Validation Kit Contents

User Guides

1. Printed user guide
2. Procedure Training Guides
3. SOP's.

Mock Patient Kits

1. BxBoard A for grossing training
2. BxBoard B for grossing training

Porcine Cores

Free-Floating Porcine Core Biopsies x30 *Immersion in liquid 10% NBF

1. Use to reload BxBoards for practicing transfer to BxChips, or
2. Use free-floating cores to practice loading the BxChip directly

Sponges

1. White large, reticulated sponges (bottom) x15
2. Blue medium reticulated sponges (top) x15

RFID Tags

If using Lumea's BxLink system

Validation BxChips

Processing Optimization A – Survivability of the BxChips

*Immersion in liquid 10% NBF

1. Pre-cassetted (small hole) Empty BxChips x6
2. Pre-cassetted (large hole) Empty BxChips x6

Processing Optimization B – Tissue Placement Survivability of the BxChips

*Immersion in liquid 10% NBF

1. Pre-cassetted (small hole) Porcine Kidney Cores BxChips x6

2. Pre-cassetted (large hole) Porcine Kidney Cores BxChips x6

Processing Validation – Optimal Results & Conditions for BxChip

*Immersion in liquid 10% NBF

1. Pre-cassetted (small hole) Porcine Kidney Cores BxChips x6
2. Pre-cassetted (large hole) Porcine Kidney Cores BxChips x6

Embedding Tools

1. Previously Processed Cassettes/BxChips for Embedding Training x 10 *Re-heat in the embedder for 30-40 min. prior to embedding.
2. Narrow Handled Embedding Tamper x1
3. Wide Handled Embedding Tamper x1
4. Complimentary Wax Scraper x1

Microtomy

1. Completed Blocks for Microtomy Training x10

Tissue Processor Validation

The validation kit contains 3 sets of BxChips in NBF-filled bottles:

1. **Set A**: Optimization A – survivability
2. **Set B**: Optimization B – survivability with tissue
3. **Set V**: Final Validation – optimal conditions

Optimization A

1. Run processor with Set A from the validation kit. An example processing protocol is included below.
2. Assess the quality of the BxChips
    1. The **initial size of a BxChip is 22 x 14 x 2 mm**.

Average shrinkage from processing is 16 x 11 x 1.5 mm. Anything below this standard may allow for the cores to be pushed free from the lanes, possible loss of site designation or the orientation of the segment within the lane. This policy and procedure will need to be documented in the lab's SOPs.

1. Pass parameters
    1. Expected shrinkage: 25% of 22 mm = 16.5 mm; 10% to 28% acceptable shrinkage.
    2. Threshold of acceptability is 16 mm with even shrinkage

        3. Any width under 10mm causes "taco" defect, cores are displaced and orientation cannot be guaranteed (seen when not using processing sponges).
        4. Pass threshold >16 x 11 x 1.5 mm in measurement.
    2. Failure parameters
        1. Shrinkage >30% is suboptimal = failure based only on size.
        2. Any width under 10mm
        3. BxChip is dry, hard, or discolored.
        4. "Hour-glass", "taco", or other non-rectangular shape.
        5. Fail threshold <16 x 11 x 1.5 mm in measurement.
    1. Contact Lumea if you need help assessing BxChip quality.

1. Repeat Optimization A until the BxChips are of optimal quality. Obtain sign-off from your medical director to move forward to Optimization B.
2. Use these BxChips to practice embedding and cutting.
    1. BxChip Embedding (file:///C:\wiki\spaces\CR\pages\2164883461\BxChip+Embedding)
    2. BxChip Microtomy (file:///C:\wiki\spaces\CR\pages\2165538909\BxChip+Microtomy)

Optimization B

1. Run processor with Set B from the validation kit. Use the approved processing protocol from Optimization A.
2. Set B contains animal tissue cores in the BxChip lanes.
3. The pass parameters are the same as in Optimization A, with the addition of assessing the quality of the tissue (including microscopically).

Final Validation

1. Run processor with Set V from the validation kit. Use the approved processing protocol from Optimization B.
2. Follow Optimization B above.
3. Prepare your documentation for the validation process.
4. Obtain Medical Director sign-off on process and results.

All 3 steps should provide at least 40 cassettes being run on the approved protocol, meeting the recommendations by CLIA and CAP.

BxChip Workflow Validation

1. Use the provided BxBoards and free-floating cores to validate the process of loading the BxChip, processing, embedding, cutting, and staining.

2. Document your protocols with the BxChip as necessary.

Notes

1. We recommend a minimum of 2 hours of fixation for tissue cores received on the BxBoard.
    1. This can be done at room temperature in a 10% NBF holding bath or in the processor prior to dehydration steps.
2. If BxChip processing is not going well, consider changing sponges, cassettes (slats vs. holes), as well as reagent times and temperatures.

Example BxChip Processing Protocol

Station	Reagent	Time	Temp °C	P/V	Mix
1	*10% NBF	0:08	40°	P/V	Slow
2	*10% NBF	0:08	40°	P/V	Slow
3	70% ETOH	0:12	40°	P/V	Slow
4	95% ETOH	0:12	40°	P/V	Slow
5	95% ETOH	0:12	40°	P/V	Slow
6	100% ETOH	0:12	40°	P/V	Slow
7	100% ETOH	0:12	40°	P/V	Slow
8	**Xylene	0:05	40°	P/V	Slow
9	**Xylene	0:05	40°	P/V	Slow
10	**Xylene	0:05	40°	P/V	Slow
11	Paraffin	0:05	58°	P/V	Slow
12	Paraffin	0:05	58°	P/V	Slow
13	Paraffin	0:05	58°	P/V	Slow
14	Paraffin	0:05	58°	P/V	Slow

*Formalin substitutes also are acceptable replacements.

** Clear Rite 3 is an acceptable Xylene replacement.

If the substitutions leave the BxChip with a less infused central area extend the fixative exposures as well as the clearing stages. Extend wax time for increased penetration based on the processor's previous programs for small biopsy processing.