



REPLY TO  
ATTENTION OF

SFAE-CBD-CBMS-MITS

DEPARTMENT OF THE ARMY  
JOINT PROGRAM EXECUTIVE OFFICE  
FOR CHEMICAL AND BIOLOGICAL DEFENSE  
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## MEMORANDUM FOR ALL HAND HELD ASSAY USERS

**SUBJECT:** Guidance On The Storage and Shipment of Joint Biological Point Detection System (JBPDS) carriers, Joint Portal Shield (JPS) Caddies, and Hand Held Assays (HHA)

The Critical Reagents Program (CRP) of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) has ongoing studies to define the stability and the appropriate shipping conditions of HHA strips and carriers. The CRP has conducted a variety of tests on strip performance and subjects each production lot to rigorous testing as outlined in the CRP HHA Conformance Test Plan.

Based on historical data collected and single point temperature studies, it is possible for the CRP to give more definitive guidance to strip consumers. This guidance is given in conjunction with continued testing which is tailored to the needs of each individual program that uses HHAs. Single point temperatures studies over periods of time, short-term humidity studies, and temperature indicator readouts within coolers during shipping allow us to make the following recommendations:

1. HHAs should be stored at 4° Celsius for prolonged periods of time. This is the preferred method of storage for HHAs and should be considered the optimal storage conditions for the assays for prolonged periods of time. If taken out of refrigerated storage, best efforts should be taken to avoid thermal cycling of HHAs. Attempt to maintain a consistent cool temperature as long as possible. Repeated changes in temperature from warm to cold accelerate the decomposition of antibodies within immunoassays.
2. HHAs have a twenty-four (24) month non-extendable shelf life when stored within their protective package at temperatures ranging from 4° Celsius to 10° Celsius or twelve (12) months at room temperature (~25° Celsius).
3. HHAs should not be frozen at any time. Freezing of strips will adversely affect the performance of the HHA through the formation of ice crystals that can destroy antibody proteins.

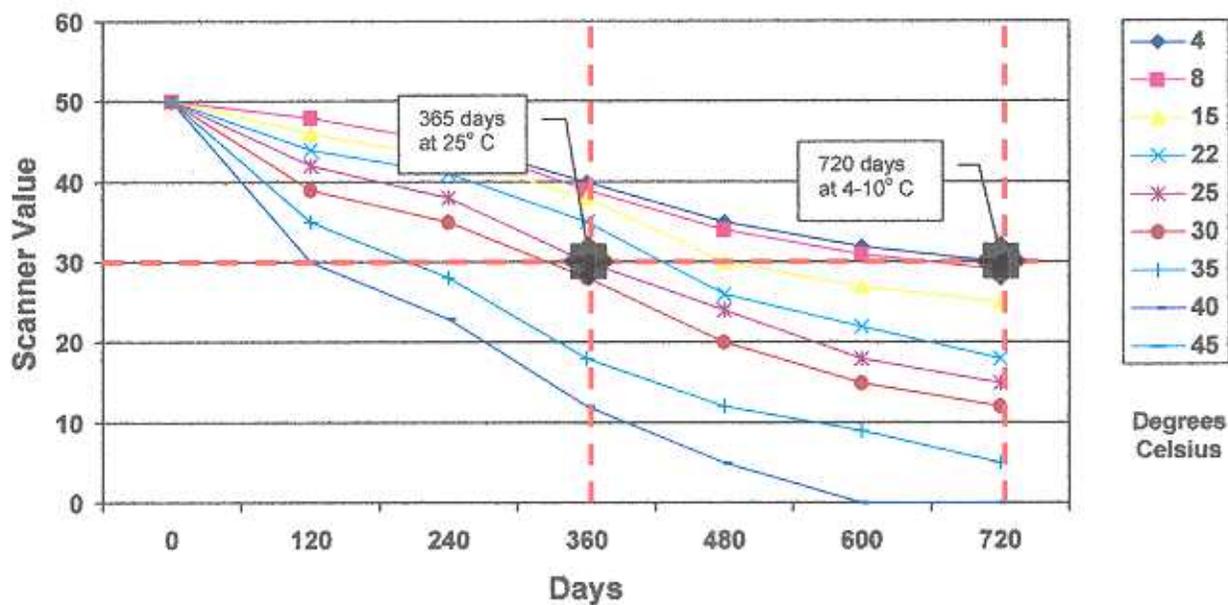
4. All HHAs in the form of Operational Panels, DoD Biological Sampling Kits, and Joint Portal Shield caddies come with a temperature sensor attached. The sensor turns black if the temperature goes above 60 ° Celsius since temperatures that high will irreversibly denature antibodies within the strips. If this occurs, assays should be disposed of in accordance with CRP HHA disposal procedures.

**To dispose of Hand Held Assays:** soak them in a 5% bleach solution (household bleach is fine) for 30 minutes in order to neutralize antibodies. After assays have been bleached, they may be disposed of as regular trash. Document destruction of HHAs in accordance with unit Standard Operating Procedures.

5. HHAs should be kept as dry as possible and users should avoid removing assays from protective foil packaging until right before use. This also acts to minimize the amount of humidity assays are exposed to. Allow assays to sit in their protective packaging for at least 15 minutes in order to come to ambient room temperature before unsealing to minimize moisture condensation forming on the strips once opened. Care should be taken to avoid direct exposure to rain or snow once assays have been removed from their protective packaging.
6. Assays can perform their function with little loss in performance due to humidity when loaded into the JBPDS carrier for the required 12.5-hour operational window. This performance will be maintained in all operational scenarios as long as assays can be maintained between 4 and 60 degrees Celsius. Humidity will not significantly impact the performance during this 12.5-hour window.
7. HHAs being shipped overseas (OCONUS) should be shipped in a heavy duty cooler, such as a Coleman<sup>®</sup>, or a fabricated crate with polyurethane protection when shipping overseas or when overnight express service is not available. This will enhance the stability of assays during extended shipping situations. Blue ice packs should be used in the cooler or box. Use COX recorders or other technologies to record temperature during shipment.
8. Assays shipped within the continental U.S. can be packaged in stable commercial shipping boxes (box must have sturdy structure) such as UPS or FEDEX if sent overnight express. Blue ice is not required for express shipping.
9. HHAs are a weapons sensitive system. Shipment records should include a chain of custody. Assays should be stored in a secure area such as an arms room or in a locked refrigerator.

The following chart depicts Shelf Life of Hand Held Assays at different temperatures. The Red Dashed Lines outlines the shelf life cut off for HHAs. When an assay decays to a scanner value of 30 at 1X sensitivity, assays have reached shelf life end date and can be disposed of following appropriate procedures.

**Estimated Shelf Life at Different Temperatures**



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