

Ansh Check™ AMH Tri-Level Controls






AL-CTR-401-i

INTENDED USE

Ansh Labs AMH Tri-Level Controls are intended for use as assay quality controls to monitor the precision and reproducibility of laboratory testing methods for the determination of AMH in serum, plasma or other biological fluids. Tri-level controls are run as unknowns against kit calibrators in any human AMH assays.


MATERIALS SUPPLIED

Ansh  CHECK™ CTR-401-L	3 x 5 mL vials. Low (L), Mid (M), and High (H) concentrations. Provided as lyophilized powder.
Ansh  CHECK™ CTR-401-M	Reconstitute each with 1 mL deionized water.
Ansh  CHECK™ CTR-401-H	Refer to control card for control ranges.

MATERIALS REQUIRED BUT NOT SUPPLIED

Deionized water
 Volumetric or precision pipet to deliver 1000 µL

Product Information

AMH Tri-Level Controls are native human AMH in human serum in three vials labeled Ansh  Check™ AMH CTR-401-L, CTR-401-M, and CTR-401-H containing a low, medium, and high concentration. Provided as lyophilized powder. Refer to control card for control ranges.

Standardization

The AMH Tri-Level Controls concentrations are standardized to recombinant human AMH preparation (>99.9 % by HPLC) that is characterized by mass spectroscopy. These controls are suitable for use in assays that detect human AMH.

Preparation for Use

Control material is lyophilized. 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 mix well by gentle inversion. Leave to stand to allow to solubilize for 10 minutes before use. Prior to use, ensure that all traces of dry material are dissolved by swirling gently.

Storage and Stability

Store unopened vials refrigerated at 2 to 8°C. Material is stable to expiration date printed on individual vials.

Reconstituted controls are stable after initial use for up to 24 hours at 2 to 8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

For multiple uses, Aliquot and Freeze in Eppendorf tubes or equivalent at -20°C or colder. Aliquot reconstituted control material into appropriately labeled vials and freeze immediately. Thaw frozen controls and mix gently prior to use. Discard any residual product after run. Avoid repeated freeze thaws. After initial use, the thawed aliquots are stable at 2 to 8°C for up to 24 hours.

ASSIGNMENT OF QUALITY CONTROLS VALUE:

The concentration of controls was derived from replicate analysis of the tri-level controls in Ansh Labs US AMH ELISA (catalog number AL-105). It is recommended that each laboratory establish its own means and acceptable ranges and use those provided herein only as guidelines.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use. Not for Internal or External Use in Humans or Animals

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 may contain some 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, 20071.

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.

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European CE Mark Version
For Illustrative Purposes Only
Refer to package insert included with
the product for exact specifications.

FOR EXPORT ONLY