



Introduction

The BxChip® is part of Lumea's commitment to making cancer diagnostics as accurate as possible by standardizing the way tissue biopsies are collected, handled, and processed. The BxChip is an engineered artificial tissue array that holds tissue biopsy specimens in place and preserves tissue identity during histology processes for multiple biopsies per block. It is also intended to maximize and preserve the amount of tissue obtained during the biopsy for pathologist review.

Notes about the Guide

This guide is intended for laboratory and procedure room staff to provide instructions and troubleshooting steps when using the BxChip. This guide is divided into sections associated with primary histology laboratory processes. It includes best practices that have been established through successful use of the BxChip. It also includes answers to commonly asked questions.

BxChip Storage and Handling

BxChip in the Surgical Suite, Operating Room, or Procedure Room (direct placement from biopsy needle)

The BxChip will come encased in a plastic mold, sealed together with a moist filter in aluminized pouches and sterilized by gamma irradiation.

Open the outer aluminized pouch and place the inner pouch (sterile) on the surgical table. Open the inner pouch and place the BxChip face up on the moist filter. If the BxChip becomes too dry, it can be remoistened with sterile saline. This will facilitate the adhesion of the cores into the channels.

Place the biopsy cores one by one from the biopsy needle into the channels of the BxChip starting with channel #1. Steady the tip of the biopsy needle while placing the biopsy cores in the BxChip.

Record the location of each core and its corresponding channel according to the laboratory protocol.

Place the loaded BxChip in the provided tissue cassette. Ensure that the lid of the tissue cassette is securely locked, without pinching the BxChip. Place the cassette in a container with enough fixative to completely cover the tissue cassette and send it to the Pathology laboratory.

BxChip in the Laboratory

BxChips will arrive at your laboratory in sealed plastic containers. Each container holds a bulk quantity of BxChips in 10% formaldehyde (non-buffered). BxChips should be stored in their original container at room temperature.

Handle BxChips gently. Users should always wear appropriate Personal Protective Equipment (PPE) when handling the BxChip. BxChips should remain moist during all stages of storage and handling. Do not let them dry out.

Specimen Collection within Clinics

The BxChip is optimal for needle-core tissue biopsy specimens that have been fixed in a linear orientation. Linear orientation is best achieved when cores are collected on Lumea's BxBoard®, rather than floating in a formalin bottle. Biopsy cores shipped in formalin bottles can be successfully loaded into the BxChip but it may require more manipulation of the tissue.

Ensure that each channel of the BxBoard is labeled with the correct anatomic site. If sending in a formalin bottle, ensure that each bottle is labeled with the correct anatomic site.

Grossing Techniques

It is recommended that BxChip is placed onto a wet sponge while it is being loaded with tissue. Sponges can be moistened with either 10% Neutral Buffered Formalin (NBF) or saline.

Loading: General Tips

During specimen loading, the BxChip should remain moist. Load the tissue quickly to prevent the BxChip from becoming too dry. When possible, load cores into the BxChip from left to right and specify which anatomic sites are placed in each channel.

Loading: Ideal Cores

Use forceps/tweezers to transfer tissue cores into the channels of the BxChip. Align one end of the long, unbroken core into the chosen channel near the bottom of the BxChip and slide to the top before releasing. This method is easier and faster than attempting to place the entire core in the channel all at once. Gently press downward on the tissue until it sits flat within the channel and is at or below the channel divider.

Loading: Fragmented, Coiled and Other Cores

Fragmented Cores

Loading fragmented cores should follow a similar method as loading ideal cores. As you load, place each core fragment into the channel at the bottom and slide up before releasing. Place pieces together without creating overlaps or bulges.

Coiled Cores

Lay the core in the channel and press, pull, or drag it until wavy areas extend and lay flat. Use the sidewalls of the BxChip to provide structure to help force the BxChip to uncoil.

Use forceps to press resilient spots flat into the channel.

Other Cores

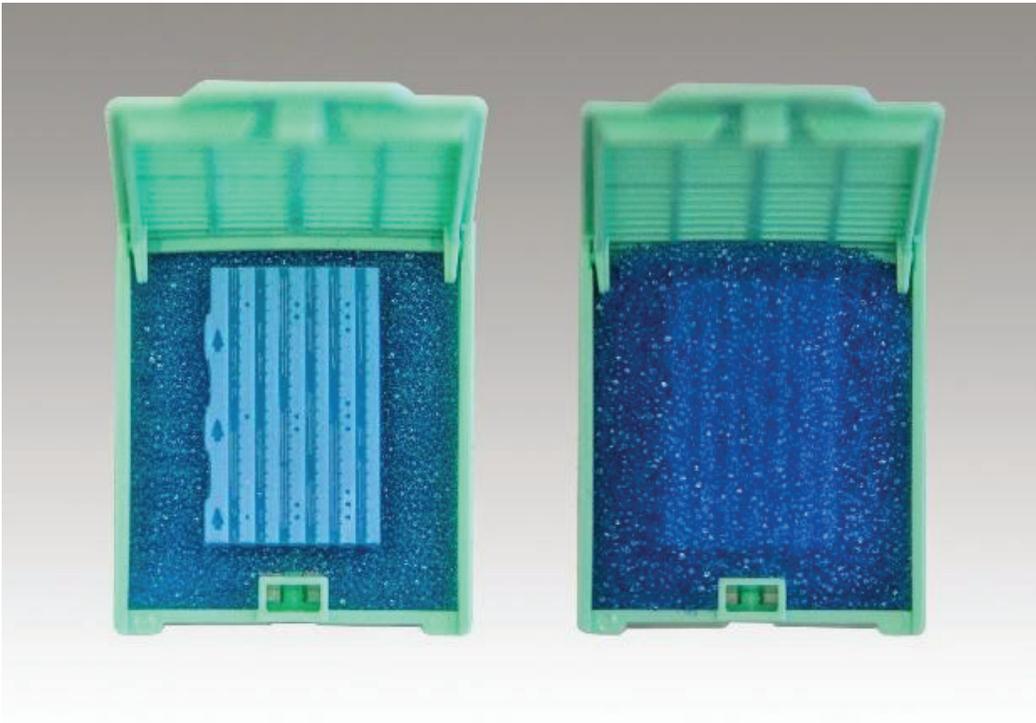
For other cores that will not lay flat in the channels of the BxChip, consult laboratory protocol or the Medical Director. For additional guidance, contact Lumea.

Grossing the Tissue

Cores should be measured after placement into the BxChip for two reasons: 1) curvy/coiled cores will be extended flat and fragmented cores will be in one channel together, creating a more accurate overall length and 2) measuring the cores in a BxChip will be faster and more efficient than measuring six separate cores.

Closing the Cassette

Use a second biopsy sponge moistened with formalin or saline to “sandwich” the BxChip in the cassette. This prevents cores from coming out of the BxChip during processing.



Exercise caution when closing the cassette lid or adjusting the sponge on top of the BxChip. Moving the sponge can cause the cores to be pulled out of their channels.

Processing Techniques

The BxChip is designed to be processed alongside other histology specimens.

Ensure that the cassettes holding BxChips are not allowed to float freely inside the processor as this can increase the risk of cores coming out of the BxChip channels during processing. If possible, place the cassettes into a designated cassette holder. For best results, cassettes should be placed to allow adequate flow around the BxChips.

Note: if specimens have not been fixed for the proper amount of time prior to processing, the fixation steps within the processor protocol may be necessary. The BxChip does not need any additional fixation beyond its storage environment.

Conventional Processor Protocol

Several processing protocols have been tested with the BxChip. An example protocol is shown below. Contact Lumea for help developing your protocol.

Station	Solution	Concentration	Time (min)	Temp. (degrees)	Press/Vac	Agitation
1	Neut. Buff. Formalin	10%	0		on	on
2	Neut. Buff. Formalin	10%	0		on	on
3	Alcohol	70%	5	40	on	on
4	Alcohol	95%	5	40	on	on
5	Alcohol	95%	5	40	on	on
6	Alcohol	100%	5	40	on	on
7	Alcohol	100%	5	40	on	on
8	Xylene	50%	5	40	on	on
9	Xylene	100%	5	40	on	on
10	Xylene	100%	5	40	on	on
11	Paraffin		5	60	on	on
12	Paraffin		5	60	on	on
13	Paraffin		5	60	on	on
14	Paraffin		5	60	on	on

Microwave Processor Protocol

The BxChip will also work with microwave processors. An example protocol is below.

Ethanol Phase

Step 1: Ambient to 50 °C over 10 minutes

Step 2: 50 °C held over 2 minutes

Step 3: 50 °C to 66 °C over 11 minutes

Isopropanol Phase

Step 1: Ambient to 55 °C over 12 minutes

Step 2: 55 °C to 68 °C over 11 minutes

Wax Phase

Step 1: Rise to 68 °C over 15 minutes

Step 2: 68 °C held over 15 minutes

Embedding Techniques

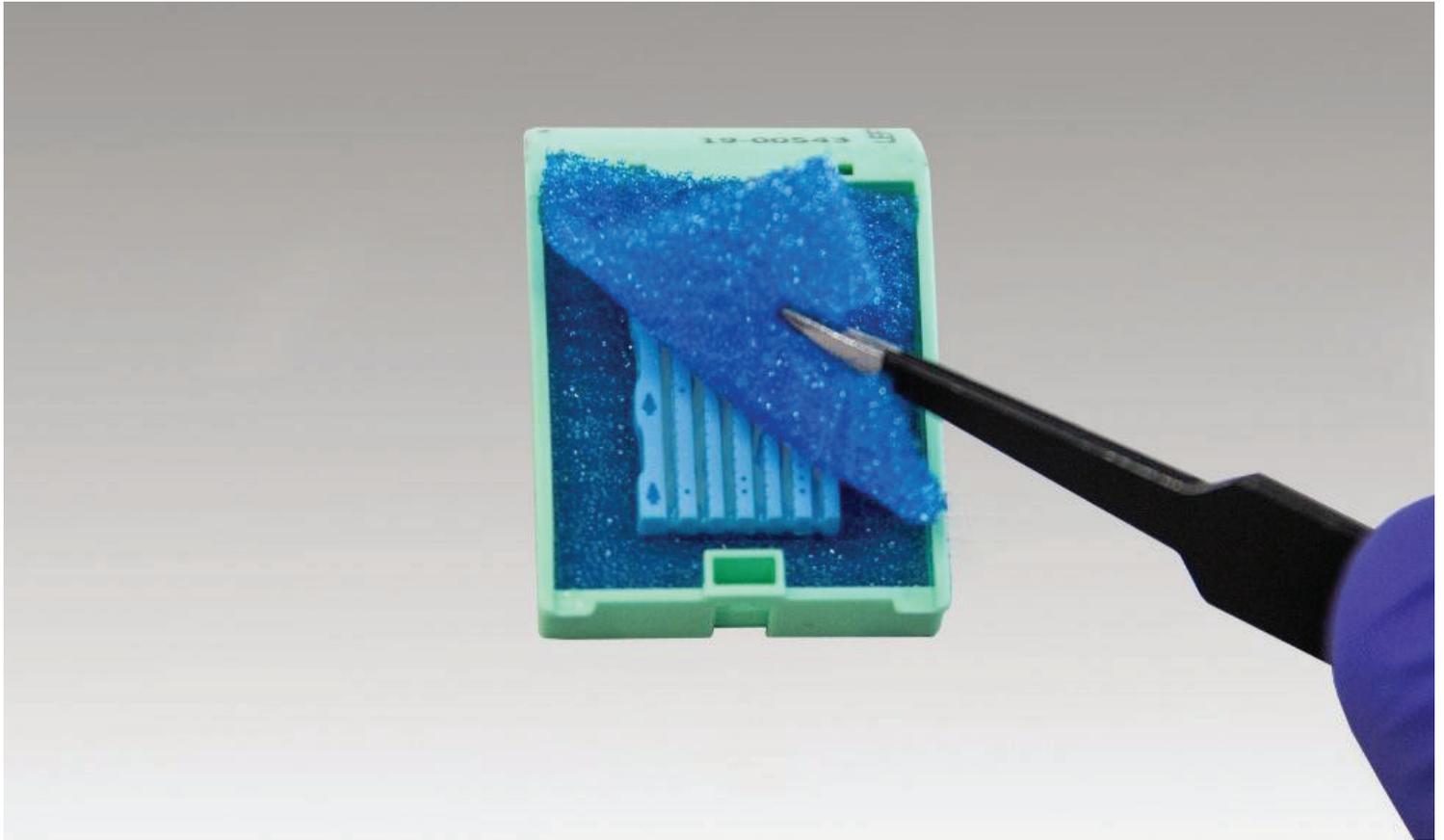
General Tips

Lumea recommends using embedding molds that allow for at least 2 mm of space between the edges of the BxChip and the mold. This will provide more structure to the BxChip during sectioning.

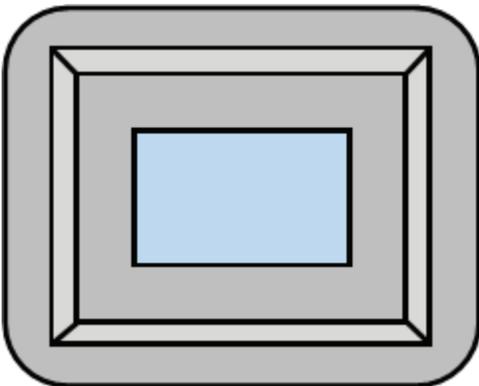
After processing, place the cassettes in the embedding station's warming chamber or on the warm plate. If the paraffin cools too much, the top sponge may become sticky and pull the cores out of the BxChip. Keep the cassettes warming on the lid side if using the warm plate.

Embedding Steps

Step 1: Gently remove the lid and top sponge. When removing the top sponge, peel back slowly and gently from one corner, ensuring that there are no cores stuck to the sponge.



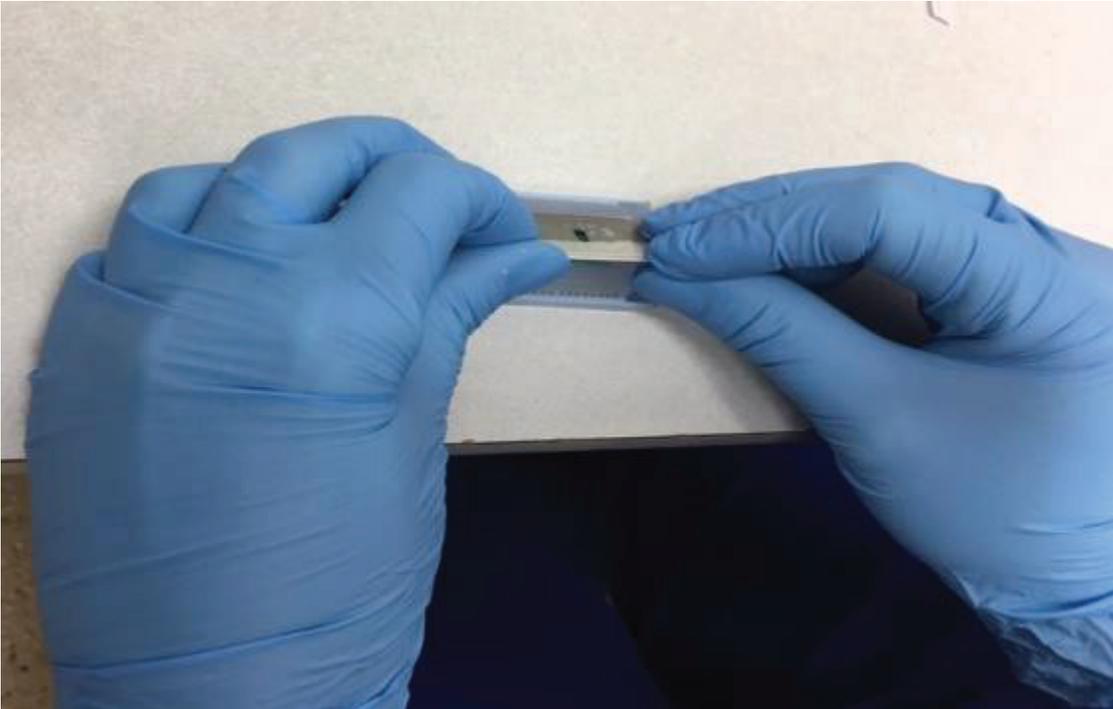
Step 2: Embed the BxChip centered in the mold, parallel to the orientation of the mold with the channels facing down. Gently press the BxChip down with a tamper while transferring it to the cooling plate. Be cautious not to move the BxChip while transferring or cores may slip from their channels.



Step 3: Once on the cooling plate, use the tamper to apply moderate pressure straight down on top of the BxChip to ensure that it is completely flat against the bottom of the mold.



Step 4: Follow standard laboratory protocol for cooling the block before removing the mold.



Step 5 (optional): If you want to place multiple sections on one slide, use a blade to trim the extra paraffin at a 45° angle. Be sure to leave an adequate paraffin margin surrounding the BxChip in the block.

Sectioning Techniques

The BxChip is engineered to process, cut, and behave like actual tissue; this makes the techniques used to face-in and section the block very similar to regular laboratory tissue handling in your lab.

Use a hot plate to melt the excess wax along the edges of the block so that it will sit flush in the microtome chuck.

Step1: Face into the block by first doing 2-3 turns at 8-15 μm and then 1-2 more turns at the desired sectioning thickness (e.g. 3-5 μm). The tissue may not immediately be seen on earlier sections due to the BxChip's channel dividers creating a gap between the tissue and the face of the block.

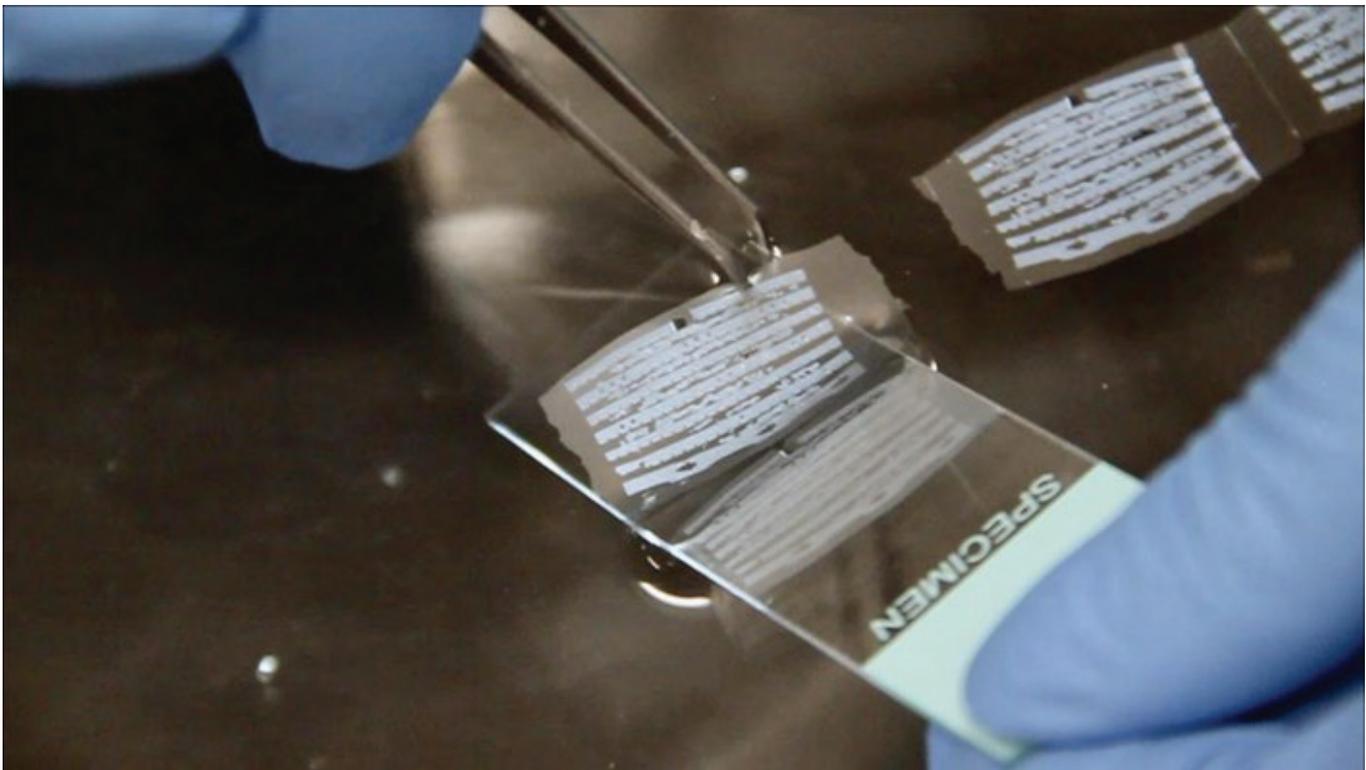
Tissue should be sectioned at 4 μm (range 3-5 μm). The number of sections taken will depend on the laboratory protocol. Each subsequent sectioning event should be preceded by a careful facing of the block. All areas of the BxChip and tissue should be visible before taking sections.

Note: Each laboratory must determine its own specific protocol for facing and sectioning the BxChip.



Step 2: After facing into the block, place it on a cold, dry surface for a few minutes. Avoid any contact between the BxChip and liquid water. For best results, consider using a freezer like in the image below.

Step 3: Place the block in the microtome chuck and begin sectioning according to your laboratory protocol. Produce the desired number of sections as quickly as possible to prevent the block from becoming too warm. Keep all other blocks on ice, preferably in a freezer, until they can be sectioned.



Step 4: Pick up the appropriate sections using a glass slide with up to 3 sections per slide. Be sure to orient the sections in the same manner.

Staining

Follow your lab's protocol for staining. A drying step is recommended before staining starts. Most automated stainers will include a drying step. If not, use a slide dryer to dry the slides for 5-10 minutes at 60 °C.

BxChip Support

For additional BxChip support, please contact Lumea support at:

Phone: 801-960-3658 or Toll Free: 844-960-3658

Email: support@lumeadigital.com (<mailto:support@lumeadigital.com>)

FAQs

How should the BxChips be stored when not in use?

The BxChips should be stored in their original container at room temperature. For non-sterile, bulk BxChips, the lid of the plastic container should be tightly secured.

What can be done if the BxChips are dry upon receipt?

Contact Lumea support (844-960-3658 or support@lumeadigital.com (<mailto:support@lumeadigital.com>)). You will be asked to return the bulk container and will be provided with a new shipment as soon as possible.

How long can the BxChip be out of liquid before it dries out?

It is recommended that the BxChip not be left out of liquid for more than 15 minutes. If this is not possible, douse the BxChip with formalin or saline to keep it wet until it is loaded with tissue and prepared for processing.

Can the BxChip be picked up with forceps/tweezers?

Yes. Pick it up carefully so that the BxChip does not break or puncture.

Can the BxChip be touched with bare hands?

Because the BxChips are stored in 10% formaldehyde, it is recommended that you do not touch the BxChips with bare hands. Wear gloves when handling the BxChip. Refer to the formaldehyde Safety Data Sheet (SDS), included in Appendix A.

Does the BxChip come with a Safety Data Sheet?

Contact Lumea for a certificate of conformance. The Safety Data Sheet (SDS) for formaldehyde is provided in Appendix A.

What if cores are received in bottles and not in the BxBoard?

The BxChip may still be successfully used for these cores, but the specimens may need additional manipulation to lay flat inside the BxChip channels. See additional information in the Grossing Techniques section.

What if tissue cores are curled or exceptionally wavy?

See the Grossing Techniques section for tips on loading non-straight cores into the BxChip.

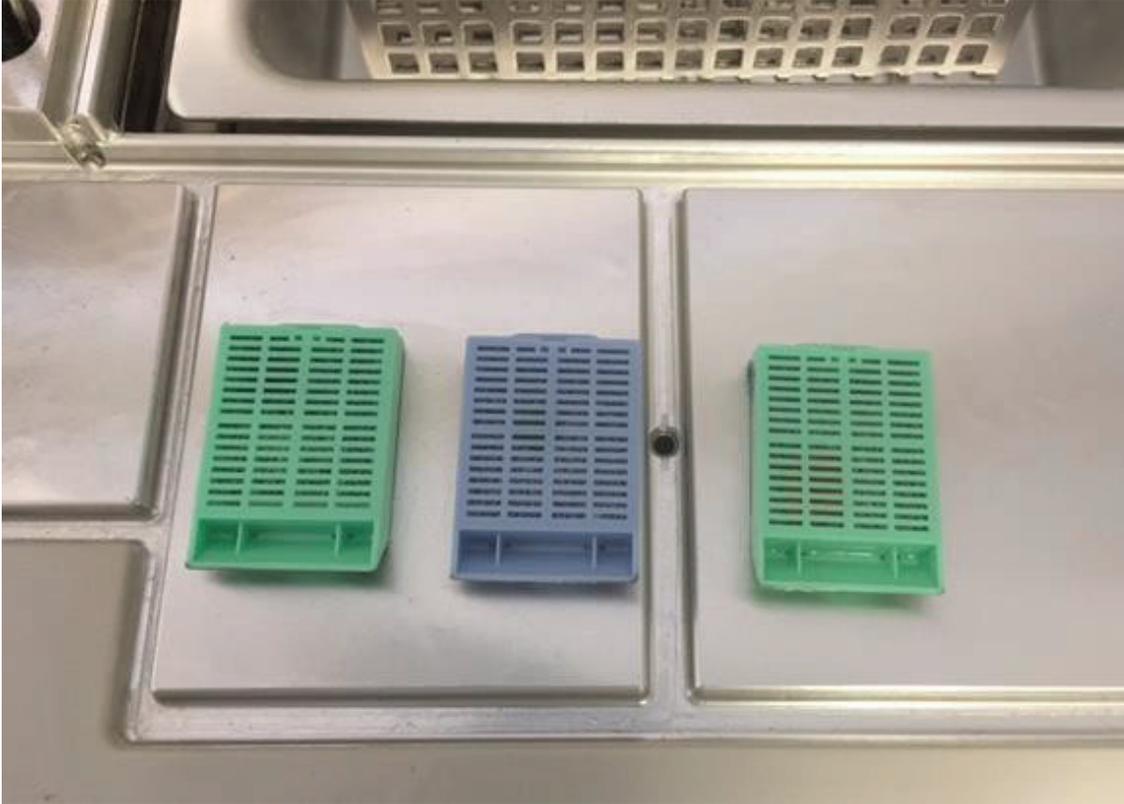
What happens if the cores are not flat within the BxChip?

This can cause the cores to stick to the top sponge, and may not remain in the BxChip during processing and/or embedding. Use every effort to ensure that cores are fully seated within the channels of the BxChip prior to processing.

How long can cassettes be held in the warming chamber of the embedding station?

It is recommended to keep BxChips in the warming chamber for 30 minutes or less.

Is it possible to have multiple cassettes on the warming plate at the same time?



Yes, but place the cassette(s) with the lid face down on the warming plate. This keeps the top sponge sufficiently warm during the embedding steps.

What if a core falls out of a channel?

If possible, use forceps to place it back into the correct channel. Ensure that the forceps, tissue core, and BxChip are warm. It may be helpful to verify the proper location of the core with grossing documentation. If the core cannot be placed back into the BxChip, embed the core in its own block and note the channel it came from. Other documentation may be necessary, depending on laboratory protocols.

What if a core sticks to the top sponge covering the BxChip?

A core sticking to the top sponge suggests that the paraffin may be too cool. Place the cassette back into the holding tank or face down on the warming plate for about one minute. If the core is still sticking to the sponge, maintain the orientation the sponge is peeled back, and gently pull the core away using clean, warm forceps to replace it into the proper channel. It may be helpful to verify the proper location of the core with grossing documentation.

What if the BxChip is misshapen after processing (e.g. appears like an hourglass, trapezoidal, etc.)?

A misshapen BxChip post-processing indicates that it was under-processed or over-processed, or that the wrong type of cassette or sponge was used. Contact Lumea for help in identifying possible causes and solutions to your specific issue.

Why is the BxChip paraffin block not allowed to touch water?

The BxChip will absorb water, causing it to swell and protrude out of the block.

What can be done if the BxChip paraffin block touches water?

Dry the block as much as possible by dabbing it on a paper towel. It is best to wait several minutes before sectioning to allow the BxChip to dry.

Can the BxChip blocks be placed on ice outside of a freezer?

Yes, it is possible to leave BxChip blocks on ice outside of a freezer for a short period of time. If this is attempted, it is important to rotate the ice frequently to prevent it from melting. It may be helpful to place the block in a metal embedding mold while it is sitting on ice to help prevent the block from becoming wet.

What type of freezer is recommended?

The Lumea lab uses the Whynter CUF-110B freezer. This freezer is capable of maintaining -10°F. This ensures that the BxChip blocks are very cold for sectioning, while taking up relatively little space.

May the laboratory use a cold plate to keep BxChip blocks cold instead of a freezer?

Using a cold plate is not recommended. Condensation on the cold plate will be absorbed by the BxChip, adversely impacting sectioning.

What if the BxChip sections break apart on the water bath?

Pick up the section as quickly as possible with the slide. Fragmentation in the water bath is likely the result of errors from earlier histology processes. Consult with Lumea and your laboratory manager to identify the cause of this issue.

How can it be determined that a section of tissue is complete?

One method is to remove the block and hold it up to the light, using the face of the block to determine if the sections have gone deep enough into the tissue. Another method is to place a section onto the water bath and observe the completeness of the tissue, ensuring that the full lengths of cores are visible.

For which stains has the BxChip been validated?

The BxChip has been successfully validated with a wide variety of stains. Contact Lumea if you have specific questions

For which genomic tests has the BxChip been validated?

The BxChip has been successfully used with the following genomic tests: Prolaris (Myriad Genetics)

Con firmMDx (MDx Health) OncotypeDx (Genomic Health) Decipher (GenomeDx) RosettaGx

How can slides be sent to a pathologist who is unfamiliar with the BxChip?

The “Introduction to the BxChip” document in Appendix B may be sent to pathologists who are unfamiliar with the BxChip. For physical copies of this document, contact Lumea support.

Appendix A: Formaldehyde SDS

Formaldehyde, 37%

1. Identification

Product Name: Formaldehyde, 37%

Item #: FX0096, FX0097, FX0098

Synonyms: Methanal, Methyl aldehyde, Methylene glycol, Methylene oxide

Recommended Use: N/A

Restrictions on Use: N/A

Manufacturer:

Cancer Diagnostics, Inc.
4300 Emperor Blvd. #400
Durham, NC 27703
1-877-846-5393

In Case of Emergency:

Chemtec US 1-800-424-9300
Chemtec International 703-527-3887

2. Hazards Identification

OSHA Hazard Classification(s):

Acute Toxicity - Oral - Category 3
Acute Toxicity - Inhalation - Category 2
Acute Toxicity - Dermal - Category 3
Skin Corrosion - Category 1C
Eye Damage - Category 1
Sensitization - Skin - Category 1A
Sensitization - Respiratory - Category 1A
Germ Cell Mutagenicity - Category 1B
Carcinogenicity - Category 1A
Specific Target Organ Toxicity (single exposure) - Category 2
Specific Target Organ Toxicity (repeated exposure) - Category 2

Signal Word: Danger

Hazard Statement(s): Toxic if swallowed. Fatal if inhaled. Toxic in contact with skin. Causes severe skin burns and eye damage. Causes serious eye damage. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause genetic defects. May cause cancer. May cause damage to organs (nose, lungs). May cause damage to organs (nose, lungs) through prolonged or repeated exposure.

Pictogram(s):



Precautionary Statement(s): Prevention: Wash body thoroughly after handling. Do not eat, drink or smoke when using this product. Do not breathe dust, vapors. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation where IDLH, OSHA STEL or PEL values reached wear NIOSH approved respiratory protection. Wear protective gloves and protective clothing. Do not breathe dusts or mists. Wear protective gloves, protective clothing, eye protection and face protection. Wear eye protection, face protection. Avoid breathing dust, vapors. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. Wear NIOSH approved respiratory protection. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Response: If swallowed: Immediately call a doctor. Rinse Mouth. Specific treatment (see first aid section on this label). If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a doctor. Specific treatment is urgent (see first aid section on this label) If on skin: Wash with plenty of water. Call a doctor if you feel unwell. Take off immediately all contaminated clothing and wash it before reuse. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Take off all contaminated clothing and wash it before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing If skin irritation or rash occurs: Get medical attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor. If exposed or concerned: Get medical attention. If exposed or concerned: Call a doctor.

Storage: Store locked up. Store in a well-ventilated place. Keep container tightly closed.

Formaldehyde, 37%

Disposal: Dispose of contents/container in accordance with local regulations.

Descriptions of Hazards not otherwise classified: N/A

Percent of mixture with unknown acute toxicity: N/A

3. Composition and Information on Ingredients

Chemical Name	Common Name	CAS #	Concentration %
Formaldehyde		50-00-0	37
Methanol		67-56-1	10-15
Water		7732-18-5	47-52

4. First Aid Measures

Eye Contact: Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). Immediately remove contact lenses if you are able to do so and it is safe. In case of burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you should be referred promptly to an ophthalmologist for evaluation.

Skin Contact: Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, get first aid to cover the area with sterile, dry dressing, and bandages. Get medical attention if you experience appreciable eye or respiratory irritation.

Inhalation: Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim, and medical personnel should be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first-aid or medical personnel should administer oxygen, if available, and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the worker should be hospitalized for observation and treatment.

Ingestion: If the victim is conscious, dilute, inactivate, or absorb the ingested formaldehyde by giving milk, activated charcoal, or water. Any organic material will inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

Symptoms: Irritation eyes, nose, throat; headache, dizziness. See section 11.

Recommendations for immediate medical care/special treatment: Get medical advice/attention if you feel unwell or if you have any of the symptoms listed above.

5. Fire-Fighting Measures

Extinguishing Media: Dry chemical, carbon dioxide, alcohol foam, water.

Fire Hazards (Chemical): Not flammable.

Special Protective Equipment: Fire fighters should use self-contained breathing apparatus and protective clothing.

Precautions for Firefighters: Carbon monoxide and unidentified organic compounds may be formed during combustion.

6. Accidental Release Measures

Emergency Procedures: Evacuate the area of all unnecessary personnel. Wear suitable protective equipment. Eliminate all sources of ignition and provide ventilation.

Protective Equipment: See section 8

Environmental Precautions: Prevent release to the environment by using barriers.

Containment and Clean-Up Procedures: Use barriers to prevent spreading. Collect spill in container. Call waste authorities.

7. Handling and Storage

Handling: Do not breathe vapors. Do not eat, drink or smoke when using this product.

Storage: Store locked up. Store in a cool, well-ventilated place. Keep container tightly closed when not in use.

8. Exposure Controls/Personal Protection

OSHA Permissible Exposure Limits (PELs):

Formaldehyde, 37%

Reagent	CAS #	OSHA PEL TWA
Formaldehyde	50-00-0	0.75ppm

ACGIH Threshold Limit Values (TLVs):

Reagent	CAS #	ACGIH PEL TLV	ACGIH STEL
Formaldehyde	50-00-0	0.3ppm	

Engineering Controls: Use in a well ventilated area to prevent exposure. Maintain eyewash fountain and quick-drench facilities in work areas.

Personal Protective Measures: Wear gloves, lab coat, eye protection and impervious footwear. Contact lenses should not be worn when working with this material.

Special PPE Requirements: If ventilation hood not available wear respirator.

9. Physical and Chemical Properties Section

Appearance: Clear, Liquid

Molecular Weight: 30.03

Molecular Formula: CH₂O

pH: N/A

Boiling Point and Boiling Range: 205 F (96 C)

Melting Point/Freezing Point: 5 F (-15 C)

Flash Point: 56 °C cc

Specific Gravity/Relative Density: 1.080

Odor: Pungent

Odor Threshold: 1ppm

Color: Clear

Flammability (solid/gas): N/A

Vapor Density: 1.03

Upper/Lower flammability or explosive limits: Lower: 7% Upper: 70%

Vapor Pressure: 67-68 mmHg @ 20C

Evaporation Rate: N/A

Partition Coefficient: n-octanol/water: N/A

Viscosity: N/A

Auto-ignition temperature: 420°C

Solubility: Soluble in water

Decomposition Temperature: N/A

10. Stability and Reactivity

Reactivity:

Chemical Stability: Stable

Conditions of Stability/Instability: Stable under normal conditions of temperature and pressure. Cold temperature storage will cause solution to appear cloudy from precipitate.

Stabilizers needed: None

Safety issue indicated by appearance change: N/A

Other: N/A

Hazardous Reactions: N/A

Hazardous Polymerization: Does not occur

Conditions to avoid: N/A

Classes of Incompatible Materials: Oxidizers, Strong Acids, Strong Bases

Formaldehyde, 37%

Hazardous Decomposition Products: Thermal-oxidation degradation can produce oxides of carbon. Toxic gases and vapors (i.e. Carbon monoxide) may be released in a fire.

11. Toxicological Information

Likely Routes of Exposure

Eyes: Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent corneal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Skin: Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

Inhalation: Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

Ingestion: Liquids containing 10 to 40 percent formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04 percent) may cause discomfort in the stomach and pharynx.

Signs or Symptoms of Exposure: Chronic Effects of Exposure Carcinogenicity: Formaldehyde has the potential to cause cancer in humans. Repeated and prolonged exposure increases the risk. Various animal experiments have conclusively shown formaldehyde to be a carcinogen in rats. In humans, formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx, and nasal passages. Mutagenicity: Formaldehyde is genotoxic in several in vitro test systems showing properties of both an initiator and a promoter. Toxicity: Prolonged or repeated exposure to formaldehyde may result in respiratory impairment. Rats exposed to formaldehyde at 2 ppm developed benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Structural changes in the epithelial cells in the human nose have also been observed. Some persons have developed asthma or bronchitis following exposure to formaldehyde, most often as the result of an accidental spill involving a single exposure to a high concentration of formaldehyde. Note.-The perception of formaldehyde by odor and eye irritation becomes less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on formaldehyde's warning properties to alert him or her to the potential for exposure.

Effects from short term exposure (delayed, immediate, chronic): Irritation to the eyes, nose, throat; headache, dizziness, nausea. May cause cancer, mutagenic and reproductive effects. May effect organs (lungs, nose) after single or repeat exposure.

Acute Toxicity (Numerical Measures): Formaldehyde CAS 50-00-0: LD50 385 mg/kg (oral, mouse); LD50 100mg/kg (oral, rat) LC50 203 mg/m3 (inh, rat); LC50 454 mg/m3/4H (inh, mouse)

Carcinogenicity (NTP, IARC, OSHA): Contains Formaldehyde IARC Group 1 Carcinogen associated with nasal sinus cancer, nasopharyngeal cancer, myeloid leukemia.

12. Ecological Information

Ecotoxicity: Formaldehyde is highly toxic to algae, protozoa and other unicellular organisms and slightly toxic to fish. In the atmosphere the material is rapidly degraded by photolysis and photooxidation. Formaldehyde is mobile in the soil. In water or soil, formaldehyde is biodegraded in a few days. Experiments performed on a variety of fish and shrimp show no bioconcentration of formaldehyde.

Persistence and degradability: N/A

Bioaccumulation Potential (octanol-water partition coefficient, BCF): N/A

Mobility in the soil: N/A

Adverse Environmental Effects: N/A

13. Disposal Considerations

Recommended Disposal Containers: Check with your local waste authorities*

Recommended Disposal Methods: Do not dispose of in drains, check with your local waste authorities.*

Physical/Chemical Properties affecting Disposal: See section 2 and section 9 applicable information.*

Special Precautions for Landfill and Incineration Activities: Check with your local waste authorities.*

Formaldehyde, 37%

Waste Stream: Consult your local or regional authorities.*

14. Transport Information

UN Number: UN2209

UN Proper Shipping Name: Formaldehyde Solutions

Transport Hazard Class(es): 8

Packing Group Number: III

Environmental Hazards (IMDG code):

Marine Pollutant: No

Transport in Bulk (IBC Code): N/A

Special Transport Precautions: N/A

15. Regulatory Information

OSHA:

DOT:

EPA:

CPSC:

Formaldehyde, 37%

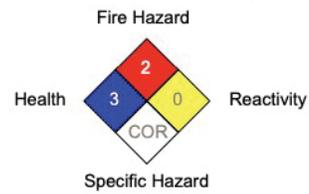
16. Other Information

Revision Date: 10/29/2015

NFPA

Health	3
Fire Hazard	2
Reactivity	0
Specific Hazard	COR

National Fire Protection Association (USA) NFPA



HMIS

Health	3
Flammability	2
Physical Hazard	0
Personal Protection	

Hazardous Material Information System HMIS

Health	3
Flammability	2
Physical Hazard	0
Personal Protection	

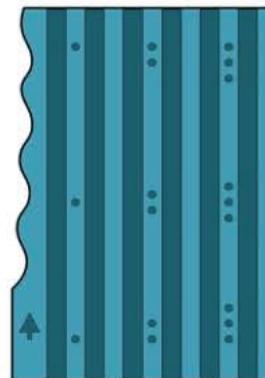
Notice to Reader:

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Appendix B: Introduction to the BxChip

Introducing the BxChip™

The enclosed slides were prepared from a BxChip®, a patented Sectionable Matrix® made by LUMEA. The BxChip is designed to hold up to 6 biopsy cores throughout tissue processing, embedding, and slide preparation and has been proven to preserve specimen orientation, reduce core fragmentation, increase viewable surface area, and increase cancer detection.* Cores are placed in channels between labeled bands (•••••).

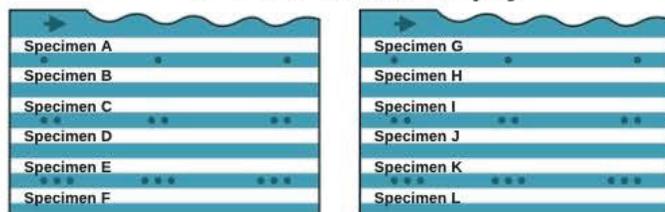


Location of Cores in a BxChip

Prostate biopsy cores have been placed in specific channels of the BxChip, depending on the number of prostate sites biopsied. One BxChip can hold up to 6 specimens, resulting in two BxChips being used for a typical 12-part patient encounter (one for left and one for right). Note that without the BxLink software, the benefits of automated quantification, site identification, and other features of the system will not be realized.

Refer to the following diagrams to determine the location of biopsy cores in the BxChip for routine sampling. Please be careful to confirm the specimen locations for this particular case.

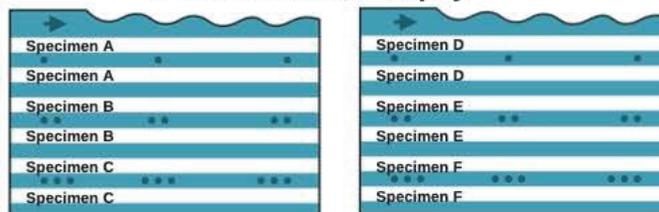
12 Site Prostate Biopsy



Left BxChip

Right BxChip

6 Site Prostate Biopsy



Left BxChip

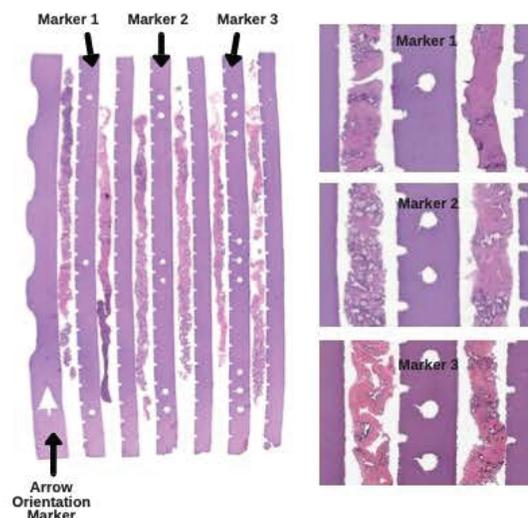
Right BxChip

How to Read BxChip Slides

The H&E slide will look like this under the microscope:

If grooves were left empty, either 1) no biopsy specimens were submitted for that given site or 2) the number of biopsy cores taken from that given site exceeded the number of BxChip grooves allotted for that site. In that case, refer to additional slides containing the specimens from that site.

If you have any additional questions about the BxChip, contact LUMEA at 844-960-3658 or www.lumea.net.



* Murugan P et al. An innovative model for reducing cost, decreasing test time, and improving diagnostic material. Am J Clin Pathol 2019, 1-12. DOI: 10.1093/AJCP/AQZ101.

* Wojno K, et al Mp16-19 BxChip™ clinical tissue array increases cancer detection rate & amount of tissue available for pathologist review. The Journal of Urology. 2016;195(4). doi:10.1016/j.juro.2016.02.2584.

BxChip

Laboratory Manual

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Feedback

We value and would appreciate your feedback to this instruction manual as we strive to make it as helpful to you as possible. Please send comments, corrections, enhancements, or suggestions to support@lumeadigital.com. (<mailto:support@lumeadigital.com>)

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