



PACKAGE INSERT – ClearPrep Laboratory Pack for Vials

Item#: CP1LABV, CP2LABV

INSTRUCTIONS FOR USE

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

Sample Preparation Process

The ClearPrep process begins with qualified medical personnel collecting a specimen and dispensing into an appropriate container, such as a ClearPrep Collection Vial. At the laboratory, follow the following procedure:

1. Vortex specimen vial approximately 5 seconds.
2. Pour half of the specimen into the ClearPrep® centrifuge tube (10 ml fill line). Save remaining sample for ancillary testing.
3. Centrifuge tube for 3 - 5 minutes (1,500 - 2,000 rpm). Where necessary, add quantity of ClearPrep Balancer to ensure all tubes in centrifuge contain equal volume.
4. After centrifugation, decant the supernatant thoroughly, leaving only the pellet at the base of the centrifuge tube.
5. Add a volume of ClearPrep Cytology Solution approximately the same as the cell pellet.
6. Vortex the mixture 3 - 5 seconds to break up the pellet, then let stand for 60 seconds to allow the Cytology Solution to penetrate the cell membrane. When complete, sample is now stable and preserved.
7. Vortex the mixture for 5 - 10 seconds until thoroughly mixed.
8. Using a disposable pipette, transfer sufficient volume (2 - 4 drops) of the mixed cell suspension onto a ClearPrep microscope slide to cover the 18 x 22 mm oval.
9. Allow the slide to dry completely at room temperature (25 - 40 minutes).
10. Stain the slide using standard and established laboratory protocol guidelines and coverslip in traditional manner.

The cells are examined under a microscope by trained cytotechnologists and pathologists in the context of the patient's clinical history and information provided by other diagnostic procedures such as colposcopy or biopsy.

LIMITATIONS

- Training by persons authorized by Resolution Biomedical is required to ensure optimal results.
- 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 Cytology Solution is an alcohol-based (<20%) general purpose reagent intended for *in vitro* diagnostic use. For laboratory use only. Non-toxic, non-flammable, non-sterile.

ClearPrep Balancer is an alcohol-based (<24%) general purpose reagent intended for *in vitro* diagnostic use. For laboratory use only. Non-flammable, non-sterile.



PRECAUTIONS

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

MATERIALS REQUIRED

Materials Provided

- ClearPrep Cytology Solution
- ClearPrep Balancer
- ClearPrep centrifuge tubes
- ClearPrep microscope slides
- Transfer pipettes

Materials Required But Not Provided

- Sample collection vial, such as ClearPrep Collection Vial with 20 ml ClearPrep Preservative
- Centrifuge
- Vortex mixer
- Slide cover slips
- Slide staining system and reagents
- Sample collection device

STORAGE

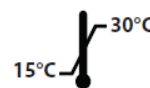
ClearPrep Cytology Solution and Preservative should be stored at room temperature (between 15°C and 30°C). Do not use beyond the expiration date printed on the container.

The storage limit for ClearPrep Collection Vials with cellular samples is 6 months at refrigerated temperature (2° to 10°C) or 4 weeks at room temperature.

TECHNICAL SUPPORT AND CUSTOMER SERVICE

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

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