tests List: Common Types of Tests
- Understanding CLIA-Waived Testing Requirements
- How to Choose the Right CLIA-Waived Test Kit
- Where to Buy CLIA-Waived Test Kits and Medical Testing Supplies
- CLIA-Waived Testing: A Quick Checklist Before You Buy
- Frequently Asked Questions


## H2: What Are CLIA-Waived Tests?

CLIA, or Clinical Laboratory Improvement Amendments, waived tests are laboratory-based tests classified as low complexity. They are diagnostic tests that can be performed with minimal training, equipment, and expertise.

CLIA classifies them as “waived” because they are simple and have a low chance of producing an inaccurate result when performed correctly. They may have been given waived status because they meet specific FDA criteria or were approved through a process that allows them to be waived.

Compared to more complex testing, waived tests do not require specialist equipment, extensive quality control, highly skilled personnel, environmental controls, or detailed validation. They are designed to be simple to perform and to produce results quickly at the point of care.

Physicians often use them in offices, urgent care centers, retail clinics, pharmacies, and other healthcare settings. They provide information quickly to aid with diagnosis and treatment. This helps make decisions in the same appointment, whether further testing, treatment, or referrals are needed. CLIA-waived diagnostic test kits and CLIA-waived rapid tests are particularly useful for tests that require quick results. Examples of this include respiratory symptoms and pregnancy confirmation.

However, they must still be properly managed. If samples are not collected correctly, stored incorrectly, have expired, or are not timed correctly or performed per the manufacturer’s

instructions, they can produce inaccurate results. They should be considered as part of a controlled process in your lab.

## H2: CLIA-Waived Tests List: Common Types of Tests

The list of CLIA-waived tests varies depending on what has been authorized. Each test is classified as “waived” for a specific test system. The following are examples of common subjects for these tests:

### 1. H3: Infectious Disease and Respiratory Tests

Influenza, COVID-19, and Group A Strep rapid tests may be waived. Respiratory testing is a common use of CLIA-waived kits because rapid diagnosis of infectious airborne pathogens can help a clinician decide what treatment is required, whether to take precautions, and how to minimize potential spread to other members of the population. However, test performance varies by product, sample, time, and patient group. A negative result may not always rule out infection.

### 2. H3: Pregnancy & Women's Health Tests

Urine pregnancy tests are one of the most common CLIA-waived kits. They detect human chorionic gonadotropin in urine, which is one of the markers of early-stage pregnancy. They are often used in family planning clinics and other facilities to determine pregnancy status, which may influence diagnosis, treatment, and imaging. Knowing when pregnancy begins eliminates behavior that could adversely affect the development of a child and reduce risks for the mother.

As with all waived tests, they must be performed with the correct sample, within the time frame, and interpreted correctly for accurate results. Some tests are only for qualitative screening and should not be used to determine hormone concentrations.

### 3. H3: Metabolic & Blood Glucose Testing

Blood glucose meters and other point-of-care metabolic tests may be waived. They screen for diabetes and monitor Type 2 progression in real time, rather than waiting for the lengthy process of outbound lab testing. They provide immediate information on symptoms related to abnormal blood sugar.

Other tests may provide information on specific metabolic markers. However, not all point-of-care devices will be waived. Confirm that the test is waived. Manufacturer instructions indicate test limitations, including sample collection, patient factors, calibration, quality control, and interpretation.

### 4. H3: Other Common CLIA-Waived Tests

Some waived tests may be used for occult blood, cholesterol, urinalysis, fecal markers, and other conditions. This will depend on the test system and manufacturer instructions, as waived kits are only waived for approved testing systems. Ensure that each test is authorized for the correct sample type, in the approved setting, and by the correct operators.

## H2: Understanding CLIA-Waived Testing Requirements

CLIA-waived tests allow eligible healthcare facilities to run simpler tests with minimal regulatory requirements. Although a test can be waived, facilities must follow the correct processes to maintain quality per the manufacturer's instructions.

Most facilities running waived tests will require an appropriate CLIA waiver certificate. When purchasing a new CLIA-waived test, make sure the product and testing system are compatible and approved.

Carry out all tests according to the manufacturer's instructions without exception. All tests should be used for their intended purpose. Follow instructions for sample collection, preparation, timing, interpretation, and disposal, or results may be incorrect. Also, store and handle the test kit properly by following temperature guidelines, avoiding light and moisture exposure, ensuring proper packaging, and checking expiration dates.

Ensure staff are appropriately trained and competent with the kit administration process. Keep the correct documentation in place, such as training records, batch numbers, expiry dates, and results, to maintain an organized clinic and allow oversight if something goes wrong. If the manufacturer requires quality control, document it as well. Quality control procedures can vary by test, so review the IFU (instructions for use) and clearly understand your facility's policies.

Your facility must comply with relevant state regulations, licensing requirements, organizational policies, and accreditation requirements. While a waived test simplifies some regulations, you must ensure you perform the tests correctly.

## H2: How to Choose the Right CLIA-Waived Test Kit

### 1. H3: Confirm the Test's CLIA-Waived Status

Check if the product, analyzer, or testing system is waived. Not all variants or brands of a generic test will be waived, so check with the manufacturer and current regulations. Recall that not all tests are waived for every system.

### 2. H3: Consider Your Clinical Setting

Depending on the setting where you perform testing, the kit may vary. For example, a physician's office, urgent care center, or community clinic may have different staffing levels, patient volumes, space, and workflows. Also consider your staff's qualifications and whether they meet the requirements to administer the tests you are considering.

### 3. H3: Evaluate Turnaround Time

Do you need a fast or instant test? A rapid diagnostic test can help you make treatment decisions while the patient is in the clinic. However, if you need a quick test, it should also be accurate, easy to use, and fit the intended purpose.

### 4. H3: Check Storage & Handling Requirements

Check whether the test needs to be stored at a certain temperature, has an expiry date, requires specific packaging, or is stable. Some tests have specific storage requirements that may not be practical for small clinics or locations without temperature-controlled storage.

### 5. H3: Consider Ease of Use and Workflow

Consider how easy the test is to use. Does it require difficult sampling? How many steps are there? Are the results easy to interpret? Are there time requirements? A test that easily fits into your workflow reduces errors and preserves clinic efficiency.

### 6. H3: Evaluate Supplier Reliability

Does the product have good availability? Can they be ordered regularly? Will the seller offer good customer service? A reliable supplier helps keep your clinic stocked and prevents shortages, saving time and helping more patients see results.

## H2: Where to Buy CLIA-Waived Test Kits and Medical Testing Supplies

When choosing a CLIA-waived test kit supplier for your clinic, make sure you are getting a reliable product. Ensure that the product is available, well documented, and consistently supplied.

If you order a variety of diagnostic products, make sure the supplier can support broader ordering needs. CLIA-Waived Test Kit Suppliers that can handle same-day shipping alongside timely, less urgent orders will allow for fewer orders and less money spent on shipping overall. A range of compatible products can also simplify your stock and accounts, creating fewer transactions and orders to track for bookkeeping and record-keeping. If you have regular requirements for medical testing products, wholesale purchasing is a practical option.

A supplier that provides complementary point-of-care testing products, such as sample collection products, PPE, and medical consumables, is a boon to any healthcare operation. Wilburn Medical prides itself on providing personal service with nearly 30 years of experience. Our team takes the time to understand your business and will continue to deliver reliable supply planning for your needs.

## H2: CLIA-Waived Testing: A Quick Checklist Before You Buy

Make sure the test you are ordering is waived and suitable for your purpose. Ensure the test is easy to store, comes in good packaging, and will not expire while in use. Make sure your staff knows how to use it and that you can supply it consistently. Ensure it suits your testing volume, workflow, and budget.

- Is the specific test CLIA-waived?

- Does it fit your clinical application?

- Are storage requirements manageable?

- Is the kit within its expiration date?

- Does your staff understand the instructions?

- Does the supplier provide consistent availability?

- Does the product fit your testing volume and budget?

**Tired of waiting for test results? Try our point-of-care solutions!**

## H2: Frequently Asked Questions

### H3: What is an example of a waived test?

Examples include pregnancy tests, glucose tests, influenza/respiratory antigen tests, and urine chemistry tests. However, not every test for these things is classified as waived, and waived status applies only to approved testing systems. Do not assume a test type or brand is waived.

### H3: Do you need a CLIA certificate?

Most facilities require a CLIA waiver certificate to perform waived tests unless another certificate or exemption applies. This provides evidence that you are authorized to carry out waived tests. You will still need to follow the IFU and manufacturer's instructions.

### H3: How do I know if a test kit is waived?

Check the manufacturer's documentation and current regulations to confirm the testing system you are considering is waived. Do not assume based on the test type. Ensure the product name, model, intended use, sample type, and any conditions are correct.

### H3: What should I look for in a CLIA-waived test kit supplier?

A reliable supplier will provide products, documentation, knowledgeable customer service, competitive repeat pricing, and consistency. They should understand point-of-care environments and will help find complementary medical testing products.

### H3: Conclusion

CLIA-waived tests provide a convenient and quick option for point-of-care testing. When choosing a test kit, ensure it is waived, understand its intended purpose, storage requirements, workflow fit, staff competency needs, and supplier reliability.

A supplier that delivers consistently, offers practical advice, and maintains responsive service will help you keep testing efficient. Wilburn Medical focuses on providing these personal and professional services to build a strong foundation for managing your regular diagnostic needs.

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