



HOUND® CANNABIS BREATHALYZER – Collect + Send

PRODUCT INSERT

NAME AND INTENDED USE

The HOUND® CANNABIS BREATHALYZER – Collect + Send is intended to detect recent cannabis use. It does not measure whether, or how much, a person is impaired. It is intended solely for use in employment, law enforcement, and insurance settings. It should not be used for any medical or therapeutic purposes, or for any Federal drug testing programs, such as programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.

STORAGE OF BREATH CARTRIDGES

Store unused HOUND® CANNABIS BREATHALYZER – Collect + Send cartridges at 15-30°C (59-86°F). Exposure to higher temperatures (>37°C or 98.6°F) should be avoided. Store cartridges in original, unopened packaging until collection.

EQUIPMENT + MATERIALS NEEDED FOR BREATH COLLECTION

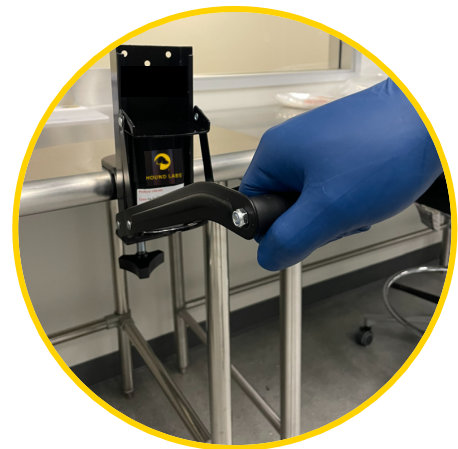
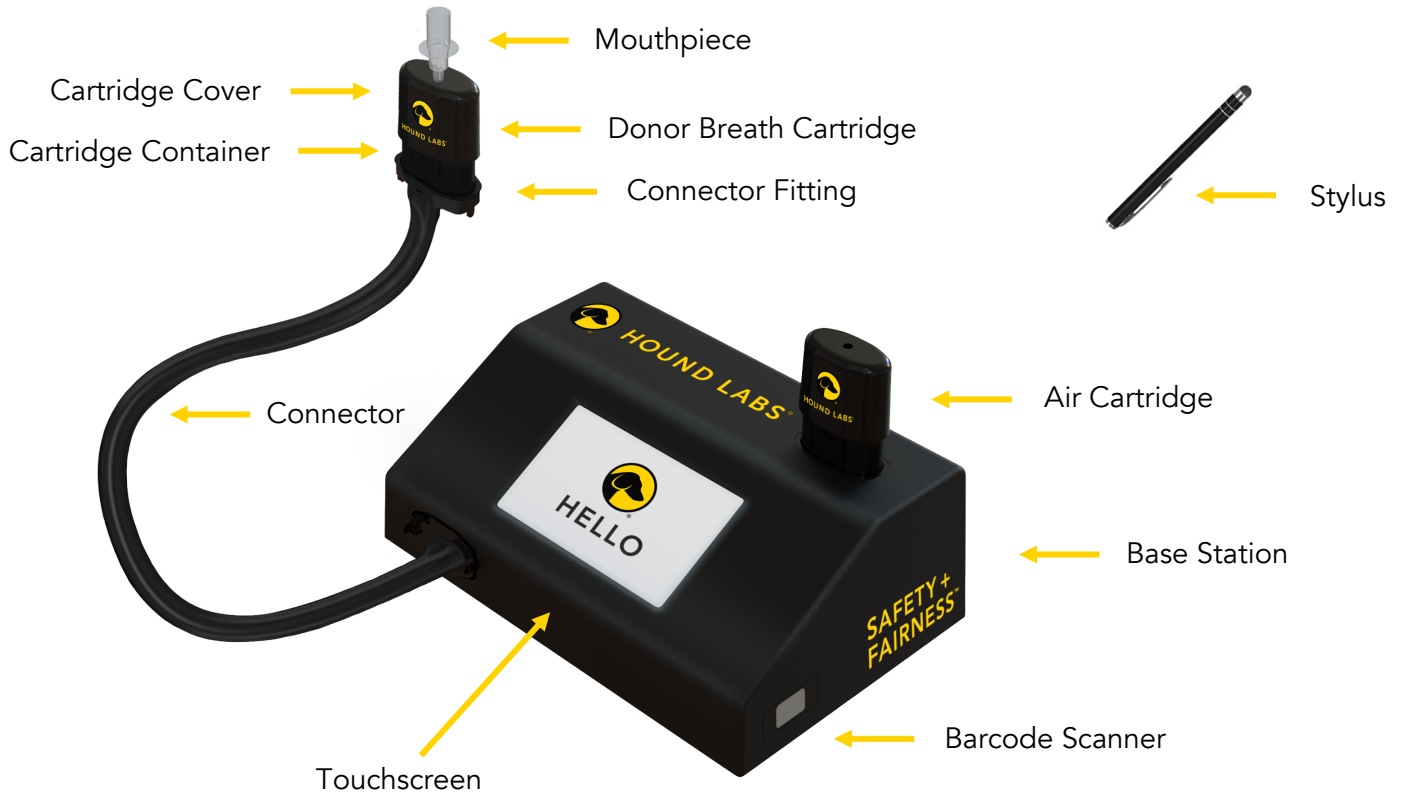
Equipment

- Base Station + Power Cord + Stylus
- Assisted Compression Equipment (ACE)
- Breath Collection Package (Single-Use Components)
 - Donor Cartridge + Connector
 - Air Cartridge
 - Mouthpiece
 - Tamper-Evident Seals (x2)

Materials

- Lab Sample Bag (aka 'Lab Specimen Bag')
- Shipping Materials
- Extra Mouthpieces
- Protective Gloves
- Ballpoint pen

PRODUCT COMPONENTS



Assisted Compression Equipment (ACE)



STEPS FOR PERFORMING A BREATH COLLECTION

1. Create Collection Event
2. Connect Cartridges
3. Collect Breath Sample
4. Complete Collection
5. Certify Collection and Ship Samples

STEP 1. CREATE COLLECTION EVENT

- Prior to first use, collector should ensure the primary administrator has configured the base station using the initial setup instructions.
- Collector ensures the power cord is firmly connected to the base station and that the system is plugged in.
NOTE: Do not unplug the base station while the system is running. Use the system menu to enable a proper shut down.
- Collector turns on the system using the power button on the back of base station, pressing the button for several seconds, or until the LED light illuminates.
NOTE: The system will take several seconds to boot up after the power button is pressed. The base station touchscreen will be blank while the system is powering on.
- Collector logs in to the system using his/her assigned username and password.
NOTE: Use the provided stylus for touchscreen navigation and data entry. Type in slashes when entering date of birth. To access symbols, press the shift key on the keyboard.
- Collector explains the collection procedure to the donor.
- Collector instructs the donor to empty mouth of gum, food, tobacco, etc., prior to collection.
- Best practice is to ask the donor to wait a minimum of ten minutes before collecting a breath sample and to observe the donor to ensure their mouth is empty for the entire waiting period.
NOTE: Select the speech bubble in the bottom right corner of the touchscreen to add remarks at any point during the collection.
- Collector selects the Lab Account Number field on the base station touchscreen to indicate the entry field.
- Collector enters the Lab Account Number or scans the barcode on the donor's collection authorization form using the scanner on the side of the base station.
WARNING: The barcode scanner light will be red when activated. Do not stare into the beam.
NOTE: When scanning, position the barcode at an angle approximately three inches from the scanner. For new account numbers, the base station will require the Lab Account Number to be entered twice.
NOTE: If the donor does not present an authorization form, the collector should contact the ordering employer or department to confirm the order and the cannabis breath test account number for laboratory testing.
- Collector confirms the scanned Lab Account Number(s) match the value printed on the donor's collection authorization form (if a form is presented).
NOTE: If the values on the base station screen match the printed value on the donor's authorization form, collector should select the Confirm button on the touchscreen to return to the collection information entry screen.
- Collector selects Enter on the base station touchscreen to advance to the next field once the Lab Account Number field is populated.
- After scanning is complete, collector can discard the form per company policy.



- Collector verifies the donor's identity and selects a method of verification using the dropdown menu to the right of the Donor ID field on the touchscreen.
NOTE: Reference employer policy for acceptable forms of verification (e.g., employer representative, driver's license, passport, employee photo ID).
- Collector enters the donor ID, first and last name, date of birth, phone number, email, and reason for testing on the base station touchscreen.
NOTE: Selecting Other as the reason for testing will require manually entering a comment in the Other Reason text field prior to proceeding with the collection.
- Collector asks the donor if they want to receive a link to the donor copy of the CCF and then selects the donor's preferred method of delivery from the dropdown menu titled, SEND CCF?.
- Collector advises the donor to remain seated during breath collection.

STEP 2. CONNECT CARTRIDGES

- Collector puts on appropriately fitting nitrile or equivalent gloves and wears them for the entire collection process.
NOTE: It is recommended to use new gloves for each collection.
- Collector asks the donor to select a breath collection package.
- Collector checks the use-by date printed on the package label and confirms that the package has not expired.
- Collector inspects the package for any signs of tampering or damage. If signs of tampering or damage are evident, collector should set it aside and instruct the donor to select a different collection package. Inspect the new package to ensure that it has not expired and shows no signs of damage or tampering.
- Collector opens the collection package and removes the donor cartridge (with connector pre-attached), air cartridge, individually-packaged mouthpiece, and tamper-evident seals.
- **WARNING: Do not remove cellophane wrappers from cartridges until after collection.**
NOTE: The air cartridge does not require the use of a mouthpiece or connector.
NOTE: Keep the cartridges clean and dry after opening the packaging to ensure proper test results. Use immediately after opening.
NOTE: Collection package contents should remain in the donor's view throughout the entire collection process.
- Collector confirms that the cartridge barcode (aka donor sample barcode) printed on the white donor cartridge label matches the cartridge barcode (aka air sample barcode) printed on the yellow air cartridge label.
- Collector selects the Scan Cartridge button on the touchscreen and uses the barcode scanner built into the base station to scan the cartridge barcode printed on either the donor or air cartridge.
- If the barcode does not scan properly, collector should enter the cartridge identification number manually using the base station touchscreen and provided stylus.
WARNING: The barcode scanner light will be red when activated. Do not stare into the beam.
NOTE: When scanning, position the label at an angle approximately three inches from scanner.
- Collector confirms that the cartridge ID shown on the base station touchscreen matches the value printed on the donor and air cartridges.
NOTE: If the values on the base station screen match the printed value on the donor and air cartridges, collector should select the Accept button in the bottom right of the screen to return to the collection information entry screen.
- Collector inserts the air cartridge into the port on the top of the base station.



WARNING: Collector should hold the base of the cartridge with two hands when inserting into the base station and take care to avoid compressing the cartridge by pressing on the top of the cartridge cover.

- Collector ensures the air cartridge is fully seated and not tilted relative to the port.
- Collector ensures the donor cartridge is firmly seated in the connector fitting.

NOTE: When fully seated, the notches at the base of the cartridge should insert into the openings on either side of the fitting.

NOTE: If the donor cartridge is not fully seated and/or is tilted relative to the fitting, collector should firmly push the cartridge into the fitting until it is fully inserted and seated. If necessary, collector can remove the lower cellophane wrapping to adjust the cartridge at the connection point. Collector should NOT remove the upper cellophane wrapping until after the collection.

NOTE: The donor cartridge should be connected to the connector at the end identified with a silver dot.

- Collector attaches the donor connector fitting to the port on the front of the base station.
NOTE: To insert, collector should position the connector fitting so the tubing is on the right and the circular airflow ports are on the left. Insert the fitting at an angle, first inserting the bottom edge, then tilting upward and pressing the fitting into the port.

STEP 3. COLLECT BREATH SAMPLE

- Depending on collector and/or employer processes, either the collector or the donor may hold the donor cartridge during the collection.

NOTE: The cartridge should be held at the cellophane wrap between the connector fitting and the cartridge to prevent misalignment during a collection.

- Collector gives the donor the individually-packaged mouthpiece. Donor removes the mouthpiece from its packaging and ensures the mouthpiece is free of obstruction.
- Donor inserts the mouthpiece into the round opening in the top of the donor cartridge, holding the cartridge above the cellophane wrap in the center to avoid compressing the cartridge.
- After ensuring all information has been entered, and both cartridges are connected, collector selects the Begin Collection button on the base station touchscreen.
- The base station will then prepare internal pumps to facilitate the collection.

NOTE: When the collection begins, the air collection pump will start immediately. The pump will stop once on an air sample has been collected and may end before completion of the breath sample collection.

- Once the base station touchscreen indicates it is prepared for collection, the collector instructs the donor to breathe into the mouthpiece for approximately 2-3 minutes, pausing between breaths as needed.

NOTE: Collector should observe the collection to ensure the donor does not pull or tug the connector and the tubing is not overextended.

- The base station touchscreen will display a breath collection progress indicator.

NOTE: The system power button and base station touchscreen should not be touched during sample collection.

- Short pauses of up to 20 seconds between breaths are allowed. When pausing between breaths, a warning message with a countdown timer will appear on the base station touchscreen, instructing the donor to continue breathing to avoid invalidating the breath collection.

- Collector should not allow donor to put anything in their mouth (including water) DURING the collection process. If this occurs, the collector should cancel the collection and follow employer policy for remediation.



- When the collection is complete, and a breath sample has been successfully collected, collector instructs the donor to remove and discard the single-use mouthpiece from the donor cartridge.
- If the donor was holding the donor cartridge, the donor should return it to the collector.
NOTE: Ensure the cartridge cover is secured while detaching the mouthpiece to avoid removing the cover from the container.
- The base station touchscreen will provide guidance for all post-collection steps.
- If a breath sample was not successfully collected (due to donor refusal, incomplete collection, cartridge error, system error, etc.), collector should follow the guidance provided on base station touchscreen.
NOTE: The decision about whether to reschedule the donor's collection should be determined based on employer policy.
- The base station will instruct the collector to prepare the cartridges for processing.
- Collector removes the lower cellophane wrapping from the connector fitting attached to the donor cartridge.
WARNING: Avoid compressing the cartridges while inserted in the base station or connector fitting to prevent system damage.
- Collector disconnects the donor cartridge from the connector by unclipping the connector fitting from the donor cartridge, holding the base of the cartridge securely as the fitting is removed.
NOTE: When properly removed, the cartridge will disconnect from the connector fitting. The fitting should not disconnect from the connector tubing.
- Collector removes the remaining upper cellophane wrapping from the donor cartridge.
- Collector disconnects the air cartridge from the base station, using two hands to grasp the base of the cartridge while removing.
- Collector removes the cellophane wrapping from the air cartridge.

STEP 4. COMPLETE COLLECTION EVENT

- Collector asks the donor to initial the identified regions of the donor and air cartridge labels.
- Collector dates the identified regions of the donor and air cartridge labels (MM/DD/YYYY).
NOTE: Use a ballpoint pen to initial and date the cartridge labels.
- Collector ensures Assisted Compression Equipment (ACE) is mounted to a rigid table or desk.
- Collector places the donor cartridge upright in the base of the ACE and pushes it against the back wall of the ACE.
- Collector uses two hands to pull the ACE handle down and compress the cover of the cartridge until the ACE hits a hard stop.
- Collector lifts the handle of the ACE and removes the donor cartridge, taking care not to tip the cartridge when removing.
- Collector places the cartridge upright on a flat surface and presses the cover down firmly by hand to ensure a full compression.
- Collector completes the same compression steps for the air cartridge.
- Collector disconnects the connector from the base station and discards the tubing.
NOTE: To detach the connector, grasp the base of the connector fitting and tilt downward to remove from the port.
NOTE: Pumps in the base station will conduct a 20-second purge cycle after the connector has been detached.
- Collector secures the cover onto the donor cartridge by applying a tamper-evident seal to the cartridge.



NOTE: Apply the tamper-evident seal by placing the end of the seal in the center of the Hound Labs logo on the front of the cartridge, wrapping the seal down around the bottom to cover the larger center hole, and ending on the back surface of the cartridge.

- Collector applies the second tamper-evident seal to the air cartridge using the same placement technique.

STEP 5. CERTIFY COLLECTION + SHIP SAMPLES

- Collector places the locked donor and air cartridges with tamper-evident seals into a lab sample bag (laboratory specimen bag), seals the bag shut, and selects the Done button on the Prepare Specimen screen.
- Collector instructs the donor to read the certification statement, sign on the touchscreen certifying the collection is complete, and select the Accept button.
NOTE: Donor may select the Clear button to reset signature field and re-sign prior to accepting.
- Collector signs the touchscreen certifying collection is complete and selects the Accept button.
- Collector places the lab sample bag into an overnight shipping envelope and then attaches a pre-printed laboratory shipping airbill.
- Collector releases the samples to an approved delivery service for shipment to the laboratory for testing the same day as collection or the next business day.
NOTE: Samples should be shipped to the lab via FedEx only.
NOTE: If the package is not shipped the day of collection, the collector should follow company policy to secure the sample and store at room temperature until it is shipped.
- Collector selects the OK button on the touchscreen to begin a new collection.

NOTE: Do not unplug the base station while the system is running. The system can be powered off using the Shut Down option from the system menu on the base station touchscreen. Alternatively, press and hold the power button on the back of base station for several seconds to turn the system off.










Clean the system by wiping all external surfaces with a non-abrasive cloth dampened with a solution of 70% isopropyl alcohol OR 70% ethanol. DO NOT spray cleaning solution directly onto the system. DO NOT submerge the system in the cleaning solution.

STORAGE AND TRANSPORT OF CARTRIDGES

Collected samples should be transported to the laboratory at ambient temperature via overnight shipping. Samples should be protected from impact and temperatures outside the range of 4-37°C (39.2-98.6°F) for a maximum of 7 days from the time of collection.



EXPLANATION OF SYMBOLS

	LOT CODE
	CATALOG NUMBER
	CONSULT INSTRUCTIONS FOR USE
	USE BY
	DO NOT REUSE
	TEMPERATURE LIMITATION
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	MANUFACTURER

Collector training for the HOUND® CANNABIS BREATHALYZER is available at <https://houndlabs.com/collector-portal/>.

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