



# **White Paper: Improving Preanalytical Specimen Protection in Courier Lockboxes With an Insulated Insert from Sun Diagnostics**

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## **Executive summary**

Specimen lockboxes are a practical handoff point between collection sites and couriers—but they are also a predictable vulnerability in the preanalytics chain. Outdoor (and even semi-sheltered) lockboxes experience “microclimates,” solar loading, and temperature extremes that can rapidly drive internal temperatures outside analyte stability limits.

An insulated insert—such as the Sun Diagnostics insulated insert for specimen lockboxes—adds a controlled thermal barrier inside the lockbox to reduce temperature excursions, slow heat gain/loss, and increase the probability that specimens remain within required temperature ranges during the highest-risk interval: “waiting for pickup.” This white paper describes (1) why lockbox storage is a high-value intervention point, (2) how an insulated insert mitigates thermal risk, (3) how the approach aligns with current best-practice guidance for external transport system evaluation, and (4) how to implement and verify performance using a risk-based quality framework.

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## **1) The problem: lockboxes are a known weak link in external transport**

External specimen transport is a multi-step system with many variables outside laboratory control (weather, traffic, pickup variability, handling). The lockbox step is uniquely exposed because it can combine uncontrolled ambient conditions with uncertain dwell time.

Current guidance explicitly flags lockboxes as increasingly common and vulnerable: outdoor lockboxes are exposed to environmental climates and microclimates and should not be located in direct sunlight; they should have documented capability to maintain appropriate internal

temperatures for the expected storage time and conditions, and their robustness should be evaluated before use and periodically throughout the year.

Operationally, courier variability amplifies the lockbox risk. In a May 2025 CAP TODAY survey, 84% of respondents reported a courier delay or error impacted timely results in the prior month, and 56% of lab leaders reported a courier error compromised an irreplaceable specimen in the prior year. Even when a lockbox is “working as designed,” the added dwell time and temperature excursions can push a marginal configuration into failure.

**Bottom line:** lockbox storage is a small slice of the transport timeline, but it is disproportionately responsible for temperature excursions, nonconforming events, and re-collection risk.

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## 2) Why temperature control matters: integrity, not just compliance

The aim of preanalytical transport controls is to preserve specimen integrity so results reflect the patient—not the journey. New CLSI guidance emphasizes that transport conditions can affect specimen integrity and bias results, and laboratories must have mechanisms to assess acceptability when deviations occur.

From a quality perspective, lockbox temperature excursions drive:

- **Re-collection and delays** (patient impact, provider dissatisfaction)
  - **Rejected or qualified results** (disclaimers, interpretive uncertainty)
  - **Irreplaceable specimen loss** (e.g., limited-volumes, time-sensitive tests)
  - **Escalating courier and staffing workarounds** (stat pickups, overtime), which are frequently reported by lab professionals when courier reliability is poor
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## 3) The intervention: what an insulated lockbox insert changes

An insulated insert is best thought of as an **internal thermal control layer** that converts a basic lockbox into a more stable “micro-environment.” The Sun Diagnostics insulated insert is designed to fit inside a common size lockbox (12” L × 9” W × 12” H) and functions as an extra thermal control layer.

### Key design elements

- **Composite insulation + radiant barrier:** 14 mm expanded polyethylene (EPE) foam insulation with an aluminum radiant barrier lining, helping reduce conductive and radiant heat transfer.

- **Durable, cleanable exterior:** 600D polyester with a coating; designed to be waterproof and easy to clean—important for real-world collection environments.
- **Controlled TMM placement:** Two integrated side pockets and a bottom flap for TMMs (e.g., gel packs). helps prevent direct contact between TMMs and blood collection tubes—reducing localized freezing/chilling risk.
- **Operational usability:** Zippered top closure and buckle-connect “handle” support consistent closure and easier handling.

An insulated insert improves performance through four practical mechanisms:

1. **Reduced conductive heat transfer**

The insert adds thermal resistance between the outer shell (steel or polymer) and the specimen payload. CLSI guidance notes that common lockbox designs already incorporate minimal insulation (e.g., polystyrene in steel lockboxes), but temperatures can still reach unacceptable ranges during storage periods. A purpose-built insulated insert strengthens this barrier where it matters most—around the specimen payload.

2. **Reduced convective mixing / drafts inside the lockbox**

Many lockboxes are opened repeatedly, and internal air mixing can accelerate warming/cooling. Inserts that create a tighter internal compartment can reduce effective convection and slow change.

3. **Lower sensitivity to solar loading and microclimates**

Because microclimates can be extreme (sun-exposed alcoves, near asphalt, against heat-reflective walls), guidance recommends avoiding direct sunlight and documenting performance under expected conditions. An insert is not a substitute for correct placement, but it provides a margin of safety when real-world conditions drift.

4. **Better integration with temperature-modulating materials (TMM)**

External transport evaluations should define the desired internal container temperature and include packing configuration, number/arrangement of TMM, and insulating material used to prevent direct contact between specimens and TMM. Inserts can help standardize this “insulation and spacing” function so staff don’t improvise with ad hoc materials.

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## 4) Alignment with best-practice guidance for external transport systems

Performance claims should be independently validated by the laboratory in the intended-use environment. This evaluation aligns directly with the risk-based evaluation framework in Clinical and Laboratory Standards Institute guideline PRE06 (Evaluation of External Transport Systems):

PRE06 identifies temporary storage in internal/external lockboxes as part of external transport processes. It further recommends that outdoor lockboxes be protected from direct sunlight and have documented capability to maintain appropriate internal temperatures for expected storage time and conditions.

System evaluation should define variables such as desired internal temperature, packing

configuration (including any insulating material), container placement prior to pick up, routes, durations, and anticipated environmental temperatures (including extremes).

Dataloggers are described as valuable for capturing transport parameters such as temperature — particularly for verifying performance during temperature extremes.

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## 5) Practical value proposition

By reducing lockbox temperature variability, an insulated insert can reduce:

- rejected specimens and re-collections,
- delay-related stability failures,
- result qualification/disclaimers due to temperature uncertainty,
- and loss of irreplaceable specimens.

Less temperature variability in the lockbox step means:

- fewer exception-handling calls and investigations,
- fewer “stat pickup” escalations and manual transport workarounds,
- and more consistent downstream processing (less triage time at accessioning).

While Return-On-Investment (ROI) is site-specific, the cost drivers a lockbox insert targets are usually straightforward:

- re-collection (labor + supplies + patient scheduling),
  - courier exception fees / stat service,
  - wasted operational costs for compromised specimens,
  - instrument/reagent utilization on specimens later deemed unacceptable,
  - and customer retention risk for outreach programs.
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## 6) Key takeaways

- Lockbox storage is a recognized vulnerability: outdoor lockboxes face occasional temperature extremes and microclimates and should avoid direct sunlight; performance should be documented and periodically re-evaluated.
- Courier variability makes “waiting for pickup” a meaningful risk; courier delays/errors are widely reported and are associated with compromised specimens.
- An insulated lockbox insert is a high-leverage mitigation that stabilizes the lockbox micro-environment, reduces thermal transfer, and helps standardize packing practices.
- The value is maximized when paired with a simple, PRE06-aligned evaluation using dataloggers and defined acceptance criteria.

**SOURCES:**

CLSI. Evaluation of External Transport Systems, 1<sup>st</sup> ed. CLSI guideline PRE06. Clinical and Laboratory Standards Institute, 2026.

Logistics and Laboratories Effectiveness Survey, CAP Today, May, 2025.

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**Figure: Comparison of air temperatures inside lockbox, with and without insulated insert. Three 250 g frozen icepacks were placed in the insert: two on the sides and one on the bottom.**

