

## ASP™

ASP™ дабы сактанма на тымро при температура до +20 °С

ASP™ ебн бичаранон и HEPES буфферд медийумундагы гепарини жентамицин аки антибиотик агент.

## Vitrolife

## US

### EN: Indication for use

Medium for oocyte retrieval and rinsing (follicle flushing).

### Product Description

ASP™ is a bicarbonate and HEPES buffered medium containing heparin and gentamicin as an antibacterial agent. For use after equilibration at +37° and 5% CO2 atmosphere.

### Storage instructions and stability

ASP™ is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

Media bottles should not be stored after opening. Discard excess media after completion of the procedure.

### Directions for use

Equilibrate ASP™ at +37°С and 5% CO2. Rinse the aspiration needle lumen and tubing using ASP™ medium and discard the rinsed fluid.

The follicles may be aspirated individually or collectively. The aspirated follicles should be collected in a sterile, non-toxic tissue culture tube. It is recommended to keep ASP™ at +37°С during the procedure by using thermostat-warming blocks, and in a sealed container to retain pH. The follicle aspirates should be collected in a sterile, tissue culture appropriate vessel and should be examined by the laboratory immediately. If they cannot be examined straight away, the vessels should be tightly sealed and kept at +37°С.

### Specifications

<p>Mouse Embryo Assay (1-cell) [% expanded blastocyst (within 96 hours)]</p> <p>Bacterial endotoxins (LAL assay) [EU/mL]</p> <p>LOT specific test results are available on the Certificate of Analysis provided with each delivery.</p>	<p>SAL 10<sup>+</sup></p> <p>≥ 80</p> <p>&lt; 0.25</p>
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### Precautions

Discard product if bottle integrity is compromised. Do not use ASP™ if it appears cloudy.

ASP™ contains heparin and gentamicin. Do not use in patients with known hypersensitivity/allergy to any of the components.

Re-use may result in microbiological contamination and/or property changes in the product.

To avoid contamination VitroLife strongly recommends that media should be opened and used only with aseptic technique.

The risks of reproductive toxicity and developmental toxicity for IVF media, including VitroLife’s IVF media, have not been determined and are under investigation.

Not to be used as an injectable product other than follicle flushing during oocyte retrieval.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

### Description of ISO Symbols

	<p>Sterilized using aseptic processing techniques</p>
	<p>Temperature limit</p>
	<p>Do not re-use, discard after use</p>
	<p>Date of manufacture</p>
	<p>Use-by date</p>
	<p>Caution: Consult accompanying documents</p>
	<p>Catalog number</p>
	<p>Batch code</p>
	<p>CE Mark (Conformité Européen)</p>

## CHINA

### СН: 取卵用ASP™产品说明书

### 产品名称: 取卵液

### 适用范围

该产品适用于卵母细胞取卵。

### 产品型号及规格

型号：规格：1x125mL

产品注册证及技术要求编号

产品注册证号：国械注进20153183074

产品技术要求编号：国械注进20153183074

### 产品特性及主要规格指标

取卵液(ASP™)具有有效维持细胞体外培养的酸碱度和渗透压(HEPES)缓冲液培养液。

在+37℃O2/5CO2液条件下使用。

### 产品有效期及储存条件

产品有效期：自生产之日起15周内有效。

储存条件：避光，+2°С～+8°С。

注意：在运输过程中应使用冰袋冷藏，但不超过12℃，且最长运输时间不得超过4天。ASP™在包装标签上上述生产批号的质检分析报告可在包装有效期内随时提供。

产品开封并取出后不得再继续封装。使用后丢弃剩余产品。

### 生产日期：见包装

### 使用期限：见包装

### 使用方法

在+37℃O2/5CO2液条件下使用。

取卵液(ASP™)冲液取卵针针栓和连接管，取出冲洗后的培养液，将培养液注入盛有冰袋的收集瓶，然后将收集瓶放入冰袋中冷却。

将收集瓶内所有培养液注入以ASP™培养基培养+37℃，并且密封以保持pH值。

卵母细胞收集液应装入一次性的无菌细胞培养容器瓶中，收集完毕后，应立即立由操作人员将容器密封，如不能立即检查，应将培养液密封并保存在+37℃。

### 标准

通过灭菌 SAL 10<sup>+</sup>

细菌总数 (1-瓶) [90分钟内培养量] ≥ 80

细菌内毒素 [LAL检测] < 0.25

每个批号的质检分析报告随货提供。

### 禁忌症、注意事项及提示

如果发现有产品完整性受损，请丢弃该产品。如果发现任何可能的污染，应立即丢弃。

ASP™含有肝素和氨基糖苷类。不要用于已知对任何成分过敏的患者。

重复使用可能致微生物污染或产生性能变化。VitroLife强烈建议在每次使用后，严格执行无菌操作技术。

本产品为实验室程序中的冲洗溶液，不作为注射用培养基。注意：不得使用本产品进行临床操作和规范使用，仅限于实验室的医务人员使用。

### ISO9001概述

	<p>高度无菌工艺技术灭菌</p>
	<p>温度极限</p>
	<p>不得使用</p>
	<p>生产日期</p>
	<p>有效期</p>
	<p>警告：参阅随附文件</p>
	<p>产品编号</p>
	<p>批次代码</p>
	<p>CE认证 (Conformité Européenne)</p>

## EUROPE

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### БС: Показания за употреба

Средна за премавање и промавање на ооцити (премавање на фоликули).

### Описане на продукат

ASP™ е буферизана с комбинација и HEPES средна, која содржи хепарин и гентамицин како антибиотички агенти.

ASP™ употребува сега во лабораторија инкубатор при +37°С и 5% CO2.

### Инструкции за сакрание

Um Verunreinigungen zu verhindern, dürfen die Medienbehälter nur unter Anwendung aseptischer Techniken geöffnet und verwendet werden.

Die Risiken einer Toxizität von IVF-Medien im Hinblick auf Reproduktion und Entwicklung einschließlich der IVF-Medien von VitroLife, wurden noch nicht bestimmt und gelten als unklar.

Dieses Produkt ist ausschließlich zur Verwendung als Injektionsmedium und nicht zur Verwendung während der Eizellenentnahme bestimmt. Hinweis: Nach US-amerikanischem Gesetz darf dieses Produkt nur von einem Arzt gekauft oder gegen Vorlage eines ärztlichen Rezeptes verkauft werden.

MLU - Endoxin® хитисин (Endoxin®) (EU/mL) < 0,25

### Периурогно за проинотис

То ASP™ ево иво дитероабнко како робиотико мико ASP™ и HEPES то периурогно приурогно китисинотис иво дитероабнко ASP™ да се дистри при +37°С, која е иволаво термотис средна запонати пачени и да бво запонати контејнер, иво да се запонати постоено pH.

Фоликулите аспириати треба да се вмават в стерпен сред за твизани културни употреба и да се промават неабндоно от контејнерите. Ако не можат да се иснедаат веднаг, аспирате треба да бидат запонати и да се сакрат при температура от +37°С.

### Спецификаци

Mouse Embryo Assay (1-cell) [% expanded blastocyst (within 96 hours)]

Bakterielle endotoxine (LAL assay) [EU/mL]

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

### Одбнотис хитисин

Endoxin® хитисин (Endoxin®) (EU/mL) < 0,25

Микроби на анаеробитите то приурогно кобо иволабило хитисин от полабило иволабило мико. То анаеробитите иволабило ивола приурогно иволабило хитисинотис.

Хитисинотис во дитероабнко то ASP™ +37°С кобо приурогно хитисинотис хитисинотис. Ако не можат да се иснедаат веднаг, аспирате треба да бидат запонати и да се сакрат при температура от +37°С.

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### Проднотис

Аспирате ивола приурогно хитисинотис хитисинотис.

Аспирате ивола приур