SENSABUES AB

Exhaled breath (EB) sampling device, specimen collection and lab testing

Frequently Asked Questions – FAQ List v1.8

1. Where can I find more technical information about EB? - There are over 30 published papers available. See the list of 'Related Papers' in pdf format, available to download on this website's RESOURCES page (http://sensabues.com/resources).

2. Does Sensabues offer a pricing discount for research projects? - Yes.

3. Can Sensabues provide bulk samples of the electret filter material separately, without the sampling device's blue plastic housing, to facilitate method development and validation studies of EB by new users (ie. labs)? - Yes.

4. What is included in one kit? - Everything needed to collect an EB sample is included in a specimen collection kit. Each kit contains one EB sampling device, individually packaged in a carton (the carton's weight is approximately 36 grams and the dimensions are 4cm x 4cm x 13cm). There are 96 cartons (96 EB kits) in a box (each box weighs 3.8kg and its dimensions are 28cm x 30cm x 39cm).

Packaging	Quantity	Weight	Size (cm)
carton	1 collection kit	37g	4x4x13
box	96 collection kits	3.8kg	28x30x39

1. Does EB offer an instant or point-of-care-test (POCT)? - Not currently. EB is a back-to-lab based confirmatory test procedure using LC-MS/MS analysis, which is legally defensible.

2. Is the sampling device available in high volumes? - Yes. Inventory is held in Stockholm. Orders of several hundred units are delivered within 10 days of receiving a purchase order. Higher volumes are available upon request.

3. Who owns the patents/IPR associated with ExaBreath® (EB) technology? - Sensabues AB.

4. Do you have the standard operating procedures (SOP) fully documented for this technique? - Yes. A set of SOP is available upon request.

5. What is the recommended filter wash procedure? - The elution process used by the Karolinska Institute can be found detailed in Section 2.5 of the following method validation paper: *Method validation and application of a liquid chromatography-tandem mass spectrometry method for drugs of abuse testing in exhaled breath* (March 2015) http://www.ncbi.nlm.nih.gov/pubmed/25687804. Alternatively, please see the elution process used by the Center for Preventive Doping Research Institute of Biochemistry, German Sport University Cologne, in Section 2.4 of the technical paper '*Expanding Analytical Options in Sports Drug*

Testing: Mass Spectrometric Detection of Prohibited Substances in Exhaled Breath' (May 2017) http://onlinelibrary.wiley.com/doi/10.1002/rcm.7903/epdf

6. What is the purpose of the small clear plastic bag attached to the sampling device? - As an integral part of the functional design, a small fraction of the exhaled breath passing through the collection device is diverted into a compact plastic bag (inflation bag). This inflation bag serves two functions. Firstly, by inflating, it visually indicates to the person collecting the sample that the donor is exhaling breath thru the EB device (filter) correctly. Secondly, when the bag is fully inflated, it indicates that the minimum required amount of exhaled breath (approx. 30 litres) has passed through the filter, which equates to approximately three minutes of normal breathing. However, should a donor prefer to provide their sample more quickly, forced expiration is permissible.

7. Can the donor blow or force air thru the device to provide a sample more quickly? - Yes. Forced expiration is permissible if the donor so choses.

8. Is the donor required to force air thru the device? – No. It is not necessary to force air thru the device. A normal tidal breathing rate is adequate.

9. Is the donor required to provide their sample within a certain time interval? - No. Normal breathing rate is sufficient. Donor can take longer than the usual 3 minutes if required.

10. Are different sizes of inflation bags available that equate to larger volumes of air passing through the filter? - Yes

11. What type of filter material is used? - An electret polymer filter with low air flow resistance.

12. Is it easy to breathe thru the filter? - Yes. It is not a mechanical resistance type filter; it's an electrostatic filter, so it is thin and offers low resistance to the exhaled breath passing through it.

13. Is this filter material expensive? - No. This filter is commercially available. Similar types of electret filter material are commonly used in a wide range of commercial and domestic applications.

14. Are different types and thicknesses of filter material available for different applications? - Yes.

15. Does the EB method collect saliva/oral fluid? - No. The EB method is not intended to collect saliva. There are patented functional features incorporated into the design of the collection device's mouthpiece to prevent saliva entering the filter section. The detection window of EB does not match that of saliva. Data to support this is well documented in the list of published technical papers. See the paper '*Does oral fluid contribute to exhaled breath samples collected by means of an electret membrane?*' (March 2019) https://onlinelibrary.wiley.com/doi/full/10.1002/dta.2597

16. Does the EB method take a DNA sample from the donor? - No. DNA is not present in the final EB analyte used by the test lab.

17. Are there any obstacles to, or factors gating, the adoption of EB technology? - None. All the processes, techniques, equipment, and services required to roll-out EB are readily available. There is no further discovery or invention required to deploy EB.

18. Can the EB specimen collection process be adulterated by the donor? - It is extremely difficult for a verified donor to adulterate or switch their sample without it being detected.

19. Is the device tamperproof? – No. The current device has not been designed to be tamperproof, but it is tamper resistant. A customer specific version of the device has been produced for anti-doping in sport, which has tamper evident features included.

20. Can the sample be stored? – Yes. A used device can be stored in a freezer. EB is a dry sample so it may be possible to store it at room temperature for a short period of time (a few weeks).

21. Are donors with respiratory problems, such as COPD, able to provide a sample? - Yes. Many EB studies have been performed, and authentic samples provided by patients with pulmonary/respiratory conditions (COPD, asthma, and TB).

22. Is the exhaled breath specimen sampling method well accepted by donors? - Yes. Data published in technical papers from field trials show that EB is preferred over other sample collection procedure (blood, urine, and oral fluid). Also, the data shows that EB has the shortest collection time. The EB sampling device is easy to use and the technique is less invasive/intrusive that other matrices. The EB method offers the best user experience for donor and collector.

23. Is the EB method analysis accurate? - Yes. The detection window for exhaled breath closely mimics that of blood and EB can detect the parent/intact drug, not just metabolites. The back-to-lab HPLC-MS/MS analysis technique, used by EB, is the same as that used by other matrices (blood, urine, oral fluid, etc.) and is court admissible and legally defensible.

24. Can EB detect intact/parent drugs? – Yes. The EB testing technique can detect intact/parent/unmetabolised drugs of diverse physico-chemical nature.

25. Is the EB method of collecting the sample reliable? - Yes. Unlike, urine and saliva, a breath sample is always readily available, so the collector never has to wait for a valid specimen.

26. Is EB the same method as exhaled breath condensate (EBC)? - No. These are two different specimen collection procedures. EB uses a completely passive device that requires no active cooling or pumping. EB is a passive technique that collects only non-volatiles expelled in exhaled breath. EB is not designed to collect volatiles.

27. Is EB suitable for anti-doping testing in sports? Yes. Substances such as anabolic agents (S1), hormone and metabolic modulators (S4), stimulants (S6), narcotics (S7), cannabinoids (S8) and beta-blockers (P2), listed in The World Anti-Doping Agency's (WADA) Prohibited List (https://www.wada-ama.org/en/prohibited-list), have be detected using EB. Unlike urine testing, the detection window for EB closely matches that for blood, which makes EB suitable as a lab-based screening test for in-competition testing. Also, post-exercise dehydration does not adversely impact the donor's ability to provide an EB sample.

28. Can EB be used to detect new psychoactive substances (NPS) and synthetic drugs or a mixture of substances? - Yes.

29. Which categories of therapeutic drugs does EB detect? - So far, EB has been able to detect medication concentrations of several different types of antibiotics, painkillers, antidepressants, and tranquilisers.

30. Is a double barrel version for A+B sample collection planned? – Yes. A dedicated A+B specimen collection device has been designed.

31. Can an A+B sample be taken using the current single barrel sampling device? - Yes. Duplicate samples can be collected sequentially. Alternatively, a simple **Y** connector can be used to collect one breath sample in two separate filters simultaneously. See picture below.

For more information please contact:

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