**Sierra Molecular Corp.**

 **Technical Data Sheet for GeneLock® AssayAssure®**

 **Molecular Urine Preservation and Transport System**

 **Cat# 32600 90 ml cup, 32625 15ml tube, 33300 250 ml bulk, 33850 4ml tubes**

 **Protected by US patents 6,458,546, 7,569,342, other patents pending**

 The Genelock urine technology has been developed to protect and stabilize a broad range of molecular targets that can be found in urine

 The targets include DNA,RNA, mRNA and gene fusion targets that have been identified as useful biomarker targets of diseases such as

 Prostrate cancer.

 The Genelock chemistry has been successfully used in stabilizing Gene fusion Transcripts TMPRSS2:ERG in urine of men with

 Prostrate cancer.

 The Chemistry has been designed and validated to fundamentally address the biological mechanisms that are responsible for the

 degradation of nucleic acid targets.

 Genelock® chemistry is only stand alone chemistry evaluated and approved by the FDA for preservation of Nucleic acid targets

 compared to the gold standard of refrigeration in STD urine specimens.

1. Urine should be added to GeneLock® cup or tube as soon as possible after urine is

collected, to optimize protection of labile or low molecular targets of interest.

1. Urine should be in contact with GeneLock® within **thirty minutes after collection for optimal results.**

Urine can be added to chemistry up to eight hours after collection at +25°C. (Clinical trial data)

1. Once urine is added to the GeneLock® cup or tube and chemistry, there is no need to refrigerate or

 freeze the specimen.

1. Once in the GeneLock® cup or tube, molecular targets may be protected up to 23 days at +25°C.

 Urine protected by GeneLock® may be tested with dipstick chemistry test systems and will not

 interfere with routine urine microbiology.

1. Any validated DNA/RNA urine extraction protocol or device may be used with GeneLock® directly

without the need to remove the Genelock® chemistry from the urine.

1. Genelock® is designed to inactivate or eliminate a broad range of amplification inhibiters found in urine.
2. The Genelock® cup should be filled to the fill line on the on the cup or tube. A minimum fill volume is 20 ml

 and a maximum is 80 ml. In Clinical trials no washout of target was seen in samples filled between 60 and 80 ml

The 15 ml tube should be filled to the red collection line 10 ml. Samples over 10 ml are acceptable. Samples under

10 ml may be problematic due to over concentration of chemistry. (**In clinical trials samples with 5ml or less of urine**

 **caused interference with analytic performance of various platforms.)**

1. GeneLock® will not lyse or destroy cells in urine, and cells of interest can be used for pathology studies.
2. GeneLock® is intended for the preservation and transportation of molecular targets in animal or human urine.

**Contact Sierra Molecular Corp technical service for additional information 209-536-0886**

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