

**Anatomie et Cytologie Pathologiques**

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
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Rockville, MD 20852  
USA

*Docket N°03D0007*

*Estrogen and Estrogen/Progestin drug products to treat vasomotor symptoms and vulvar and Vaginal atrophy symptoms. Recommendations for clinical evaluation.*

18 February 2003

To whom is concerned,

Pr Nogales and myself are involved as readers of endometrial biopsy slides in many studies evaluating the safety and efficacy of estrogen/progestin drug products (see CV). Most of these studies concern drugs to be developed in the European market. The industry follows the recommendations provided by the European Agency for the Evaluation of Medicinal products. These recommendations are updated in accordance with the scientific advances made in this area. Being involved as experts for updating the European recommendations, we are interested by the FDA recommendations. We read carefully your draft guidance (**docket number : 03D0007**) published in January 2003 and have some comments concerning the monitoring and the Appendix histologic descriptions recommended for use when reading endometrial biopsy slides.

258-260 (page 7)

**For the efficacy evaluation, three independent expert pathologists, blinded to treatment group and to each other's readings, determine the diagnosis for endometrial biopsy slides during the conduct of the study.**

Do you mean that one pathologist will read the biopsy at screening and three pathologists read the final biopsy after 12-month of treatment?

266-268 (page 7)

**Standardized criteria as provided in Blaustein's pathology text (Pathology of the Female Genital Tract) be used for the diagnosis of endometrial hyperplasia (see Appendix for recommended histologic characteristics of the endometrium).**

While the diagnosis of the different types of hyperplasia is well covered in many books of gynecological pathology such as Blaustein's or Haines and Taylor's pathology texts, the other types of benign endometrium are not so clearly defined. For instance, the difference between atrophic and inactive endometrium is not made in most books. We are surprised that the proliferative category has been divided in this working document in three subcategories which are not considered in any reference book. We do not know which are the criteria, or where the

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limit is drawn to differentiate a "weakly" versus "active" proliferative endometrium  
Furthermore, the third category "disordered proliferative endometrium" is considered to be

nothing but a focal simple hyperplasia in the Blaustein's. This term is not considered by any classifications issued by International Agencies such as the WHO. Thus, we believe that dividing proliferative into three entities which are not fully accepted by most gynecopathologists will lead once again to poor reproducibility, lacking any practical value in the evaluation of the endometrial tissue.

269-270 (page 7)

**Endometrial polyps be fully characterized as to the glandular proliferation and atypia (see Appendix for additional histologic characteristics of the specimen).**

Do you mean that polyps with hyperplastic features and more at the end of the treatment have to be counted as an hyperplasia and thus a treatment failure? or do you believe that it has to be described as a different entity? At the initial screening, it is usually requested to remove polyps of any histologic type during hysteroscopy in order to prevent bleeding during treatment and improve the compliance. If it cannot be performed, the patient is excluded from the study. Considering this classification, what is the recommendation when a polyp is diagnosed at screening? Is this recommendation different according to the histologic type of the polyp?


279-282 (page 7)


**For the efficacy evaluation, the concurrence of two of the three pathologists be accepted as the final diagnosis. If there is no agreement among the three pathologists, the most severe pathologic diagnosis (i.e., atypical hyperplasia > complex hyperplasia > simple hyperplasia > benign endometrium) would be used as the final diagnosis.**

This rule has been applied before only when a diagnosis of simple hyperplasia or more was diagnosed by one of two pathologists. In this case, a third pathologist had to be involved and the concurrence of two of the three was accepted as the final diagnosis. Now that three pathologists will read all the final biopsies, which diagnosis will be accepted as the final diagnosis if a different diagnosis of benign endometrium (atrophic versus proliferative versus secretory) is proposed by the three readers? Is it considered as benign endometrium only? If so, why to use a classification which include all the different types of benign endometrium?

We thank you very much for considering these comments and giving your answer when appropriate.

Sincerely yours,

  
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## CURRICULUM VITAE

### Personal Data:

#### Francisco Nogales

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SPAIN  
Birthdate 3 October, 1946 Badajoz. Spain  
Graduation University of Madrid, June 1969  
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### SPECIAL APPOINTMENTS

1975: **Visiting Fellow** University of Southampton, U.K.  
(Professor D. H. Wright)  
1975-1980: **Guest Lecturer** for Postgraduate courses, University  
of Colorado, Aspen, Colorado (USA). Given Institute  
of Pathobiology.  
1983: **Visiting Professor,** Department of Pathology,  
University of Colorado, Denver, Colorado (USA).  
1992-96: **President, International Society of Gynecological  
Pathologists**  
1993 **Academician** Royal Academy of Medicine  
1995 **Scientific Advisor,** European School of Pathology,  
Turin, Italy  
2002 **Member.** Consensus Committee on Nomenclature of  
Gynaecologic Tumours WHO-IARC. Lyon. Francia  
2002 **Advisor.** European Society of Pathology. Working Group  
on Gynaecological Pathology

**HONORARY APPOINTMENTS**

Société Française de Gynéco-Pathologie 1993	<i>Membre d'Honneur</i>
Sociedad Cubana de Anatomia Patologica 1999	<i>Miembro de Honor</i>
Sociedad Colombiana de Anatomia Patologica 2000	<i>Miembro de Honor</i>
The Adriatic Society of Pathology 1999	<i>Honorary Member</i>
Asociación Peruana de Patologos 2002	<i>Miembro de Honor</i>
Universidad Central de la Habana 2001	<i>Profesor de Honor</i>
Universidad Mayor de San Marcos, Lima 2002	<i>Profesor Invitado</i>

**PARTICIPATION IN LEARNED JOURNALS**

<b>Histopathology</b> (Blackwell). London	Member Advisory Board 1982-actual
<b>Current Topics of Pathology</b> (Springer). Heidelberg y New York	Member Editorial Board 1986-actual
<b>International Journal of Gynecological Pathology</b> (Raven Press). New York	Member Editorial Board 1986-actual <b>Associate Editor</b> 1994-1998 Member Editorial Board 1998-actual
<b>Current Diagnostic Histopathology</b> (Churchill Livingstone). London	Member Advisory Board 1993-actual
<b>Pathology Case Reviews</b> (J.B. Lippincott). Philadelphia	Member Editorial Board 1995-actual

**REVIEWER OF:**

*Virchows Archiv A. (Pathology)*  
*International Journal of Gynecologic Cancer*  
*Pathology Research and Practice*  
*Obstetrics and Gynecology*

*European Journal of Obstetrics and Gynecology and Reproductive Biology.*

*Cancer (Philadelphia)*

*J Clin Pathol (London)*

*Path. Res Pract (Germany)*

*J clin Path (London)*

*Int J Surg Pathol (Milan)*

*Maturitas (Amsterdam)*

Pathologist in various menopause studies with the following companies :

*Solvay Arzneimittel, Postfach 22, D 30002 Hannover. Germany*

*Effik Laboratories, Burospace 7, 91571 Bievres. France*

*Merck Darmstadt, Postfach 64271, 64293 Darmstadt. Germany*

*Laboratoire Théramex, 6 Av. du Prince Héréditaire Albert. 98000 Monaco*

*IRIS- Servier, 6, Place des Pleiades, 92415 Courbevoie Cedex. France*

## MAINSTREAM PUBLICATIONS

### International Books

- The Regeneration of Human Endometrium under normal and pathologic conditions. In: Mechanisms of Endometrial Bleeding. (Cook C. & Discfalusy M. Eds.) W.H.O. Geneva 1980
- Neural Tissue in Human Teratomas. In: The Biology of Teratomas. (Damjanov I. & Solter D. Eds.) Humana Press. Clifton N.J. 1983 ISBN 089603-040-7
- The Pathology of Germ Cell Tumours. In: Haines and Taylor's. Obstetrical and Gynaecological Pathology. 3rd Edition (Fox H. Ed.) Churchill Livingstone London 1987 ISBN 0-443-02405-7
- The Pathology of Germ Cell Tumours. In: Haines and Taylor's Obstetrical and Gynaecological Pathology. 4th Edition (Fox H. & Wells M. Eds.) Churchill Livingstone. London 1995 ISBN 0-443-04537-2

- The Pathology of Human Yolk Sac In: Haines and Taylor's. Obstetrical and Gynaecological Pathology. **4th Edition** (Fox H. & Wells M. Eds.) Churchill Livingstone. London **1995** ISBN 0-443-04537-2
- The Pathology of Germ Cell Tumours. In: Haines and Taylor's. Obstetrical and Gynaecological Pathology. **4rd Edition** (Fox H. Ed.) Churchill Livingstone. ISBN 0-443-04537-2. London **2002**
- Organization of a Department of Pathology. In: University Management Handbook; Development of modernized management structures. Åbo Academy Press. Åbo, Finland 2000 ISBN 92-12-0737-X
- **Nogales FF**, Talerman A, Kubik-Huch RA, Devouassoux-Shisheboran M, Tavassoli FA *Ovarian germ cell tumours (2.3)*. WHO Classification of Tumours (Blue Books). III Pathology and Genetics of Tumours of the Breast and Female Genital Organs. Edited by F.A. Tavassoli and M.R. Stratton. IARC Lyon **2003** ISBN 92 8322412 4
- **Nogales FF**. *Tumours and lesions of the rete ovarii (2.5)* WHO Classification of Tumours (Blue Books). III. Pathology and Genetics of Tumours of the Breast and Female Genital Organs. Edited by F.A. Tavassoli and M R Stratton. IARC Lyon **2003** ISBN 92 8322412 4
- Silverberg SG, Kurman RJ, **Nogales FF**, Mutter GL, Kubik-Huch RA, Tavassoli FA, Roth LM. *Epithelial tumours and related lesions of the uterine corpus (4.1)* WHO Classification of Tumours (Blue Books). III. Pathology and Genetics of Tumours of the Breast and Female Genital Organs. Edited by F.A.Tavassoli and M.R. Stratton. IARC Lyon **2003** ISBN 92 8322412 4

## SCIENTIFIC PAPERS

(does not include contributions in languages other than english)

### Continuing Education Programs of the American Society Of Clinical Pathology

- ASCP Check Sample April 1977 Silverberg S. G. **Nogales F. F.**, ; Ovarian mucinous tumor of borderline malignancy.
- ASCP Check Sample June 1982, Silverberg S.G., **Nogales F.F.**; Endolymphatic Stromal Myosis.
- ASCP Check Sample September 1995; **Nogales F.F.**, Luna M.A.; Small cell epidermoid carcinoma with melanocyte colonization arising in a mature ovarian benign cystic teratoma.

### Letters to the editor

1. **Nogales FF**. Primary chondrosarcoma of the ovary. (letter) **Histopathol** 6: 376-377; 1982
2. Urdiales-Viedma M; Martos-Padilla S; **Nogales FF**; Lopez-Yevenes A. Lymph node changes in echinococcosis [letter]. **Arch Pathol Lab Med** 108. 528; 1984
3. **Nogales FF**, Alvaro T, Fernández Ruiz PL. Alpha-fetoprotein positive globules in involuting human yolk sac. (letter) **Hum Pathol**19: 995-996; 1988

4. Alvaro T, **Nogales FF**. Villous adenoma and invasive adenocarcinoma of the cervix. **Int J Gynecol. Pathol** 7: 95-96; 1988
5. **Nogales FF**. Fatty change in the endometrium (letter) **Histopathol** 20: 599; 1992
6. **Nogales FF**. Myxoid endometriosis (letter) **Am J Surg Pathol** 19: 972; 1995
7. Valenzuela M, Martín Ruiz JL, Caballero AM, **Nogales FF**, : Acid secretion, parietal cell mass and helicobacter pylori (letter). **Am J Gastroenterol** 92: 1070-1071; 1997
8. **Nogales FF**. Carvia R. Tamoxifen effects (letter). **Am J Surg Pathol** 22: 907-908; 1998
9. Bergeron C, **Nogales FF**, Masseroli M, Abeler V, Duvillard P, Müller-Holzner E, Pickartz H, Wells M. Response to Endometrial hyperplasias. **Am J Surg Pathol** 24: 754-755 2000
10. **Nogales FF**. Isaac MA, Bosincu L. (Letter) Reply to Adenomatoid tumours. **Int J Gynecol Pathol**. 21:305; 2002
11. **Nogales FF**. Aguilar D. (Letter). Florid vascular proliferation in grade 0 glial implants from ovarian immature teratoma. **Int J Gynecol Pathol**. 21:305-307; 2002
12. **Nogales FF**. Critical commentary to Thymus in teratoma. Possible clues to its histogenesis **Path Res Pract** 196: 798-799; 2000

#### Review Articles

13. **Nogales FF**, Fernández PL. La patología de los tumores germinales del ovario. Nuevos conceptos y reconsideraciones. **Revisiones en Cancer** (Madrid). 3: 3-10; 1989
14. **Nogales FF**. Beltran E. Fernández PL. The Pathology of Human Yolk Sac in Spontaneous Abortion. Findings in 103 cases. **Progress in Surgical Pathology**. 12: 291-303; 1992
15. **Nogales FF**. Mesonephric (WOLFFIAN) tumours of the female genital tract. **Current Diagnostic Pathology**. 2: 94-100; 1995
16. **Nogales FF**. Prognostic factors in endometrial neoplasia: old and new. **Current Opinion in Obstetrics and Gynecology** 8: 74-78; 1996

#### Original Contributions to International Journals

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18. Mendez J. A, Bedoya J. M, Matilla A, **Nogales FF**, Galera H; Carcinoma in situ of the fallopian tube associated with cervical carcinoma. A case report. **Int J Gynecol Obstet** 14: 353-355; 1976
19. **Nogales FF**, Favara BE, Major F. J, Silverberg SG. Immature teratoma of the ovary with a neural component ("solid" teratoma): A clinicopathologic study of 20 cases. **Hum Pathol** 7: 625-642; 1976
20. **Nogales FF**, Silverberg SG, Epidermoid cysts of the ovary. A report of 5 cases with histogenetic considerations and ultrastructural findings. **Am J Obstet Gynecol** 124: 523-528; 1976
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25. Carapeto R, **Nogales FF**, Matilla A. Ectopic pregnancy coexisting with a primary carcinoma of the fallopian tube: A case report. **Int J Obstet Gynecol** 16: 263-264; 1978
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33. **Nogales FF**, Ortega I, Rivera F, Armas JR. Metanephrogenic tissue in immature ovarian teratoma. **Am J Surg. Pathol** 4: 297-299; 1980
34. Silverberg SG, **Nogales FF**. Endolymphatic stromal myosis of the ovary: A report of 3 cases and literature review. **Gynecol Oncol** 12: 129-138; 1981
35. González Campora R **Nogales FF**, Lerma E, Navarro A, Matilla A. Lymphoma of the penis. **J Urol** 126: 270-271; 1981
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40. Aguilar D, Martín Linares J. M, Aneiros J, Arjona V, **Nogales FF**. The fine structure of choroid plexus carcinoma. *Histopathol* 7: 939-946; 1983
41. Caballero T, Aneiros J, López J, Gómez MM, **Nogales FF**. Fibrolamellar hepatocelular carcinoma. *Histopathol* 9: 445-456; 1985
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49. Aguilar D, Alvaro T, Camara M. , **Nogales FF**. Differentiation in medulloblastomas: Immunohistochemical study of 21 cases *Appl. Pathol* 7: 277-284 ; 1989
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53. **Nogales FF**, Ayala A, Ruiz Avila I, Sirvent JJ. Myxoid leiomyosarcoma of the ovary. Analysis of 3 cases. *Hum Pathol* 22: 1268-1273; 1991
54. García CR, Toro M, Morales C, Beltran A. L, **Nogales FF**. Uterine müllerian adenosarcoma with a histiocytic mesenchymal component. *Histol Histopathol* 6: 363-367; 1991
55. Clavero P. A, **Nogales FF**, Ruiz Avila J, Linares J, Concha A. Regression of peritoneal leiomyomatosis after treatment with gonadotropin releasing hormone analogue. *Int J Gynecol. Cancer* 2: 52-54; 1992
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58. **Nogales FF**, Beltran E, Pavcovich M, Bustos M. Ectopic somatic endoderm in secondary human yolk sac. **Hum Pathol** 23: 921-924; 1992
59. Verdejo J.J, Fernández PL, Haddad A, Carriazo A. G, Zuluaga A, **Nogales FF**. Extra skeletal Ewing's Sarcoma Metastatic to Penis. **Brit J Urol** 70: 206-207; 1992
60. **Nogales FF**, Plata C, Ruiz Avila I, Concha A. Granulosa cell tumour with true hepatocytic metaplasia simulating luteinized stromal cells. **Am J Surg. Pathol** 17: 85-90; 1993
61. **Nogales FF**. Embryological clues to the yolk sac tumor group; The Robert Mayer Festschrift. **Int J Gynecol Pathol** 12: 101-107; 1993
62. **Nogales FF**, Martín F, Linares J, Naranjo E, Concha A. Myxoid change in decidualized scar endometriosis: A pseudomalignant histological appearance. **Cutaneous Pathol** 20: 87-91; 1993
63. **Nogales FF**, Ruiz Avila I, Concha A, Del Moral A. Immature endodermal teratoma of the ovary: Embryologic correlations and immunohistochemistry. **Hum Pathol** 24: 364-369; 1993
64. Reymundo C, Toro M, Morales C, López Beltrán E. Nogales F, **Nogales FF**. Hyaline globules in uterine carcinosarcomas; a diagnostic aid? **Pathol Res. Pract** 189: 1063-1066; 1993
65. González Moles MA; Ruiz Avila I; González Moles S; Martínez I; Ceballos A; **Nogales FF**: Detection of HPV DNA by in situ hybridization in benign, premalignant and malignant lesions of the oral mucosa **Bull Group Int Rech Sci Stomatol Odontol** 37: 79-85; 1994
66. **Nogales FF**. Andujar M, López Beltrán E, Martínez JL, Zuluaga A. Adenocarcinomas of the renal pelvis. **Urol Int** 52: 172-175; 1994
67. López Beltran A, **Nogales FF**, Donné C.H, Sayag J.L. Adenocarcinoma of the urachus showing extensive calcification and osseous metaplasia **Urol Int** 53: 110-113; 1994
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Nocales

Mesonephric, Trophoblastic and Clear Cell Tumors. Am J Surg Pathol  
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### *DIPLÔMES*

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- Baccalauréat Mathématiques-Mention AB, Académie de Clermont-Ferrand

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- Interne des Hopitaux Privés de Paris

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- Doctorat en Médecine, Université Pierre et Marie Curie, Paris VI

1985

- Certificat d'Etudes Spéciales d'Anatomie Pathologie et Cytologie Humaines, Université Pierre et Marie Curie, Paris VI
- Certificat d'Etudes Supérieures de Biologie Humaine, Université René Descartes, Paris V

1989

- PhD, Mc Gill University, Montréal, Canada Mention très bien

1993

- Réparation juridique du dommage corporel Université René Descartes Paris V

1994

- Diplôme de Statistique Appliquée à la Médecine Option Recherche Clinique

1995

- Compétence non exclusive en Gynécologie Médicale

*POSTES OCCUPES***07/1988-04/1992**

- Directeur adjoint, Institut de Pathologie et de Cytologie Appliquée, Professeur J de Brux, 53 rue des Belles Feuilles - 75016 Paris

*FORMATION***1973 - 1979**

- Faculté de médecine, Université Pierre et Marie Curie, Paris VI

**1979 - 1980**

Stage interné, Département de Pédiatrie, Hôpital d'Owendo, Gabon

**10/1980-10/1982**

- Interne, Département de gastro-entérologie et Département de cardiologie, Hôpital Saint Camille, Bry/Marne

**10/1982-03/1985**

- Interne, Département de Médecine Interne et Département de Pneumologie, Hôpital St Joseph, Paris

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- Attachée, Département d'Anatomie Pathologique et de Cytologie, Hôpital St Joseph, Paris

**07/1985-06/1986**

- Clinical Fellow in Gynecological Pathology, Department of Gynecology and Pathology, Jewish General Hospital Montréal Québec

**07/1986-06/1988**

- Clinical and Research Fellow in Gynecological Pathology, Department of Gynecology and Pathology, Jewish General Hospital and PhD Student Mc Gill University, Montréal, Québec

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- Stagiaire, Unité des papillomavirus, Institut Pasteur, Paris

*BOURSES***07/1985-06/1986**

- Echange France-Québec, Ministère de La Santé, Paris

**07/1986-06/1988**

- Bourse d'étude, Société pour la Recherche contre le Cancer Montréal, Québec
- Meilleure présentation par un résident, Congrès annuel de l'association des Pathologistes du Québec, 13 octobre 1986



**SOCIETES****1987**

- International Society of Gynecological Pathology
- Club de Recherches cliniques du Québec

**1989**

- Société Française de Cytologie Clinique
- Société Française de Colposcopie et de Pathologie Cervico-Vaginale
- Société Française de Gynécologie

**1990**

- Conseil de Direction de la Société Française de Colposcopie et de Pathologie Cervico-Vaginale
- Membre du Jury de la Conférence de consensus sur le dépistage du cancer du col utérin Fédération des Gynécologues et Obstétriciens, XXXIII Congrès de la langue française Lille

**1991**

- International Academy of Cytology
- Comité d'organisation du projet CANOGEN du groupe PETRI
- Expert de la conférence de consensus morphologique sur les néoplasies du col utérin Paris-Tolbiac

**1992**

- Comité de Rédaction de Reproduction Humaine et Hormones
- Groupe d'Etude de l'Endométriose
- Evaluator in Cervicography validated by the European Society For Oncological Research
- Société Française d'Anatomie Normale et Pathologique
- Conseil scientifique de la Société Française de Cytologie Clinique

**1993**

- Comité Editorial de Références en Gynécologie et Obstétrique
- Secrétaire Adjointe du Bureau du Centre de Regroupement Informatique et Statistique d'Anatomie Pathologique en Ile de France (CRISAP-IDF)
- Membership of the International Society for the Study of Vulvar Disease
- International Gynecologic Cancer Society

**1994**

- Groupe de travail sur la Pratique de frottis cervicaux pour le dépistage du cancer du col Agence Nationale pour le Développement de l'Évaluation Médicale (ANDEM)
- Groupe de travail sur l'Assurance de qualité en anatomocytopathologie Cancer du col Haut Comité de la Santé Publique

**1995**

- Editorial Board of the International Journal of Gynecological Pathology

**1996**

- Groupe de travail sur les recommandations pour la pratique clinique Conduite à tenir devant un frottis anormal du col de l'utérus Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES)

**1998**

- Conseil d'Administration de la Société Française de Cytologie Clinique

**1999**

- Conseil d'Administration de l'Association Française d'Assurance de Qualité en Anatomie et Cytologie Pathologiques (AFAQAP)
- Editorial Board of the European Menopause Journal
- Editorial Board of Maturitas

**2000**

- Comité Scientifique de Gynécologie Obstétrique Fertilité
- Comité Scientifique d'Abstract Gynécologie
- Member of Scientific Advisory Committee (SAC) of the International Federation Cervical Pathology and Colposcopy (IFCPC)

**2001**

- Secrétaire du Bureau du Centre de Regroupement Informatique et Statistique d'Anatomie Pathologique en Ile de France (CRISAP-IDF)
- Membre du Comité de suivi et de pilotage du Schéma Régional d'Organisation Sanitaire (SROS) d'Ile de France
- Member of the HPV triage Group, Bethesda System Workshop, National Cancer Institute Bethesda (April 30 - May 2)
- ASCCP Consensus Conference on the Management of cytological abnormalities and cervical cancer precursors Representative of the IFCPC National Cancer Institute Bethesda (September 6-9)
- Member at large of the International Society of Gynecological Pathology
- Membre du Comité Technique Régional de dépistage des cancers Direction Régionale des Affaires Sanitaires et Sociales (DRASS) de la région Ile de France

**2002**

- Secrétaire adjointe de la Société Française de Colposcopie et de Pathologie Cervico-Vaginale
- Secrétaire adjointe de la Société Française de Cytologie Clinique
- Member of the Laboratory Guidelines Committee of the International Academy of Cytology
- Member of the General Policy and Long Range Planning Committee for the tenure 2002-2004 of the International Academy of Cytology
- Editorial Board of the Journal of Lower Genital Tract Disease
- Member at large of the American Society for Colposcopy and Cervical Pathology (ASCCP)
- Organizing Committee of HPV Clinical Workshop and 20<sup>th</sup> International Papillomavirus Conference HPV 2002 (Paris, October 4-9)

***PARTICIPATION A L'ENSEIGNEMENT***

- Directeur de l'Institut de Brux Association d'Enseignement et de Recherche en histo et cyto-pathologie
- Cours d'initiation et de perfectionnement de la Société Française de Colposcopie et de Pathologie Cervico-Vaginale Antennes de Paris et de province
- Forum multidisciplinaire sur les infections génitales à papilloma virus Société Française de Colposcopie et de Pathologie Cervico-Vaginale
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- Diplôme Universitaire sur les Infections à Papillomavirus Humains Université de Paris XII, Faculté de Médecine de Créteil
- Diplôme Interuniversitaire de Colposcopie et de Pathologie Cervico-Vaginale Universités Lille, Amiens, Reims
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- Organon, 5340 BH OSS, The Netherlands
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## PUBLICATIONS

## Revue Internationale

- 1 **Bergeron C**, Naghashfar Z, Cnaan C, Shah K, Fu Y, Ferenczy A. Human papillomavirus type 16 in intraepithelial neoplasia (bowenoid papulosis) and coexistent invasive carcinoma of the vulva *Int J Gynecol Pathol* 6: 1-11, 1987
- 2 **Bergeron C**, Ferenczy A, Shah KV, Naghashfar Z. Multicentric human papillomavirus infections of the female genital tract. Correlation of viral types with abnormal mitotic figures, colposcopic presentation and location *Obstet Gynecol* 69: 736-742, 1987
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- 5 **Bergeron C**, Ferenczy A, Toft DO, Schneider W, Shyamala G. Immunocytochemical study of progesterone receptors in the human endometrium during the menstrual cycle *Lab Invest* 59: 862-69, 1988
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- 9 Shatz P, **Bergeron C**, Ferenczy A. The anatomy of the vulvar skin with emphasis on the piloselaceous unit and subcutaneous fat *J Gynecol Surg* 5: 183-191, 1989
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- 11 Ferenczy A, **Bergeron C**, Richart RM. Human papillomavirus DNA in fomites on objects used for the management of patients with genital human papillomavirus infections *Obstet Gynecol* 74: 950-4, 1989
- 12 Ferenczy A, **Bergeron C**, Richart RM. Human papillomavirus DNA in CO<sub>2</sub> laser-generated plume of smoke and its consequences to the surgeon *Obstet Gynecol* 75: 114-8, 1990
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- 35 Six C, Heard I, **Bergeron C**, Orth G, Poveda JD, Zagury P et al. Running head: impact of HIV infection on cervical SIL. Comparative prevalence, incidence and short-term prognosis of cervical squamous intraepithelial lesions (SIL) amongst HIV-positive and HIV-negative women. *AIDS* 12 : 1047-56, 1998
- 36 La Ruche G, Leroy V, Mensah-Ado I, Ramon R, You B, **Bergeron C**, Mothebesoane-Anoh S, Touré-Coulibaly K, Dabis F, for the DYSCER-CI Group. Short-term follow up of cervical squamous intraepithelial lesions associated with HIV and human papillomavirus infections in Africa. *Int J STD AIDS* 10 : 363-8, 1999
- 37 La Ruche G, Mensah-Ado I, **Bergeron C**, Welffens-Ekra C, Dabis F for the DYSCER CI Group. Cervical Screening in Africa: discordant diagnosis in a double independent reading. *J Clin Epidemiol* 52 (10) : 953-8, 1999

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- 39 Guarch R, Nogales F, **Bergeron C**, Puras A. Menopausia y tratamiento hormonal sustitutivo: biopsia endometrial. *Rev Esp Patol* 32 (1) 41-7, 1999
- 40 **Bergeron C**, Jeannel D, Poveda JD, Cassonnet P, Orth G. Human papillomavirus testing in women with minor grade cytologic atypia. *Obstet Gynecol* 95 (6) 821-827, 2000
- 41 Mutter GL and the Endometrial Collaborative Group. Endometrial intraepithelial neoplasia (EIN): will it bring order to chaos? *Gynecol Oncol* 76, 287-290, 2000
- 42 **Bergeron C**, Masseroli M, Ghesi A, Lemarié A, Mango L, Koss L. Quality control of cervical cytology in high risk women: the PAPNET system compared with manual rescreening. *Acta Cytol* 44, 151-7, 2000
- 43 Mattsson LA, Christiansen C, Colau JC, Palacios S, Kenemans P, **Bergeron C**, Chevallier O, von Holst T, Gangar K. Clinical equivalence of intranasal and oral 17  $\beta$ -estradiol for postmenopausal symptoms. *Am J Obstet Gynecol* 182(3) 545-51, 2000
- 44 **Bergeron C**, Fox H. Low incidence of endometrial hyperplasia with acceptable bleeding patterns in women taking sequential hormone replacement therapy with dydrogesterone. *Gynecol Endocrinol* 14 275-281, 2000
- 45 **Bergeron C**. Morphological changes and protein secretion induced by progesterone in the endometrium during the luteal phase in preparation for nidation. *Hum Reprod* (15, suppl) 119-128, 2000
- 46 Delmas MC, Larsen C, van Benthem BV, Hamers F, **Bergeron C**, Poveda JD, Anzen B, van den Hoek JA, Meier F, Pena JM, Savonius H, Sperandio D, Suligoi B, Vernazza P, Brunet JB, de Vincenzi I, for the European Study Group on Natural History of HIV infection in Women. Cervical squamous intraepithelial lesions in HIV-infected women: prevalence, incidence and regression. *AIDS* 14 (12), 1775-84, 2000
- 47 Gompel A, **Bergeron C**, Jondet M, Dhont M, van der Mooren MJ, Toth KS, Panay N, von Holst T. Endometrial safety and tolerability of AERODIOL (intranasal estradiol) for 1 year. *Maturitas* 36, 209-215, 2000
- 48 **Bergeron C**. Problems of endometrial histology interpretation. *Climacteric* 3, 288-293, 2000
- 49 Monsonago J, Autillo-Touati A, **Bergeron C**, Dachez R, Liaras J, Saurel J, Zerat L, Mottot C, Chatelain P. Liquid-based cytology for primary cervical cancer screening: a multicentric study. *BMJ* 323, 360-66, 2001

- 50 **Bergeron C**, Ferenczy A. Endometrial safety of continuous combined hormone replacement therapy with 17 $\beta$ -oestradiol (1 or 2mg) and dydrogesterone. *Maturitas* 37,191-199,2001
- 51 **Bergeron C**, Bishop J, Cas F, Ayivi J, Huynh B, Barrasso R. Accuracy of Thin Layer Cytology in Patients Undergoing Cervical Cone Biopsy. *Acta Cytol* 45, 519-524, 2001
- 52 Lecce G, Meduri G, Ancelin M, **Bergeron C**, Perrot-Applanat M. Presence of estrogen receptor beta in the human endometrium through the cycle - expression in glandular, stromal, and vascular cells. *J Clin Endocrinol Metab* 86,1379-86, 2001
- 53 **Bergeron C**. ASCUS and AGUS. 14<sup>TH</sup> International Congress of Cytology. *Acta Cytol* 46,92, 2002
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- 1 **Bergeron C**, Balaton A, Baviera E. Les filaments intermédiaires et l'intérêt de leur détection immunohistochimique dans le diagnostic anatomopathologique. *L'Union Médicale du Canada* 115: 636-40, 1986
- 2 **Bergeron C**, Ferenczy A. Screening devices for cervical and endometrial carcinoma. *Contemp Ob/Gyn* 28: 55-66, 1986
- 3 **Bergeron C**. Bowenoid papulosis and vulvar intraepithelial neoplasia: two terms for the same disease. *Contemp Ob/Gyn Canada* 4 (2): 5-11, 1987
- 4 **Bergeron C**. Bowenoid papulosis is intraepithelial neoplasia. *Contemp Ob/Gyn Canada Technology* 27-33, 1987
- 5 **Bergeron C**. Molecular technology for improved HPV detection. *Contemp Ob/Gyn Canada Technology* 22-31, 1987
- 6 **Bergeron C**, Ferenczy A. Les infections à papillomavirus humains de l'appareil génital féminin. *Rev Prat* 37: 107-14, 1987
- 7 Litton M A, **Bergeron C**. Un lymphome primitif du pénis. *J d'Urologie* 93: 99-101, 1987
- 8 Ferenczy A, **Bergeron C**. Le rôle de la cryocoagulation dans le traitement des néoplasies intraépithéliales cervicales. *Gynécol* 38 (6): 391-396, 1987
- 9 **Bergeron C**, Ferenczy A, Shak K. Search for human papillomaviruses in normal hyperplastic and neoplastic endometria. *Obstet Gynecol* 72: 383-387, 1988
- 10 **Bergeron C**, Ferenczy A, Toft D O, Shyamala G. Immunocytochemical study of progesterone receptors in hyperplastic and neoplastic endometrial tissues. *Cancer Res* 48: 6132-6136, 1988
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