

PACKAGE INSERT – CLEAR PREP COLLECTION VIALS

INSTRUCTIONS FOR USE

ClearPrep® is a liquid-based thin layer slide preparation process for cytological samples.

The ClearPrep process begins with qualified medical personnel collecting a specimen and dispensing into an appropriate container, such as a ClearPrep Collection Vial, which has been designed with internal ridges to improve cellularity of the sample:

- 1. Remove the cap from the ClearPrep Collection Vial.
- 2. After collecting the sample, place the portion of the device containing the cellular material into the preservative fluid in the vial. Rinse the device thoroughly to ensure the release of the material, using the internal ridges of the vial to enhance this process.
- 3. Discard the collection device in the usual manner.
- 4. Replace and tighten the cap on the collection vial.
- 5. Assign the required patient information on the vial label and forward to the lab for processing.

NOTE: It is strongly recommended that the collection device not be left in the vial.

LIMITATIONS

Proper performance requires use of supplies provided or recommended by Resolution Biomedical, Inc. for use in connection with ClearPrep. Product performance may be compromised if other supplies are used. After use, supplies should be disposed of in accordance with local, state, and federal regulations.

REAGENTS

ClearPrep Preservative is an alcohol-based (>30%) general purpose reagent intended for *in vitro* diagnostic use. For laboratory use only. Contains methanol, combustible, non-sterile.

PRECAUTIONS

Good laboratory practices should be followed and all procedures for use of ClearPrep should be strictly observed.

MATERIALS REQUIRED

MATERIALS PROVIDED

Sample collection vial with 20 ml ClearPrep Preservative

MATERIALS REQUIRED BUT NOT PROVIDED

Sample collection device, such as the Gynemed Brush



ClearPrep Cytology Solution

ClearPrep Balancer

ClearPrep centrifuge tubes

ClearPrep microscope slides

Transfer pipettes

Centrifuge configured to accept ClearPrep centrifuge tubes

Vortex mixer

Slide cover slips

Slide staining system and reagents

STORAGE

ClearPrep Cytology Solution and Preservative should be stored at room temperature (between 15°C and 30°C). Do not use beyond the expiration date printed on the container.

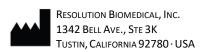
The storage limit for ClearPrep Collection Vials with cellular samples is six months at refrigerated temperature (2° to 10°C) or 30 days at room temperature.

TECHNICAL SUPPORT AND CUSTOMER SERVICE

For training, technical support and customer service, please contact Resolution Biomedical, Inc.

Telephone: 949-551-8000

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REF CP13001 CP13025 CP13500