

MedSchenker Smart ParaTube PARA15 Ova and Parasite (O&P) Testing Tube

Product Insert & How-to-Use Guide

INTENDED USE

MedSchenker Smart ParaTube™ Para15 Ova and Parasite Testing Tube is used to test stool samples and extract the Ova and parasites by lab and hospital professionals

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of Ova and Parasites involves the collection of stool samples to test tubes. This can be accomplished using the MedSchenker Smart ParaTube. MedSchenker Smart ParaTube™ are made from Premium Poly

PRECAUTIONS

1. Carefully follow the instructions for use.
2. If the test tube is submitted to a chemical or physical sterilizing or micro-biostatic process, its intended functioning could be compromised.
3. Product cannot be reused or re-sterilized

STORAGE

Store the MedSchenker Smart ParaTube devices at 2-30°C. If the product is stored at a different temperature, it would not maintain the stated specifications.

PRODUCT DETERIORATION

The content of the unopened and undamaged units is guaranteed to be sterile. MedSchenker Test tubes should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the test tube package is open or damaged, or (4) there are other signs of deterioration.

DIRECTIONS FOR USE, SPECIMEN COLLECTION

NOTE: Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens

1. A lab technician/Professional places the stool sample into the MedSchenker Smart ParaTube PARA15 (O&P) Testing Tube.
2. Open the MedSchenker Smart ParaTube and pour 9ml formalin which is diluted by 10%.
3. Place Stool Sample into our MedSchenker Smart ParaTube using the appropriate tools and close the lid.
4. Shake it to mix the stool sample and formalin by hand or put it on a Shaker for shaking at 250 rpm for 5minutes.
(After shaking, remove the inner tube. Make sure to dip the inner tube thoroughly to ensure the maximum amount of (O&P) will be collected from the inner tube to the outer tube .)
5. Open the lid of the Tube and pour 3ml Ethyl acetate and close the lid.
6. Centrifuge it at a centrifuge at 500G for 10 minutes.
7. After centrifuge, open the lid and remove the excess liquid that has been separated during the centrifuge process.
8. Smear the filtered and remaining liquid onto a slide and inspect accordingly.

Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines. Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with internal guidelines of the institution.

LIMITATIONS

1. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe Biosafety recommendations when handling or analyzing patient samples.
2. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. MedSchenker Smart ParaTube Test tubes must be used by skilled personnel only.

WARNINGS

1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. Do not re-sterilize unused test tubes.
3. Do not re-pack.
4. Not suitable for any other application than intended use.
5. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
6. Do not use if the test tube is visibly damaged (i.e., if the test tube tip or test tube shaft is broken).
7. Do not use excessive force, pressure or bending when collecting test tube samples from patients as this may result in accidental breakage of the test tube shaft.
8. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
9. To be handled by trained personnel only.
10. It must be assumed that all specimens contain infectious micro-organisms; therefore all specimens must be handled with appropriate precautions. After use, tubes and test tubes must be disposed of according to laboratory regulations for infectious waste

WASTE DISPOSAL

Unused test tubes may be considered as non-hazardous waste and disposed of accordingly. Dispose of used test tubes as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

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