

Convenience Kit for Collecting and Transporting Upper Respiratory Specimens

Re-order No. 207128

For in vitro Diagnostic Use - Rx Only

INTENDED USE

Quest Diagnostics™ Convenience Kit for Collecting and Transporting Upper Respiratory Specimens contains a PBS Transport Tube and a nasopharyngeal swab, and is intended for use by healthcare professionals to collect and transport clinical specimens to Quest Diagnostics for testing. Phosphate buffered saline can be used for collecting specimens for pathogen testing when better alternatives are not available.

THIS COLLECTION KIT IS NOT APPROPRIATE FOR EVERY TEST. PLEASE SEE THE SPECIMEN COLLECTION GUIDE FOR THE RELEVANT TEST AT https://testdirectory.questdiagnostics.com/test/home.

MATERIAL PROVIDED

Phosphate Buffered Saline Transport Tube (PBS Transport Tube). Contains 3 mL phosphate buffered saline (PBS). Ready for use and no further preparation is necessary. The product should be stored in its original container at 4°C to 25°C until used. Do not overheat. Do not incubate, or freeze prior to use. Improper storage may result in a loss of efficacy. This product is sterilized by E-Beam.

The convenience kit contains one nasopharyngeal swab and one PBS transport tube. The product should be stored in its original container at 4°C to 25°C until used. Please refer to the swab's manufacturer website for the swab instructions.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Consider all human specimens, blood derivatives, reagents and materials used for processing as capable of transmitting infectious
 diseases and handle them in a manner which prevents infection of personnel. No known test method can offer complete assurance
 that infectious agents are absent.
- Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.
 Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit. Wash hands thoroughly after handling.
- Pathogenic microorganisms, including hepatitis viruses (e.g., HBV, HCV), human immunodeficiency virus (e.g., HIV-1 and HIV-2), Human T-cell lymphotropic virus (HTLV, types I and II), STS, etc. may be present in clinical specimens. "Standard Precautions" and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Sterilize all biohazard waste including specimens, containers, and media after use. Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- · Directions must be read and followed carefully.
- Not for use with multiple patients.
- · Do not re-pack.
- Do not ingest the PBS. Avoid contact with skin, mucosal membranes and eyes with the PBS. Do not use the PBS to moisten nasal passages. Do not use the PBS for pre-moistening or pre-wetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites.

PROCEDURE

- 1. Write the patient's name, date of birth, date of collection and other information on the PBS Transport Tube and collect the specimen according to the package insert for the specimen collection swab.
- 2. After breaking off the swab, securely attach the cap to the PBS Transport Tube. Note: the PBS Transport Tube has a "screw cap" (not a push cap). Please ensure the screw cap is gently turned in clockwise rotation until seated (firm stop).
- 3. Package the PBS Transport Tube in a secondary container, for example a zip log bag, along with a completed test requisition. See the specimen collection guide for the relevant test at www.questdiagnostics.com for the appropriate storage temperature and speed for shipping the specimen.

Do not use PBS Transport Tube or Swab if:

- There is evidence of damage or contamination to the product;
- The PBS Transport Tube has evidence of leakage, the cap does not fit properly, or the tube or cap is cracked or mis-shaped;
- The color of the PBS is no longer clear and transparent;

- The expiration date has passed;
- There are other signs of deterioration or the integrity of the Swab's packaging has been compromised.

ASSISTANCE

To place an order, please contact a Quest Diagnostics Representative at 1.866.697.8378.

For kit problems, please call 1.866.697.0040 or contacts us at QuestConvenienceKit@questdiagnostics.com.

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