



How To Perform An Evaluation Of The OSOM[®] Influenza A & B Test



Where do I obtain samples to use for evaluation?

- 1) You may request flu evaluation swabs by contacting your Sekisui Diagnostics Sales Rep or calling 800 332 1042 opt. 3.

-Or-

- 2) If you are associated with a nearby sister site that is willing to send you patient samples, you may use these samples to evaluate the OSOM Influenza A & B Test Kit.

-Or-

- 3) You may request Influenza A & B samples from your proficiency organization such as CAP, API, AAB (See contact numbers below). Inform them that you would like to obtain proficiency material from previous surveys to use for evaluation of a diagnostic test kit.

How many samples should I test when performing an evaluation?

There is no set number of samples required to be tested, however 20 samples is considered a “rule of thumb” for statistical purposes. For more information, refer to the CMS Interpretive Guidelines 493.1235 at http://www.cms.hhs.gov/CLIA/03_Interpretive_Guidelines_for_Laboratories.asp **Subpart K.**

What should I do if I have questions about the OSOM Influenza Test Procedure or results?

For technical assistance or additional information on the OSOM Influenza A & B Test, please call 800 332 1042 opt. 3

How may I contact a proficiency agency to obtain evaluation material (option #3 above)?

American Academy of Family Physicians	(AAFP)	800 274 7911
American Association of Bioanalysts	(AAB)	800 234 5315
American Proficiency Institute	(API)	800 333 0958
College of American Pathologists	(CAP)	800 832 7000
Medical Evaluation Evaluation	(MLE)	800 338 2746