IH-LISS Rack and IH-LISS Solution


FOR IN VITRO DIAGNOSTIC USE
Low Ionic Strength Solution for use with the IH-System
No U.S. Standard of Potency

Product-Identification: 76000

IH-LISS Rack: VOL 10 racks with 60 wells with 700 µl............ REF 813 510 100
IH-LISS Solution: VOL 2 x 100 mL bottle....... .                          ..... REF 813 520 100

INTENDED USE

IH-LISS is a modified Low Ionic Strength Solution for preparation of red blood cell suspensions for use with appropriate IH-Cards. The IH-LISS is “Rx only”.

SUMMARY

In 1964, Mollison and Polley discovered that reducing ionic strength with a Low Ionic Strength Solution, antigen-antibody reaction is considerably accelerated in blood group serological tests.

PRINCIPLES OF THE TEST

The test combines the principles of hemagglutination and gel filtration for detection of blood group antigen-antibody reactions.

The test sample (red blood cell suspension and/or plasma/serum) is distributed into the microtubes containing the appropriate reagent(s) and centrifuged. Non-agglutinated red blood cells are collected at the bottom of the microtube while the agglutinates are dispersed throughout the length of the gel, depending upon their size. Their position in the gel determines the intensity of the reaction.

Refer to the instructions for use for the specific IH-Card.

REAGENT

OBSERVABLE INDICATIONS

Do not use if markedly turbid.


IH-LISS is a Low Ionic Strength Solution containing phosphate buffer, glycine and bovine albumin.

The bovine albumin used for the production of this reagent is purchased from BSE-free sources.

Preservative: 2.5mg/L 0.01mM Trimethoprim, 47.5mg/L 0.19mM Sulfamethoxazole

STORAGE REQUIREMENTS

• Store at 2 to 8 °C.
• Do not use beyond expiry on the label which is expressed as YYY-MM-DD (Year-Month-Day).
• Store in an upright position.
• Do not freeze or expose to excessive heat.
• Do not store near any heat, air-conditioning sources or ventilation outlets.

PRECAUTIONS

• All IH-System reagents and test samples must be brought to room temperature (18 to 25 °C) prior to use.
• Use reagents as furnished.
• The use of diluents other than IH-LISS for the red blood cell suspension may modify the reaction and lead to incorrect test results.
• The use of volumes and/or red blood cell suspension in concentrations other than those indicated in the method may modify the reaction and lead to incorrect test results, i.e., false positive or false negative results.
• Once the IH-Card has been used for testing, it may contain infectious material and should therefore be handled and disposed of as biohazardous waste in accordance with local, state, and national regulations.

SPECIMEN COLLECTION AND PREPARATION

Please refer to the instructions for use for the IH-Card used for manual testing and to the IH-1000 User Manual NA for sample requirements.
TEST PROCEDURE FOR MANUAL AND AUTOMATED SYSTEMS

Materials provided
IH-LISS Rack
IH-LISS Solution

Materials recommended but not provided
Please refer to the instructions for use for the specific IH-Card.

Method
Please refer to the instructions for use for the specific IH-Card.

INTERPRETATION OF RESULTS

Please refer to the instructions for use for the IH-Card that was used for testing.

STABILITY OF REACTIONS

For visual reading of reactions, best results are obtained within six (6) hours of centrifugation. Interpretation may be affected by drying of the gel, hemolysis of red blood cells and slanting of reaction patterns due to storage in a non-upright position. Processed cards that are stored in the refrigerator (2 to 8 °C) and properly sealed to protect from evaporation may be interpreted for up to one (1) day. Gel cards should not be interpreted after the first sign of drying, or if hemolysis is observed. The age and condition of red blood cells, as well as the temperature at which the card is stored, will affect how long cards can be stored. The presence of sodium azide in the gel may cause the red blood cells to become dark in color over time. This darkening does not interfere with the test result.

QUALITY CONTROL

The performance of this reagent is evaluated each day of use in routine quality control testing performed with IH-Cards to help determine if technical errors or reagent failures have occurred.

LIMITATIONS

Erroneous and abnormal results may be caused by:
• Bacterial or chemical contamination of the serum, plasma, red blood cells or equipment.
• Patient medication or disease yielding a cross-reaction.
• A red blood cell concentration or suspension medium different from that recommended.
• Incomplete resuspension of the red blood cells.
• Sample or Reagent Red Blood Cells hemolysis prior to testing.
• Contamination between microtubes through pipetting errors.
• Use of procedure other than the one described above.
• Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results.
• Fibrin, clots, particulates or other artifacts may cause some red blood cells to be trapped at the top of the gel that may cause an anomalous result. They may appear as a pinkish layer. In a negative reaction the false appearance of a mixed field could lead to misinterpretation. It is recommended to re-clot the serum and repeat the test.
• If red blood cells (pellet at the bottom of the microtube) are too low in concentration they become difficult to visualize, and, in certain cases, a weak positive reaction can fail to be detected.

SPECIFIC PERFORMANCE CHARACTERISTICS

The final release testing is performed according to product specific Standard Operating Procedures. As part of the lot release process, each lot of Bio-Rad Blood Grouping Reagents is tested against antigen positive and negative samples to ensure suitable reactivity and specificity.

For technical support or further product information, contact Bio-Rad Laboratories, Inc at 800-224-6723.
GLOSSARY OF SYMBOLS

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<tr>
<td>LOT</td>
<td>Batch code</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
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BIBLIOGRAPHY

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