Gen-Probe Transplant Diagnostics, Inc.
550 West Avenue, Stamford, CT 06902
Tel: (203) 328-9500 or (888) 329-0255, Fax: (203) 328-9599
WWW.GEN-PROBE.COM

Product Documentation and Translations available at: www.gen-probe.com/lifecodes/documents

PRODUCT INSERT

SeraClean™

For General Laboratory Use

INTENDED USE

Lifecodes SeraClean™ is designed to reduce the high background signal found in some sera caused by nonspecific binding of human serum components in Luminex bead based antibody assays.

SUMMARY AND EXPLANATION

SeraClean is designed to reduce the high background signal found in some sera due to nonspecific binding of human serum components in Luminex bead based antibody assays. The microparticles are preincubated with high background producing sera and then removed. The treated sera can then be used in assays employing Luminex xMAP beads, such as the LIFECODES Antibody detection kits.

PRINCIPLES OF THE PROCEDURE

In xMAP-based assays such as LIFECODES Class I ID, an aliquot of the LIFECODES beads is allowed to incubate with a small volume of test serum sample. The sensitized beads are then washed to remove unbound antibody. An anti-human IgG antibody conjugated to phycoerythrin is then added. After another incubation, the test sample is diluted and analyzed on the Luminex instrument. The signal intensity from each bead is compared to the signal intensity of a negative control bead included in the bead preparation to determine if the bead is positive or negative for bound alloantibody.

Nonspecific binding of human serum components to the LIFECODES beads can obscure the true results of the assay leading to false positives or negatives, with specific beads. Pre-incubation of the serum with SeraClean is used to reduce the high background signal due to nonspecific binding of human serum components to the LIFECODES beads. Once the background signal is reduced for the LIFECODES beads, the assay results should be easier to interpret.

REAGENTS

A. IDENTIFICATION

Reagent	Product Number	Fill volume	Storage	Σ 25
SeraClean™ Beads	628222	100uL	2-8°C	Sufficient for 25 samples

B. WARNINGS OR CAUTIONS

1. For General Laboratory Use.
2. Biohazard: All biological and sera samples should be treated as potentially infectious. **Use Universal Precautions when handling**.
3. Due to the viscosity of the product, SeraClean beads may appear dried after 2-8º C storage. **Vortex the vial and spin briefly to recover the full volume.**

C. STORAGE INSTRUCTIONS

Store at 2 – 8º C.

D. INSTABILITY INDICATIONS

Do not use SeraClean product that is beyond the expiration date.

E. INSTRUMENT REQUIREMENTS

Luminex Instrument and XY Platform (Product Number 888300)

F. SPECIMEN COLLECTION AND PREPARATION

Serum samples should be prepared in accordance with the Luminex assay being performed.

PROCEDURE

A. Materials Provided:
SeraClean Beads

B. Materials, Reagents and Equipment *Required,* but Not Provided (as listed or equivalent):

1. Vortex Mixer
2. Pipettors, Multichannel pipettors and Barrier filter tips (1-10µL, 20-200µL).
3. Rotator
4. Centrifuge

DIRECTIONS FOR USE

Note: If SeraClean beads appear dried, vortex and spin briefly to recover the full volume.

1. Vortex SeraClean beads thoroughly just prior to use.
2. Dispense 4 µL of SeraClean beads to a microcentrifuge tube labeled with the serum ID.
3. Aliquot 20 µL of the high background serum into the microcentrifuge tube and vortex for 30 seconds.
4. Continue mixing on a rotator for 30 minutes at room temperature.
5. Centrifuge the treated serum for 3 minutes at 15,000 x g to pellet the SeraClean beads.
6. Being careful to avoid disrupting the pellet, transfer 12.5 µL of the treated sera to a new, labeled tube.
7. Serum is now ready for use in the assay of choice.

Note: If a larger volume of serum is desired, increase the SeraClean beads and serum proportionally in steps 2 and 3. Follow the remainder of the protocol as written.

RESULTS

- Pretreatment of serum with SeraClean should result in a reduced background in Luminex Antibody detection assays.

LIMITATIONS OF THE PROCEDURE

- Because there are different sources of high background, it is not expected that SeraClean will result in reduced background in all cases.
- In instances where background is not reduced, it is not recommended to try larger amounts of the SeraClean Beads.
- Care should be taken to make sure that SeraClean Beads are not carried over into the assay.

EXPECTED VALUES

Pretreatment with SeraClean should reduce the background for negative control beads in the LIFECODES LifeScreen Deluxe, Class I ID and Class II ID assays. As noted in the ***Limitations of the Procedure*** section, background will not be reduced in all cases.

SPECIFIC PERFORMANCE CHARACTERISTICS

An in-house study with 15 high background sera was conducted using the LIFECODES Class I ID Kit to assess the reduction in background of negative control beads. Pretreatment of sera with SeraClean resulted in reduced backgrounds for 15/15 sera. The average MFI value for the CON was reduced 55% by treatment with SeraClean.

SeraClean™ is a trademark of Gen-Probe Transplant Diagnostics, Inc.

DEFINITION OF SYMBOLS (Product Labels and Supplemental Documents)

Lot Number	LOT	Catalog Number	REF	Temperature limitations		Caution – See instructions for Use	
Expiration Date	(exp)	Sufficient for N Tests	Σ	Do Not Freeze		See instructions for use	
Manufacturer		European Representative	EC REP				