

Ansh Check™ 1T-2T Maternal Screening Bi-Level Controls




AL-CTR-404-i and AL-CTR-404-5-i

INTENDED USE

Ansh Labs Maternal Serum (MS) Bi-Level Controls are intended for use as quality controls to monitor the accuracy and reproducibility of laboratory testing methods for the determination of AFP, Inhibin A, free beta hCG, Estriol, PAPP-A and Intact hCG in human serum. This product is not intended for diagnostic or therapeutic use.

MATERIALS SUPPLIED

Part Numbers	
AL-CTR-404-i (Mini Pack)	<ul style="list-style-type: none"> Mini pack contains one vial each of CTR-404-L and CTR-404-H, Low (L) and High (H) Analyte Controls. Five vials each for CTR-404-L and CTR-404-H, Low and High Analyte Controls per pack. 
AL-CTR-404-5-i (5-pack)	<ul style="list-style-type: none"> Provided as lyophilized powder. The powder contains low and high levels of PAPP-A, Free β-hCG, AFP, Intact hCG, Inhibin A and unconjugated Estriol. Reconstitute each vial with 1 mL deionized water. Refer to control card for analyte specific control ranges.

Storage and Stability

Store unopened vials refrigerated at 2 to 8°C until the expiration date printed on individual vials. Reconstituted controls are stable for 7 days at 2 to 8°C, if kept capped in original container and free from contaminants. For multiple uses, aliquot and freeze at -20°C or colder. The frozen aliquot is stable for 9 months, if stored appropriately and free from contaminants. Avoid multiple freeze-thaws and discard controls after use. The thawed aliquots are stable up to 7 days at 2 to 8°C. The controls are shipped ambient and are stable at 37°C for 7 days.

AN EXAMPLE OF ANALYTE CONCENTRATIONS:

The concentration of low and high controls was derived from replicate analysis of the Bi-level controls in commercially available analyte specific ELISA methods. *It is recommended that each laboratory should establish its own acceptable control ranges. The values provided herein are example and may vary by methods.*

MS Controls For	Analytes	Target Value*	
		CTR-404-L (Low)	CTR-404-H (High)
First Trimester	PAPP-A	860.0 ng/mL	2500.0 ng/mL
	Free β-hCG	22.0 ng/mL	67.0 ng/mL
Second Trimester	AFP	15.0 ng/mL	46.0 ng/mL
	Estriol	1.0 ng/mL	3.6 ng/mL
	Inhibin A	129.0 pg/mL	413.0 pg/mL
	Intact hCG	9.4 IU/mL	33.0 IU/mL

*Determined by ELISAs, PAPP-A (Ansh Labs AL-106), Free beta hCG (DRG, EIA 4178), AFP (Ansh Labs, AL-104), Intact hCG (Ansh Labs, AL-103), unconjugated Estriol (Ansh Labs, AL-138) and Inhibin A (Ansh Labs, AL-123).

WARNINGS AND PRECAUTIONS

For in-vitro diagnostic use only.

The following precautions should be observed:

- Follow good laboratory practice.
- Use personal protective equipment. Wear lab coats and disposable gloves when handling immunoassay materials.
- Handle and dispose of all reagents and material in compliance with applicable regulations

WARNING: Potential Biohazardous Material

This reagent contains human source material (e.g. serum) or materials used in conjunction with human source materials. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 5th Edition, 2007.

WARNING: Potential Chemical Hazard

This product contains Pro-Clean 400 as a preservative. Pro-Clean 400 in concentrated amounts irritants skin and mucous membranes. For Further information regarding hazardous substances in this reagent, please refer to the MSDS, either at AnshLabs.com or by request.



Manufactured by:
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MATERIALS REQUIRED BUT NOT SUPPLIED

- Deionized water
- Volumetric or precision pipet to deliver 1000 µL.

Product Information

Ansh Check™ MS Bi-Level Controls are human serum-based controls spiked with purified native or recombinant human antigens labeled as MS CTR-404-L and MS CTR-404-H containing a low and high analyte concentration. Provided as lyophilized powder. Refer to control card for factory suggested ranges.

Traceability

The MS Bi-Level Controls native and recombinant antigen concentrations are traceable to manufacturers working concentrations. These controls are suitable for use in first and second trimester maternal screening methods that measures human AFP, Inhibin A, free beta hCG, Estriol, PAPP-A and Intact hCG in serum.

Preparation for Use

Controls are provided as lyophilized powder. Gently tap the bottom of the vial. Open the vial carefully to avoid any loss of the material and reconstitute with 1mL of deionized (DI) water. Replace the rubber stopper and swirling gently to solubilize the powder and allow to stand for 10 minutes before use.



European Representative:
RD-RatioDiagnostics GmbH
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FOR EXPORT ONLY

Ansh Labs consumables are being shipped with English Instructions for Use (IFUs). You may contact your local Ansh Labs sales representative or technical support organization to obtain translated IFUs.

Les consommables pour Ansh Labs sont livrés avec des instructions d'utilisation en anglais. N'hésitez pas à contacter votre société d'assistance technique ou votre représentant Ansh Labs local pour obtenir des instructions traduites.

Die Verbrauchsmaterialien von Ansh Labs werden mit englischer Gebrauchsanweisung (IFU) geliefert. Wenden Sie sich gegebenenfalls an Ihren zuständigen Vertreter von Ansh Labs oder den technischen Kundendienst, um übersetzte Gebrauchsanweisungen zu erhalten.

Los consumibles para Ansh Labs se entregan con las instrucciones de uso (IFU) en inglés. También puede ponerse en contacto con el representante local de ventas de Ansh Labs o con la empresa de asistencia técnica para obtener las IFU traducidas.

Symbol	English	Deutsch	Français	Español	Italiano
	European Conformity	CE-Konformitätskennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	Caution	Vorsicht	Mise en garde	precaución	attenzione
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	In vitro diagnostic device	In-vitro Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeitsdatum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Date of Manufacture	Herstellungsdatum	date de fabrication	fecha de manufactura	Data di produzione
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità