

Product Data Sheet

Her2/neu

TruQ™ Bioengineered Tissue Microarray Controls



PRODUCT CODE
TRUQ-HER2-BLOCK
TRUQ-HER2-SLIDES
TRUQ-HER2-EVAL

INTENDED USE Research Use Only (RUO) and validation purposes.

PURPOSE This product is designed to confer confidence in results obtained from the sample on the same slide. TruQ™ bioengineered tissue microarray control blocks and slides are to be used to monitor the performance of the IHC staining assay during initial validation and for troubleshooting activities. Fixation and processing parameters may differ from the test cases and, as such, provide control for all reagents and method steps except fixation and tissue processing. The clinical interpretation of any positive staining or its absence must be evaluated within the context of clinical history, morphology, and other histopathological criteria. This material cannot be used independently as a means of optimizing assays in the laboratory.

QUANTITY

TRUQ-HER2-BLOCK	1 paraffin block
TRUQ-HER2-SLIDES	25 slides in plastic slide box
TRUQ-HER2-EVAL	2 unstained slides in plastic slide mailer

STORAGE 4° - 8° C. Avoid freezing as this may cause damage to the slides/paraffin blocks.

DESCRIPTION TruQ bioengineered TMA control block and slides include 3 cores (diameter 2.0 mm) containing three distinct tissues that are manufactured using a StatLab patented technology, producing a reference standard control designed for Her2/neu marker. The tissues are formalin fixed and paraffin embedded following ASCO/CAP guidelines.

Fixative: 10% Neutral Buffered Formalin
Embedding: Paraffin wax

DIRECTIONS FOR USE If in block format, StatLab recommends cutting sections at 3-4 µm thick and mount sections on a positively charged slide (See note). Sections should be cut and arranged as appropriate. StatLab recommends use of positively charged TOMO (M5000) slides for patient tissue. Other slides may be used but need to be validated in conjunction with the automated platform employed in the laboratory.

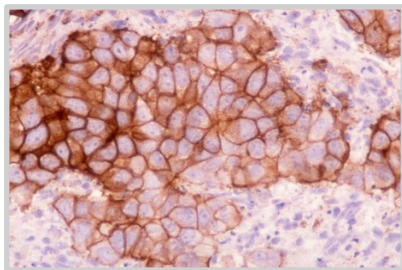
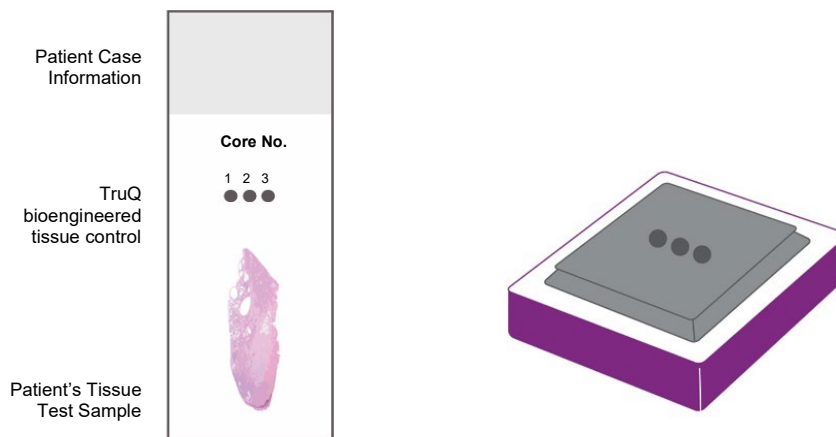
If in slide format, TruQ bioengineered tissue controls are placed on slides to accommodate for the patient's tissue test sample to be added to a slide and serve as a same-slide control.

StatLab recommends drying TruQ bioengineered tissue controls (whether slide format or prepared slides) at 37°C overnight followed by 1-2 hrs incubation at 60°C.

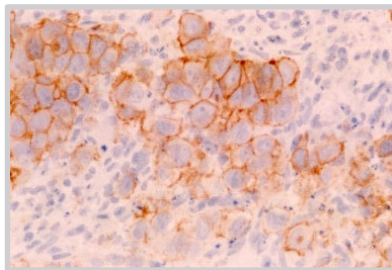
Note: When cutting blocks, it is recommended to align the block as closely as possible to the knife edge to avoid excess trimming away of microarray tissues. Laboratories may wish to determine the average usage of control slides in the laboratory and prepare enough control slides to cover 3-4 weeks of average use to ensure that there is no loss of antigenicity over longer periods of time.

EXPRESSION PROFILE

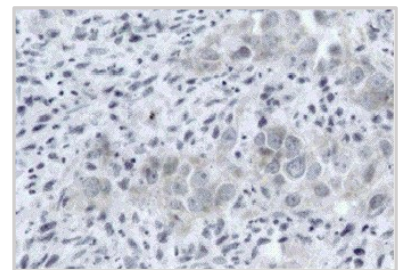
Core no.	Her2/neu IHC Score
1	3+
2	2+/3+
3	Negative



Core 1: Her2/neu - positive (3+)



Core 2: Her2/neu - positive (2+/3+)



Core 3: Her2/neu - Negative

TROUBLESHOOTING

For more information, contact StatLab Technical Support:

tech@statlab.com

800-442-3573, Option 5