
QMP-LS Histotechnology

On-Site Consultation Pro Forma



QUALITY MANAGEMENT PROGRAM - LABORATORY SERVICES

**250 Bloor Street East, Suite 1510
Toronto, Ontario M4W 1E6
Tel: (416) 323-9540
Fax: (416) 323-9324
www.qmpls.org**

*The information collected in this document will be held in the strictest confidence and will
not otherwise be distributed, copied or disclosed without prior approval*

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

Name of person completing
this Pro Forma: Lynn Wade, RT, B.Tech
 Title: Program Manager, Safety & Quality Management
 Date: Dec 4/07

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Consultant's Comments

Type of Laboratory (Community, Hospital, PHL, etc.): Hospital
 Owner of Laboratory: Eastern Health

1. CLINICAL LABORATORY SERVICE

Is the laboratory part of a regional program or community laboratory network?
 Yes No N/A

If yes, give names and administrative address of program/network
(Attach separate sheet, if necessary.)

Eastern Health
300 Prince Philip Drive, St. John's NL A1B 3V6

Does the laboratory provide services for other laboratories/facilities?
 Yes No N/A

If yes, give names of laboratories/facilities and services provided.
(Attach separate sheet, if necessary.)

The IHC lab is the only one of its kind in
the province and thus provides services
to all the regional health authorities.

1.1 General Information

Area served (sq. km) provides IHC
services for
the Province _____

Population served (# people) _____

Is area served mostly urban? Yes No N/A

Number of general practitioners served by the laboratory _____

Number of specialists served by the laboratory _____

List these specialties: _____

1.2 Extent of Histotechnology Services Provided

Is a range of histotechnology services (EM, immunohistochemistry, molecular testing) provided to the full extent required to support histopathological diagnosis and therapeutic decision making?
 Yes No N/A

Is a limited range of histotechnology services provided with referral to a reference laboratory for further ancillary techniques to assist in diagnostic and therapeutic decision making?
 Yes No N/A

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

If yes, which ancillary techniques are referred out?

- a) EM to Memorial University
- b) Immunohistochemistry Some
- c) Molecular testing Some

Yes No N/A
 Yes No N/A
 Yes No N/A

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What percentage of the histotechnology workload is:

- Inpatient?
- Outpatient?
- Referred in?

~80%
 ~10%
 ~10%

What are the routine hours of service? 0800 - 1700hr Mon-Fri

Describe your arrangements for off-hour coverage

1700 - 0900hr General Lab Call List plus on
 Weekends - assigned pager 0800 - 1600hr
 Pathologist + Technologist Assigned on-call
 What tests are available off hours?
 full menu

If immunohistochemistry (IHC) techniques are performed on-site;

- Is a range of primary antibodies available to the full extent required to assist in diagnostic and therapeutic decision making? Yes No N/A
- Is a limited range of primary antibodies available with referral to a reference laboratory for further assistance in diagnostic and therapeutic decision making? Yes No N/A

List the primary antibodies available on-site (Attach separate sheet, if necessary.)

See attached sheet

1.3 Hospital Information (for hospital laboratory only, complete Section 1.3) St. John's only

Total number of beds 979 Occupancy rate 88%

How many beds are assigned to each of the following:

- Acute medical
- Acute surgical
- Obstetrical/gynecological
- Pediatric (excluding neonatal)
- Neonatal
- Chronic care
- Critical care

167
385
53
71
30
152
92

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

- Other, (please specify): _____

Does your hospital provide services to specialized care units such as:

- ICU (adult)
- CCU
- Oncology
- Transplant
- Other, (please specify): _____

Yes No N/A
 Yes No N/A
 Yes No N/A
 Yes No N/A

Is your hospital a university-affiliated teaching hospital? Yes No N/A

Is there an emergency service? Yes No N/A

Do you provide service to outpatient clinics? Yes No N/A

If 'yes', name and describe the service:

Day Surgery

Various Ambulatory Clinics

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2. LABORATORY WORKLOAD

Specify the average number of histology cases per month done on-site or referred in/out.

Type of case	No. per Month Performed On-site	No. per Month Referred In	No. per Month Referred Out
Surgical pathology	2,500	100	
Autopsy	20		
Other (Please specify)			

Indicate number of WMS units per year: 2,734,530 units / 427,414 exams

Does the laboratory have a protocol or referral pathway for proper utilization of reference laboratory services?

Yes No N/A

Is there a referred in test log? assigned RI# in the LIS

Yes No N/A

Is there a referred out test log? all are documented in LIS as well as a logbook

Yes No N/A

List reference laboratories used: Dynacare, Mayo Clinic, AFIP, BC Cancer Agency, Calgary Health Services

Specify the average number of histology blocks per month done on-site or referred in/out.

10,000 blocks/month

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

Type of case	Blocks per Month Performed On-site	Blocks per Month Referred In	Blocks per month Referred Out	For QMP-LS use only Consultant's Comments
Surgical pathology	9,500			
Autopsy	500			
Other (Please specify)				

Does the histotechnology staff perform duties other than histology testing? Yes No N/A

If yes, what other duties? Assist pathologist with frozen sections

- Retrieve biopsies from DI for kidney
- Prepare biopsies (muscle, kidney) for immunofluorescence stains
- Assist physician with fine needle aspirations
- Grossing all specimens

If immunohistochemistry is performed on-site;

Specify the average number of IHC slides per month done on-site or referred in/out.

Type of case	Slides per Month Performed On-site	Slides per Month Referred In	Slides per month Referred Out
General pathology	1200	250	
Lymphoid pathology	200		
Breast pathology (ER, PR)	32		
Breast pathology (HER2)			32
Breast pathology (FISH)			20% of Her 2
Cytopathology	60		
Autopsy	40		
Other (Please specify)			

Is the immunohistochemistry staff specifically trained in these techniques? Yes No N/A

Does the immunohistochemistry staff perform duties other than IHC testing? Yes No N/A

If yes, what other duties? as noted above.

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

		For QMP-LS use only Consultant's Comments
2.1 LABORATORY SPACE/DESIGN		
Does the histology laboratory have sufficient bench space /person?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
Is the design of the histology laboratory appropriate for the safe handling of specimens and effective operation of equipment?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
Comments:	<p>- fume hoods, air purifiers in use</p> <p>- air quality checks performed</p>	
3. LABORATORY ORGANIZATION STRUCTURE		
Is there a laboratory management committee with responsibility for Histotechnology?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
Are there meetings of the histotechnology staff to make recommendations regarding the service?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
4. PERSONNEL <i>See attached</i>		
4.1 Staff List (Appendix A)		
List the histology staff on Appendix A attached, including consultants (indicating qualifications, positions, number of years' experience, working hours, full-time, part-time or casual, and total FTE).		
4.2 Laboratory Director		
Manager Director of Laboratory: <u>Mr. Barry Dyer</u>		
Is the Laboratory Director full-time?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
If not, how much time does the Laboratory Director spend in the laboratory per week for histotechnology? <u>35</u> hours/week		
List other laboratories to which the Director is appointed:		
<u>Regional Manager, includes responsibilities for laboratories in Clarenville and Gairboneas</u>		
In addition to the Laboratory Director, does the laboratory have a physician or allied health professional specializing in immunohistochemistry available as an employee or consultant?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
If yes, give name and qualifications:		
<u>Dr. Ford Elms, Pathologist, FRCP</u>		
Is there a mechanism by which the consultant's recommendations are received, reviewed and implemented as appropriate?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
5. STAFF CONTINUING EDUCATION		
Are employees encouraged to participate in continuing education (CE) programs?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

If 'yes', list CE courses taken by your staff over the last three years in Appendix B attached.

Do you subscribe to any laboratory medicine or histotechnology journals? Yes No N/A

List, on Appendix C attached, the learning resources (journals, textbooks, etc.), available to the staff.

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Consultant's Comments

6. MANUALS

6.1 User Manual

Is there a manual regarding specimen collection and handling instructions available in all specimen collecting areas within the institution (patient care units, operating rooms, emergency room, outpatient areas) and referring physicians' offices? Yes No N/A

Does the manual include instructions for: Nursing Manual Protocols.

- Patient and sample identification? Lab is developing a User Guide Yes No N/A
- The method of proper collection of specimens from different sites? Yes No N/A
- Instructions for proper labelling and fixation of specimens? Yes No N/A
- Procedures for safe handling and transportation of specimens (e.g., tightly sealed containers, no external spillage)? Yes No N/A
- Specimen acceptance and rejection (if sub-optimal)? Yes No N/A

6.2 Procedure Manual (for histotechnology)

Are all tests and procedures performed within histology documented in the manual? Yes No N/A

Is there a procedure for validating new methods, reagents and instruments? Yes No N/A

Are all procedures based on published referenced methods? Yes No N/A

If no, please comment:

The lab program is currently developing quality management program, reviewing P&P

7 LABORATORY PROCEDURES

7.1 Specimen Receipt Procedures

Is an appropriate specimen identification and accessioning system in use and consistently applied? Yes No N/A

Are specimens accepted only from authorized sources (i.e. persons authorised by law to collect specimens and use medical information)? Yes No N/A

7.2 Specimen processing

Is the tissue preparation done on site? Yes No N/A

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

- Is there a written policy designating minimum fixation duration requirements for specimens requiring IHC testing e.g. breast tumours, lymphomas etc? Yes No N/A
- Are tissue processing reagents replenished or changed on a regular basis? Yes No N/A
- Are tissue processor logs detailing these steps maintained? Yes No N/A
- Are daily embedding logs provided and maintained? *Worksheets* Yes No N/A
- Are daily technologist cutting logs maintained? *at each cutting sta.* Yes No N/A
- Are the routinely stained slides checked against the embedding log? Yes No N/A

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7.3 Staining Methods

- Is all of the staining done on site? Yes No N/A
- Are all working solutions & stains properly labeled & dated? Yes No N/A
- Are storage requirements & expiry dates indicated on stains & solutions? Yes No N/A
- Are staining methods available at the work bench? Yes No N/A
- Are staining dishes clean? Yes No N/A
- Are staining solutions covered when not in use? Yes No N/A
- Are stained slides satisfactorily mounted? Yes No N/A
- Is the staining of good quality (good cellular and nuclear detail)? Yes No N/A
- Is the stain checked regularly and results documented? *H&E control slides daily* Yes No N/A

8. LABORATORY EQUIPMENT AND PERFORMANCE VALIDATION

Please provide a list of equipment used in histology and immunohistochemistry

Instrument Name, Model Manufacturer	Age in Years	Yearly Preventive Maintenance (Y/N)
Benchmark XT Ventana	2	Y
OHI 1101 - Tissue Processing	10+	
VIP Tissue-Tek E 300	15	

Is there documentation to indicate automated instruments were evaluated and validated prior to being placed into use?

Yes No N/A

Does the laboratory have sufficient and appropriately maintained equipment (e.g. incubators, microscopes) to provide the expected level of histology and immunohistochemistry service (workload and test menu)?

Yes No N/A

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

If not, what type of equipment does your laboratory require?

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9. RECORD KEEPING

- Is a patient index maintained for easy retrieval of information? LIS Yes No N/A
- Does the laboratory comply with the Provincial and/or National Guidelines with regard to the storage of specimens, blocks, slides and reports? Yes No N/A
- Are control slides retained as long as the patient test slides? Yes No N/A
- Are control slides retained in a separate file? IHC control is on patient slide Yes No N/A
- Are IHC evaluation records and validation slides retained for at least 20 years? - currently lab is 10 yrs old Yes No N/A
- retaining records.

10. QUALITY ASSURANCE

- Is the Director of the laboratory responsible for assuring that a program for monitoring and evaluating patient care services is implemented in the laboratory? Yes No N/A
- Are there procedures for the processing of External Quality Assessment (EQA) samples and the review of EQA reports? Yes No N/A
- Does the Laboratory Director and/or designated responsible person monitor results of QC and EQA and participate in implementation and documentation of corrective actions? Yes No N/A
- Is there documentation of corrective action of QC records and EQA reviews? Yes No N/A
- Does the laboratory participate in EQA schemes other than QMP-LS? Yes No N/A

If yes, please list:

UK NEQAS
CAP

11. QUALITY CONTROL

- Are the results of tests run by the night and weekend personnel, in the absence of on-site supervisors, reviewed using the same criteria applied during routine working hours by the Laboratory Director, Supervisor or Chief Technologist? same documentation and follow up processes. Yes No N/A

10.1 Internal Quality Control

- Is there a written system in operation to routinely detect clerical errors, significant analytical errors and unusual laboratory results? Yes No N/A
- Are written criteria available for the acceptance and rejection of QC results? Yes No N/A

Comments: Corrective Actions procedure

Lab. Name: _____
 Lab. Code: _____
 Lab. Licence No: _____

10.2 Histotechnology Quality Control

- | | |
|---|---|
| Are tested and approved tissue blocks maintained as control material? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are records of appropriate histological control materials maintained? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are appropriate procedural staining controls used for every staining run? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are records of the results on these staining controls maintained? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are these logs reviewed by a supervisor? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are test and control slides reviewed by a senior technologist before being sent to the pathologist? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are new lots of all IHC reagents tested in parallel with the existing reagents on validated control material before being put into use? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |
| Are records of these parallel tests maintained? | <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> N/A |
| Are positivity/negativity rates for ER/PR and HER2 tests maintained? | <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A |

11. ADDITIONAL INFORMATION AND COMMENTS

Please provide any additional information and/or comments in the space provided.

- There is a "Breast Group" which oversees quality & documentation for that tissue type including +ve / -ve rates.
 - Positive external controls are run on each antibody slide
 - Refrigerator temperature checks performed daily
 - Water bath temperature checks performed daily
 - Slide oven temperature checks performed daily
 - Antibody technical Information Log maintained
 - Ancillary Products Log maintained
 - Daily Maintenance Log maintained
 - IHC Equipment is under Service Contract and preventative maintenance performed annually
-
-
-
-
-

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Consultant's Comments

Lab. Name: _____
Lab. Code: _____
Lab. Licence No: _____

Appendix A
QMP-LS Histotechnology On-site Consultation Pro Forma

For QMP-LS use only
Consultant's Comments

List laboratory staff (physicians, MLTs, and laboratory assistants) having any responsibility in histotechnology. Include name, qualifications, position, CMLTO Registration Number, number of years of histotechnology experience, total hours worked per week and if full-time, part-time and/or casual.

Ken Green, RT csmls, PFT - 35h/wk

Les Simms, RT csmls, PFT - 35h/wk

Beverly Rowe, RT csmls, PFT - 35h/wk

Kim Voisey, RT csmls, PFT - 35h/wk

Dr. Ford Elms, FRCP, PPT

*NOTE - Currently recruiting a IHC lab Technical Director with Masters or PhD qualifications.

Clerical—Number of staff that assist in histotechnology: IHC 5

Number of full-time equivalent (FTE) staff working in histotechnology: IHC 4

Number of full-time equivalent (FTE) staff working in histotechnology: IHC 0

Number of part-time equivalent (FTE) staff working in histotechnology: IHC 0

Number of casual equivalent (FTE) staff working in histotechnology: IHC 0

*Please place an asterisk beside staff that rotate through other disciplines

Date: _____

Surgical/Cytology #: _____ Block I.D. _____

Referring Hospital #: _____

Name: _____

Pathologist/Resident: _____

Diagnosis: _____

Undifferentiated Malignancy

<input type="checkbox"/> AE1/AE3	<input type="checkbox"/> HMB-45	<input type="checkbox"/> Pankeratin (AE1/AE3/PCK26)	<input type="checkbox"/> Vimentin
<input type="checkbox"/> EMA	<input type="checkbox"/> LCA (CD45RO)	<input type="checkbox"/> S-100	
Epithelial	Mesenchymal	Lymphoid	Virus
<input type="checkbox"/> α -1AT	<input type="checkbox"/> Desmin	<input type="checkbox"/> BCL 2	<input type="checkbox"/> CMV
<input type="checkbox"/> α -Fetoprot.	<input type="checkbox"/> Factor VIII	<input type="checkbox"/> BCL 6	<input type="checkbox"/> EBV
<input type="checkbox"/> CA 125	<input type="checkbox"/> Muscle Actin	<input type="checkbox"/> BCL xL	<input type="checkbox"/> HBV (Core)
<input type="checkbox"/> CEA Monoclonal	<input type="checkbox"/> Myogenin	<input type="checkbox"/> C3 Comp	<input type="checkbox"/> HBV-s
<input type="checkbox"/> Chromogranin	<input type="checkbox"/> Myoglobin	<input type="checkbox"/> CD 1a	<input type="checkbox"/> HPV
<input type="checkbox"/> CK 7	<input type="checkbox"/> Smooth Muscle Actin	<input type="checkbox"/> CD 3	<input type="checkbox"/> HSV-I
<input type="checkbox"/> CK 20		<input type="checkbox"/> CD 4	<input type="checkbox"/> HSV-II
<input type="checkbox"/> Cytoker (CK19/BA17)		<input type="checkbox"/> CD 5	<input type="checkbox"/> VZV
<input type="checkbox"/> Cytokeratin 34 β E12		<input type="checkbox"/> CD 8	
<input type="checkbox"/> Est. & Prog. Rec.	<input type="checkbox"/> Chromogranin	<input type="checkbox"/> CD 10	
<input type="checkbox"/> Her2neu	<input type="checkbox"/> NSE	<input type="checkbox"/> CD 15 (Leu M1)	
<input type="checkbox"/> PLAP	<input type="checkbox"/> Synaptophysin	<input type="checkbox"/> CD 20 (L26)	
<input type="checkbox"/> PSA		<input type="checkbox"/> CD 21	
		<input type="checkbox"/> CD 23	
			<input type="checkbox"/> CD 30 (BerH2)
			<input type="checkbox"/> CD 35
			<input type="checkbox"/> CD 43 (MT-1)
			<input type="checkbox"/> CD 45 RA (MT-2)
			<input type="checkbox"/> CD 68
			<input type="checkbox"/> CD 79a
			<input type="checkbox"/> Cyclin D1
			<input type="checkbox"/> Kappa
			<input type="checkbox"/> Lambda
			<input type="checkbox"/> IgA
			<input type="checkbox"/> IgG
			<input type="checkbox"/> IgM
			<input type="checkbox"/> TdT
			<input type="checkbox"/> UCHL 1

Endocrine/Hormonal	Neural & Special Muscle	Others
<input type="checkbox"/> ACTH	<input type="checkbox"/> α Synuclein	<input type="checkbox"/> Lysozyme
<input type="checkbox"/> FSH	<input type="checkbox"/> GFAP	<input type="checkbox"/> Melanin A
<input type="checkbox"/> GH	<input type="checkbox"/> NeuN	<input type="checkbox"/> Myeloperoxidase
<input type="checkbox"/> LH	<input type="checkbox"/> Neurofilament	<input type="checkbox"/> MYO D1
<input type="checkbox"/> Prolactin	<input type="checkbox"/> Spectrin	<input type="checkbox"/> NSE
<input type="checkbox"/> TSH	<input type="checkbox"/> Tau-2	<input type="checkbox"/> P-53
	<input type="checkbox"/> Ubiquitin	<input type="checkbox"/> P-63
		<input type="checkbox"/> PCNA
<input type="checkbox"/> Calcitonin	<input type="checkbox"/> Alpha Sacroglycan	<input type="checkbox"/> PNL-2C
<input type="checkbox"/> Gastrin	<input type="checkbox"/> Beta Sacroglycan	<input type="checkbox"/> Synaptophysin
<input type="checkbox"/> GCDFP	<input type="checkbox"/> Delta Sacroglycan	<input type="checkbox"/> Toxoplasma
<input type="checkbox"/> Glucagon	<input type="checkbox"/> Gamma Sacroglycan	<input type="checkbox"/> TTF-1
<input type="checkbox"/> HCG	<input type="checkbox"/> B Dystroglycan	<input type="checkbox"/> Ubiquitin
<input type="checkbox"/> Insulin	<input type="checkbox"/> DYS 1 (Rod)	<input type="checkbox"/> Ulex Europeaus
<input type="checkbox"/> Somatostatin	<input type="checkbox"/> DYS 2 (c)	<input type="checkbox"/> Others:
<input type="checkbox"/> Thyroglobulin	<input type="checkbox"/> DYS 3 (N)	
<input type="checkbox"/> VIP	<input type="checkbox"/> Dysferlin	
	<input type="checkbox"/> Emerin	
	<input type="checkbox"/> Merosin	
	<input type="checkbox"/> Myosin Heavy Chain Fast	
	<input type="checkbox"/> Myosin Heavy Chain Slow	
		<input type="checkbox"/> FISH (Her2neu)

Lab Technologists OnlyBlocks Cut _____
Technologist/Date Completed _____

Slides Labelled _____

Units Taken _____

Lab. Name: Ken Green
Lab. Code: _____
Lab. Licence No: _____

Appendix B

List the continuing education (CE) courses taken by your staff over the last three years:

For QMP-LS use only
Consultant's Comments

Lab. Name: Bey Howe
Lab. Code: _____
Lab. Licence No: _____

Appendix B

List the continuing education (CE) courses taken by your staff over the last three years:

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Consultant's Comments

Lab. Name: JAC Lab. Code: JKM V
Lab. Licence No: _____

Appendix B

List the continuing education (CE) courses taken by your staff over the last three years:

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Lab. Name: Les Simms
Lab. Code: _____
Lab. Licence No: _____

Appendix B

List the continuing education (CE) courses taken by your staff over the last three years:

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Consultant's Comments

Lab. Name: Barry Dyer
Lab. Code: _____
Lab. Licence No: _____

Appendix B

List the continuing education (CE) courses taken by your staff over the last three years:

For QMP-LS use only
Consultant's Comments

Lab. Name: Pathology
 Lab. Code: _____
 Lab. Licence No: _____

Appendix C
QMP-LS Histotechnology On-site Consultation Pro Forma

List the learning resources (textbooks, etc.) available to the staff

Authors	Editor(s)	Title	Edition	Publisher	Year
	CAP	CAP Today			
Leong, Cooper, Leong,		Manual of Diagnostic Antibodies for Immunohistology		GMM	1999
Dahbs, David		Diagnostic IHC		Churchill/ Livingstone	2002
AFIP	Prophet Mills, Arrington Sabin	Laboratory Methods in Histotechnology		APP	1992
Leeson & Leeson		Histology		Saunders	1976
Nadji, Nassiri, Morales		Efficient Tumor IHC		ASCP	2006
Cell Marque	Ardi Williams Lacey	Cell Marque Reference Guide	Vol 7		2003

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