

Intended use

CytogenPrena Medium is used for the cultivation of a) cells from chorionic villus biopsy and abortion material as well as b) primary and passaged amnion cells. It is intended for human genetic *in vitro* diagnostics.

Composition

It is a complete medium composed of a basal medium, pretested FBS, hormones and growth factors for the corresponding cell or tissue type, phenol red, NaHCO₃ as buffer plus gentamicin and L-glutamine.

Shelf life and storage

Unopened CytogenPrena medium can be stored for 18 months from the date of manufacture if stored at \leq -18°C. After opening, store the bottle at +2°C to +8°C and use for a maximum of 7 days. Avoid repeated thawing and freezing.

Thawing

Thaw CytogenPrena medium at + 2 °C to + 8 °C overnight. Thawing in a water bath at 37 °C is not recommended. Mix well before using Lymphogrow medium. The normal ph value is 7,2 as indicated by the phenol red indicator. In the case of a ph deviation (yellow or pink), the ph value is obtained by incubating the slightly open bottle (approx. ¼ rotation of the lid) in a 5% CO₂ incubator equilibrated until the medium has reached the normal color red. Lymphogrow medium contains no components whose quality is affected by ph fluctuations of +/-2. Heated medium at 37 °C and correct ph-value ensures an optimal start of the culture.

Sample preparation

Separate both the chorionic villus biopsy and the abortion material from maternal material (decidua) and other contaminants (e.g., blood coagulum). Mince the material with a sterile scalpel. Spread out the sample in a culture bottle. Alternatively, use the enzyme dispase or collagenase for maceration during 10 minutes at an adequate concentration. Keep cells in a 'humid chamber' for one hour with the addition of 3 ml CytogenPrena, i.e., place the culture bottle upside down and then slowly and carefully turn it to prevent the material from peeling off.

Standard protocol

The method described below is a standard guide for the use of CytogenPrena Medium in the cultivation of appropriate tissue samples.

Bottle method

- Concentrate cells via low-speed centrifugation
- Remove 90–95% of the supernatant and resuspend the cells in the remaining supernatant.
- Dilute the pellet to at least 2 mL with pre-warmed CytogenPrena to obtain 2 mL per culture bottle.
- Incubate at +37°C, 5% CO₂, in the incubator
- Check growth on day 5 and replace the medium with fresh CytogenPrena Medium
- Replace the used medium regularly until harvest
- For best results, change the medium the day before harvest

in situ method

- Concentrate cells via low-speed centrifugation
- Remove 90–95% of the supernatant and resuspend the cells in the remaining supernatant.
- Dilute the cell suspension with pre-heated CytogenPrena Medium to at least 2 ml to obtain 0.5 ml suspension per coverslip (4 in total)

- Incubate at +37°C, 5% CO₂, in the incubator
- On the second day, add 2 ml of CytogenPrena
- After 4–5 days, check cell growth
- Immediately afterwards, carefully aspirate the entire medium and replace with 2 ml of pre-heated fresh CytogenPrena Medium
- Recommendation: change the medium every 2 days
- For best results, change the medium the day before harvest

Warnings and precautions

- Maintaining the sterility of the product is necessary for its use, and this must be strictly adhered to by the user.
- Not suitable for therapeutic use with humans or animals.
- May only be used by trained, specialist personnel.
- Do not use bottles whose packaging has been damaged.
- Do not use CytogenPrena Medium beyond its expiry date, which is stated on the label.
- The patient samples constitute biological material, and, therefore, safety precautions must be taken in accordance with local regulations for working with potentially infectious material.
- Cytogen GmbH does not guarantee the success of diagnostic testing solely through the use of Cytogen products.
- Report serious incidents that have occurred in connection with this product to the manufacturer and the competent authorities.

CE marking

With CytogenPrena, Cytogen offers a CE-marked medium that meets the regulatory requirements for *in vitro* diagnostic medical devices set by the European Commission.

Explanation of symbols

ĺ	Observe instructions for use		Manufacturer
IVD	In vitro diagnostic medical device	$\overline{\mathbf{x}}$	Date of manufacture
REF	Article number	STERILE A	Sterilised using aseptic methods
LOT	Production lot number, batch		Do not use if the packaging is damaged
М	Use by	**	Keep away from sunlight
X	Temperature limit		

Manufacturer



Cytogen Produkte für Medizin + Forschung GmbH Nordwalder Str. 120 48268 Greven

Tel.	+49 2571 560180			
Fax	+49 2571 9219118			
Email:	info@cytogen.net			
Website: www.cytogen.net				

CE