Instrument Validation and Implementation Record

Instrument:
Model
Serial Number

Item	Date	Person	Signature
Date Installed			
Location:			
Initial Validation by Vendor			
Staff Training by Vendor			
Procedure Manual in Place			
Supervisor Approval			
Medical Director Approval			
Maintenance Record in Place			
Supervisor Approval for Instrument Use			
Medical Director Approval for instrument Use			

Notes:

Instrument Validation and Implementation Record

Instrument: Leica Peloris Tissue Processor
Model Peloris 1
Serial Number 0265185B/PEL10

Item	Date	Person	Signature
Date Installed	12/17/2012	Leica	
Location: Histology lab room B234, Mt Zion	N/A	N/A	N/A
Initial Validation by Vendor please see note below	12/17/2012	Leica	
Staff Training by Vendor	12/17/2012	Leica	
Procedure Manual in Place: On instrument	12/17/2012	Leica	
Supervisor Approval	12/17/2012		
Medical Director Approval	12/17/2012		
Maintenance Record in Place	12/17/2012		
Supervisor Approval for Instrument Use	12/17/2012		
Medical Director Approval for instrument Use	12/17/2012		

Notes: Instrument was installed as a demo on Dec 17, 2012 then purchased on 12/26/2012

Note regarding validation - upon installation Instrument performed to manufacturer specifications

Special Stain Validation

Date: 8-17-2011

Special Stain: Warthin-Starry

Check one: ____ Stain Validation X Control Slide Validation

Is this special stain comparable to the current manual method and suitable for general use?
(Circle one) X YES NO

Approved by: _____
If NO, explain inadequacy:

Date	**Test Case**	**Tissue Type**	**Manual Result** (check/circle one)	**Comments**	**Suitable to use for staining?**
8-17-2011	Current control slide	W-S CSS01	Inadequate X Satisfactory	Positive, but scant organisms	Yes
8-17-2011	"Spirochete-2"	Liver	Inadequate X Satisfactory	Numerous thin spirochetes	Yes
8-17-2011	"H. pylori"	Stomach	Inadequate X Satisfactory	Numerous organisms	Yes
8-17-2011	ZS07-8828	Colon	Inadequate X Satisfactory	Positive lawn of spirochetes on mucosa	Control only
8-17-2011	W-S Negative control		Inadequate Satisfactory N/A	Negative	Negative control
			Inadequate Satisfactory		

Equipment Validation
VIP5 Unit "C"

Model Number: VIP5A-B1
Serial Number: 52140113
Installed 6/28/2008

Clinical Engineering Number: 040252
Electrical Check Done (115 VAC ± 10%, 60 HZ, 11.0A): 7/2007
Operating Conditions: Ambient Temperature: 10 C – 40 C
Relative Humidity Range: 30% - 85 % (noncondensing)
Ambient Temperature and humidity checked Using Traceable Calibration Control Co (www.control3.com)
Model Number: ISO17025, S/N: 72544734, Certificate No: 4096-1713981
Fisher Catalog No: 11-661-13

Validation Methodology:

1. **Run processor on regular overnight processing schedule using five practice blocks.**
2. **Run processor on weekend brain processing schedule using a practice block**
3. **Record oven temperature daily.**

Overnight processing schedule with test tissue: Date completed_____
Ambient temp_____, Humidity_____, Oven Temp_____

Tissue processed	Approved By/date

Equipment Validation
VIP5 Unit "C" (cont.)

Weekend brain processing schedule with test block:
Date completed_____, Ambient Temp_____, Humidity_____
Oven temp_____

Tissue Processed	**Approved By/date**

k\\validation.VIP5.C

Equipment Validation
ISOTEMP REFRIGERATOR

Model Number: Isotemp 20FREEFSA
Serial Number: 01258874901150730

Installed: August 31, 2015

Clinical Engineering Number: MZB-REF-90
Electrical Check (115Hz 60amps : 3phase)

Operating Conditions:
Ambient temperature range: -10 C to 10 C
Temperature checked using traceable calibration control
Model Number: FB50267
S/N: 150103038
Expiration date: 3/13/2017
Fisher Catalog No: 06-664-11

Validation methodology:
Record temperatures for 6 consecutive working days using Traceable thermometer Serial #150103038 and compare with digital readout ± 4 C for consistency.

Date/tech	Temperature	Digital Readout	Ambient Temperature	Humidity

Supervisor_____ Date_____
Notes:

Medical Director _____ Date_____

Equipment Validation
Microtome

Manufacturer: Reichert-Jung

Model Number: 2030

Serial Number: _____

Clinical Engineering Number: N/A – not electrical

Installed: June 27, 2008 (relocated)

Specifications: None stated

Validation Methodology: Cut slides from a current case for approval by a pathologist.

Date/ Tech	Case#/ Tissue type	Approved by/date

Assigned to (tech)_____ Date_____

K\\validation.Marvin

UCSF Medical Center **Whole Mount Blocks**

Date:_____

Is the Peloris tissue processor comparable to the current tissue processing method as the Core lab?
(Circle one) YES NO

Does the tissue placed in the Peloris processor, run on the UCSF Bigs program, produce diagnostic slides?
(Circle one) YES NO

Approved by: _____
If NO, explain inadequacy:

Date	**Test Case**	**Tissue Type**	**Core lab Results** (circle one)	**Peloris Results** (circle one)	**Comments**	**Suitable for UCSF MZ Histo lab?**
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		

Histology Medical Director approval: _____ Date: _____

Supervisor review: _____ Date: _____

UCSF Medical Center **Artisan Stain Validation**

Date:_____

Special Stain:_____

Is this Artisan stain comparable to the current manual method and suitable for general use?
(Circle one) YES NO

Approved by: _____
If NO, explain inadequacy:

Date	**Test Case**	**Tissue Type**	**Manual Result** (circle one)	**Artisan Automation Result** (Circle one)	**Comments**	**Suitable to use Artisan for staining?**
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		
			Inadequate Satisfactory	Inadequate Satisfactory		

Immunohistochemistry Instrument Validation Testing

Date:________9-26-2011__________

Instrument:___Leica Bond III__________ **Serial Number**____________________________

Circle one: New instrument Relocated instrument **Comparison Instrument**____Leica Bond Max_________

Installation Date____________

Instructions: Run parallel tests on the existing instrument and the new, or relocated instrument

Approved by: ____
If NO, explain inadequacy:

Date	**Test Case**	**Antibody**	**Existing Instrument Result** (circle one)	**New / Relocated Instrument Result** (circle one)	**Comments**
9-26-2011	CD3 Control	CD3	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	CD20 Control	CD20	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	MLH1 Control	MLH1	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	MSH-6 Control	MSH-6	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	E-Cadherin Control	E-Cadherin	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	CDX2 Control	CDX2	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	Arginase Control	Arginase	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	p63 Control	p63	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	p63 + HMWK Control	p63+HMWK	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	SOX-10 Control	Sox-10	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	Kappa Control	Kappa (IHC)	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	Lambda Control	Lamda (IHC	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	p16 Control	p16	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	EBER Control	EBER (ISH)	Satisfactory / Inadequate	Satisfactory / Inadequate	
9-26-2011	RNA Positive Control	RNA (ISH)	Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	
			Satisfactory / Inadequate	Satisfactory / Inadequate	

Tissue-Tek® Glas™ g2

SAKURA

Automated Coverslipper Demo Unit

Installation Checklist-Product # 6500

Serial Number:	Institution: UCSF	Customer:
Sakura Representative: Andy Anand	City/State: San Francisco, CA	
Installation Date:	Customer Signature:	

Check after completion=
☐ Check area for space and proper ventilation.
☐ Remove packing materials from coverslipper according to unpacking protocol Double check for materials inside unit. Remove tie wraps and protective foam from Coverslipper. Inspect for physical damage.
☐ Place unit on counter and check for proper level adjust as needed.
☐ Install activated carbon filters and/or duct adaptor.
☐ Connect Power cord and plug into an 115V, 60Hz power receptacle.
☐ Turn on power and allow initialization.
☐ Prime instrument with clearing agent according to operators manual.
☐ Position mounting medium on stage.
☐ Load coverslips into unit
☐ Install Link system if Prisma Stainer is to be connected.
☐ Run test slides.
☐ Train user on the following:
☐ Review operating manual.
☐ Using compatible clearing agents and mounting mediums.
☐ Adjusting mounting medium dispensing.
☐ Adjusting coverslip angle and speed.
☐ Utilization of programming and program interface.
☐ Loading slides and coverglass.
☐ Recommended slide types.
☐ Daily operation and maintenance.
☐ Fill out warranty card.
☐ Review service contract options and provide contact information.
☐ Instruct customer on proper Technical support procedures.