

Recommendations - Immunohistochemistry Service  
(Spreadsheet Dr. D. Banerjee/Trish Wegrynowski) – Updated June 30/06

Recommendation	Recommended By	Agree With	Current Status	Expected Completion Date
1. Pathologists should subspecialize.	Dr. D. Banerjee	Yes	Drs Cook/Denic working on	TBA - <i>done</i>
*2. One Pathologist appointed as Director of Immunohistochemistry service. Backup designate should be appointed (Trish).	Dr. D. Banerjee/ Trish Wegrynowski	Yes	Implemented. Drs Makarla/ Elms	TBA—Drs will be trained <i>done</i>
(*) 3. Consideration to use rabbit monoclonal antibody SP1 for ER testing.	Dr. D. Banerjee		Being discussed <i>→ not considered standard of care</i>	
*4. Dedicated Technologist for IHC.	Dr. D. Banerjee Trish Wegrynowski	Yes	3 staff dedicated	Completed
5. Pathologists attend educational and scientific conferences. (IHC)	Dr. D. Banerjee	Yes	In progress	Ongoing
6. Pathologists' Assistants hired to standardize grossing procedures.	Dr. D. Banerjee Trish Wegrynowski	Yes	3 hired to date 4 <sup>th</sup> to start in Aug 06	Training started May 06
7. Implement Tissue-Tek X-Press and Pathologists/Technologists should redesign workflow/practices.	Dr. D. Banerjee	Yes	Partially implemented	6-12 months
(*) 8. Reinstitute Ventana ER/PR service.	Dr. D. Banerjee	Yes	Drs Makarla & Elms are investigating	Jun 06
*9. Enroll in external quality assurance programs.	Dr. D. Banerjee/ Trish Wegrynowski	Yes	Enrolled in CAP and UK proficiency testing	Completed
*10. Redesign communication structure to provide better joint technical/medical accountability. IHC Tech's report to Division Manager and Section Head depending upon issue.	Dr. D. Banerjee/ Trish Wegrynowski	Yes	Regular meetings to be scheduled	Ongoing
11. Documented internal control results by Pathologists. (Linked to #25 recommendation by Trish)	Dr. D. Banerjee	Yes	Dr. Cook standardized reporting procedures	In progress
*12. Ensure blocks submitted for ER/PR have normal ductal epithelium.	Dr. D. Banerjee	Yes	Dr. Cook has informed Pathologists.	Completed
*13. Tissue processing consolidated to HSC site and SOP be available.	Trish Wegrynowski	Yes	All processing at HSC	Completed
(*) *14. Pathologists need to establish a mechanism to express IHC concerns/issues. Documentation required. <i>Process in IF established - b. be adopted in IHC</i>	Trish Wegrynowski	Yes	Dr. Cook to address in memo to all Pathologists	Completed Mar 06
*15. Succession planning to be evaluated for technical and professional staff.	Trish Wegrynowski	Yes	Plan in place	1 Year
16. Procedure manual outlining the SOP's to be created for all IHC antibodies and methods including the Ventana operator's manual.	Trish Wegrynowski	Yes	In progress	Ongoing
(*) *17. Antibody data specification sheets be available for all antibodies in use including lot #, clone, expiry date, etc. <i>done</i>	Trish Wegrynowski	Yes	In progress	Ongoing
*18. Routine equipment maintenance performed and documented as per company protocols.	Trish Wegrynowski	Yes	Completed	Ongoing

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19.	Documented evaluation of IHC antibodies to ensure sensitivity and specificity of results.	Trish Wegrynowski	Yes	In progress	Ongoing
*20.	Evidence of training/competency of technical staff trained on Ventana system.	Trish Wegrynowski	Yes	Completed	
*21.	Retired procedures/antibodies information must be retained for 2 years.	Trish Wegrynowski	Yes	In progress	Ongoing
*22.	All technical/professional issues, concerns and corrective actions must be documented.	Trish Wegrynowski	Yes	In progress	Ongoing
23.	Implement Her-2 testing on the automated Ventana system.	Trish Wegrynowski	Yes	In progress	TBA
24.	IHC Technologist to be trained to assess the quality and specificity of staining for IHC daily controls.	Trish Wegrynowski	Yes	In progress	Ongoing
25.	Standard report headings for both Pathology sites including predictive/prognostic information on specimen processing, antibody clone, and scoring method used.	Trish Wegrynowski	Yes	Dr. Cook – In progress	TBA
*26.	Internet availability for IHC workbench and purchase IHC textbooks as needed.	Trish Wegrynowski	Yes	Completed	
*27.	Funding available for 1 IHC Technologist to attend the annual NSH convention.	Trish Wegrynowski	Yes	Approved (Ventana)	Completed
*28.	Relocate the automated special stainer from the IHC Lab.	Trish Wegrynowski	Yes	Equipment installed	Completed
29.	Laboratory to send out up to 10 cases per month for correlation of results.	Dr. D. Cook	Yes	Upon retesting	Ongoing
*30.	Send technologists to Mt. Sinai and Jewish General.	Internal	Yes	Completed	Feb 06
31.	SOP's for accessioning, grossing, & fixation	Trish Wegrynowski	Yes	B. Dyer, Drs Morris-Larkin & Carter working on	Sep 06 – Mar 08
32.	SOP's and performance evaluation of PA's documented	Trish Wegrynowski	Yes	Dr. Morris-Larkin, B. Dyer	Mar 08
33.	Refrigerators for OR's	Trish Wegrynowski	Yes	Received	Jul 06
34.	Document courier service times	Trish Wegrynowski	Yes	Completed	
35.	SOP's for tissue processor, embedding	Trish Wegrynowski	Yes	In progress	Sep 06
36.	Procedures for handling of suboptimal specimens	Trish Wegrynowski	Yes	B. Dyer, Dr. Denic In progress	Oct 06
37.	SOP's for IHC in compliance with Clinical & Laboratory Standards Institute	Trish Wegrynowski	Yes	Latest version available of CD to be purchased	Jul 06
38.	Compilation of antibody specification sheets	Trish Wegrynowski	Yes	In progress	Ongoing
39.	Microscope maintenance & documentation	Trish Wegrynowski	Yes	In progress	Oct 06
40.	Pipette accuracy & calibration documentation	Trish Wegrynowski	Yes	In progress	Ongoing
41.	Thermometers placed in all temperature controlled instruments	Trish Wegrynowski	Yes	Completed	
42.	External alarm system for antibody refrigerator	Trish Wegrynowski	Yes	Completed	
43.	Documentation for all pH dependent reagents/meter	Trish Wegrynowski	Yes	In progress	Ongoing
44.	Equipment/instrument selection criteria	Trish Wegrynowski	Yes	In progress	Ongoing
45.	Corrective action log	Trish Wegrynowski	Yes	B. Dyer, Dr. Denic In progress	Ongoing
46.	Establish protocol for false positive staining	Trish Wegrynowski	Yes	In progress	Ongoing

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47. Evaluation & appropriate use of negative controls	Trish Wegrynowski	Yes	Dr. Denic – In progress	Ongoing
48. Evaluation & appropriate use of “sausage” block for positive & negative controls	Trish Wegrynowski	Yes	Dr. Denic – In progress	Ongoing
49. RT’s trained to assess the quality of EXTERNAL positive & negative controls with signed documentation retained for 2 years	Trish Wegrynowski	Yes	B. Dyer, Drs Makarla, Elms, Denic – In progress	Ongoing
50. Standard report headings for Eastern Health	Trish Wegrynowski	Yes	B. Dyer	Sep 06
51. The quality management policies be shared with other regions in the province	Trish Wegrynowski	Yes	Dr. Denic – In progress	Ongoing
52. The QM team should be involved with quality improvement, establish quality indicators for monitoring purposes, provide a mechanism to ensure recommendations are dealt with, and create corrective action logs to investigate underlying causes.	Trish Wegrynowski	Yes	QC Dept, T. Gulliver, B. Dyer, Dr. Denic – In progress	Ongoing