# Why IFU Limitations Matter in Urgent Care Lab Testing

**Urgent Message:** Urgent care teams can take practical steps to safeguard quality for Clinical Laboratory Improvement Amendments (CLIA)-waived testing by following detailed Instructions for Use information.

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Laboratory tests commonly used in urgent care are only reliable when their Instructions for Use (IFU)—including any limitations—are followed. For urgent care leaders, this isn't just about compliance with federal regulations. Patient outcomes, safety, and even a site's Clinical Laboratory Improvement Amendments (CLIA)-waived status depend on it. Because IFU limitations are often a "blind spot" in urgent care, this article explains why they matter, common pitfalls, and practical steps urgent care teams can take to safeguard quality.

## Waived Doesn't Mean Worry-Free

On a busy weekday afternoon, an urgent care provider may order a CLIA-waived test for a patient with sore throat, cough, vaginitis, or urinary complaints, as just a few examples. Results may come back within minutes, shaping treatment decisions, yet few pause to consider the fine print in the test's IFU, which may affect the accuracy of the test result.

IFUs do more than explain how to run the test. They also include limitations that can lead to significant consequences if ignored, such as incorrect results, missed diagnoses, inappropriate treatment, and regulatory noncompliance for the medical director. A framework for embedding IFU limits into workflow and purchasing

decisions, however, can help reduce callbacks, re-collections, and regulatory risk.

## CLIA Waived Testing

Under CLIA, waived tests are defined as tests with a low risk of incorrect results. To perform them, a facility must hold a valid Certificate of Waiver and follow the manufacturer's IFU precisely, including the limitations section. Direct oversight for CLIA-waived tests is typically light with inspections occurring randomly, in response to complaints, or when the Centers for Medicare & Medicaid Services—which administers the overall program, issues certificates, and enforces regulations for laboratories—has reason to believe testing poses risk.[1] Even so, compliance is everyone's responsibility.

Many operators assume their waived certificate is sufficient to run waived tests, however, following IFUs in everyday practice is equally critical. Failure to follow IFUs can reclassify a test as high complexity, requiring added

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**Table 1. Examples of IFU Limitations and Urgent Care Implications**

| Test | IFU Limitation Example | Urgent Care Implication |
|---|---|---|
| Quidel Sofia Strep A+ | "Blood, mucin, and Nacho Flavor Doritos may interfere with the assay."[2] | Tests for patients who have recently eaten Nacho Cheese Flavored Doritos may yield false results. |
| Beckman Coulter Hemoccult | Lists multiple diet-related causes of false positives and negatives. Also notes in the precautions that test should not be interpreted by individuals with blue color deficiency.[3] | Dietary history and staff training affect accuracy. |
| Quidel Sofia RSV | "Suitable for pediatric patients <7 years old. Performance not established for older or immunocompromised patients." Note: This test is waived for patients <7 years of age and moderately complex for patients 7-19 years of age.[4] | This is considered off-label use if adults are tested using this method, and results may not be valid. Yet, respiratory syncytial virus is a rising concern in seniors. |
| Abaxis Piccolo CMP | Elevated creatine kinase from muscle trauma may cause falsely high potassium results.[5] | Trauma/heart attack/seizure patients could be misclassified without confirmatory testing and could be treated on an inaccurate result. |

oversight, training, and inspections. Additionally, a medical director may be held personally responsible for consequences such as incorrect results, patient harm, or loss of the site's waived status when staff doesn't follow IFUs.

## What IFU Limitations Look Like

Limitations often describe conditions that may lead to inaccurate or uninterpretable results. Many seem intuitive, such as inadequate specimen collection, but others can be surprising. **Table 1** provides a few examples of the many limitations that can affect how results are interpreted in urgent care.

## Why Limitations Matter in Urgent Care

Urgent care centers tend to operate with small teams, often including medical assistants with limited lab training. High turnover and heavy patient volume create a situation in which IFUs may only be reviewed for the initial setup and not reinforced with staff regularly. That creates risk across multiple fronts.

- **Patient safety:** Misinterpreted results can lead to inappropriate treatment or missed diagnoses.
- **Public health:** For communicable diseases like sexually transmitted infections (STIs) or COVID, false negatives mean ongoing transmission.
- **Regulatory compliance:** Deviating from IFUs puts the urgent care center's non-waived classification at risk and may result in penalties.

## Hypothetical Case Example

Consider a hypothetical presentation of a 22-year-old patient with dysuria and vaginal discharge. A waived nucleic acid amplification test (NAAT) for chlamydia and gonorrhea might be ordered. The test's IFU notes that certain, non-approved swab types can cause false results, but the staff member collecting the specimen may not be aware of the limitation and use a non-approved swab for collection. The patient is soon reassured of a negative result and is sent home without treatment.

Days later, the patient is diagnosed at a different site of care with pelvic inflammatory disease, and it is believed the non-compliant swab used in the NAAT may have caused a false negative at the outset, likely causing unnecessary disease progression that may have been avoided with earlier diagnosis.

## Common Categories of Limitations

While specifics vary, most waived tests include limitations in a few broad categories. Urgent care teams must be aware of these pitfalls to interpret results responsibly.

- **Specimen integrity:** Adequate collection, storage, and transport are essential.
- **Population restrictions:** Many tests are validated only for certain age groups or patient types.
- **Cross-reactivity:** Interference from other organisms, foods, or medications may cause false positives or negatives.
- **Visual interpretation:** Colorblindness in the interpreter or subjective qualities of color changes can affect results.
- **Sample volume and contamination:** Insufficient material or cross-contamination can skew polymerase chain reaction and other assays.

## Making It Actionable

One way to operationalize IFU limitations is by em-

**Table 2. Examples of Variations in IFUs For Similar Tests**

| Test | Population Restrictions | Vaginal Product Limitations | Other Limitations |
|---|---|---|---|
| Binx io CT/NG[6] | Manufacturer IFU states it is validated for use in male and female patients. | Manufacturer IFU states no restrictions for vaginal products. | Manufacturer IFU requires Binx io vaginal swab kit or Binx io male urine collection kit. |
| Visby CT/NG[7] | Manufacturer IFU states it is validated for use in females only. | Manufacturer IFU lists several vaginal products that should not be used within 48 hours of collection. | Manufacturer IFU requires Visby Medical vaginal specimen collection kit. |
| cobas liat CT/NG/MG[8] | Manufacturer IFU states it is validated for use in male and female patients. | Manufacturer IFU lists several vaginal products that should not be used during or prior to collection. | Manufacturer IFU requires cobas PCR media for urine sample or vaginal swabs. |

bedding them into a simple pretest questionnaire that staff can complete quickly at the point of care. By standardizing these checks, urgent care centers reduce variability and improve compliance.

### Sample Pretest Screening Questions

1. Has the patient eaten within the past 30 minutes?
2. What is the patient's age? Is the test validated for this age group?
3. Does the patient have other conditions (eg, muscle trauma; immunocompromised) that could interfere with results?
4. Was the specimen collected, labeled, and transported according to instructions?
5. Does the patient's clinical presentation align with test results?

## Comparing STI Waived Assays

STI testing is an important area for urgent care with significant impact on both individual patients and public health. Different waived assays vary in their IFU limitations, and these differences should be considered when bringing in new testing. The examples in **Table 2** are illustrative, not exhaustive. Always verify IFUs for complete details.

Limitations vary widely—some platforms have multiple limitations—and should be reviewed often for potential impact. Operational leaders should assess IFU limitations against their site's workflow and patient mix, for example.

## Steps for Urgent Care Leaders

Urgent care directors and administrators can take immediate steps to make IFU compliance part of daily workflow. Consider starting with a simple checklist approach:

- Run a quick audit of your top 5 waived tests and document their IFUs, including the limitations.
- Create a 6–8 item pretest checklist and laminate copies for triage and other staff stations.
- Embed IFU guardrails into your electronic health record order sets to reinforce correct use at the point of care.
- Train staff on why IFU limitations matter for patient outcomes and compliance.
- Evaluate new platforms by including IFU limitations as a scored criterion during selection.
- Implement ongoing quality checks with extra attention to high-impact tests.

By operationalizing IFUs in this way, urgent care leaders can reduce risk and improve consistency of testing across their teams.

## Conclusion

Urgent care thrives on speed and efficiency, but accuracy is equally critical. CLIA-waived status comes with ongoing responsibility beyond obtaining the Certificate of Waiver. By bringing the IFU limitations into daily practice through staff education, checklists, and thoughtful test selection, urgent care leaders can protect patients, maintain compliance, and strengthen public health outcomes.

The fine print matters. Now is the time to make it part of your frontline workflow. ■

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