Sound bites. . . .

NEW COAGULATION INSTRUMENTS
The laboratories are changing coagulation instrumentation at the metro hospitals, Red Wing, and Northland. Correlations will be completed in February with an anticipated live date of mid to late March. Reference and therapeutic ranges will be revised accordingly. Once implemented, all sites will be able to provide STAT and routine D-Dimer testing.

HEMOGRAM TO BECOME CBC WITH PLATELETS!
Effective Apr. 1, Blood Count Complete (CBC, formerly hemogram) will include a platelet in addition to hemoglobin, hematocrit, white blood count, and red blood count. Tests may be ordered individually, as a CBC, or as a CBC with leukocyte differential.

The AMA's CPT coding manual for 2003 eliminated all hemogram codes without a platelet count. This was a result of the negotiated rulemaking process, which resulted in 23 national medical necessity policies. Former policies had much stricter payment rules if a platelet count was ordered.

PROPOSED LMRP FOR PHENYTOIN AND FREE PHENYTOIN
The currently proposed Local Medical Review Policy (LMRP) for phenytoin and free phenytoin testing is open for comment to Noridian before March 5. The policy suggests that phenytoin monitoring is indicated if:

1. the drug is initiated or dosage has changed
2. there is absence of therapeutic response
3. toxic symptoms occur
4. there are suspected drug interactions.

Note: The measurement of the free fraction is generally not cost-effective on a routine outpatient basis, but may be clinically relevant in unusual clinical situations that can be associated with alterations in the binding of phenytoin to plasma proteins-in uremia, hepatic disease, late pregnancy or postpartum, cases of head injury associated with a hypermetabolic state and certain instances of polypharmacy. Free levels may occasionally be helpful in overdose situations where active removal of drug is contemplated, because only the free portion is cleared by dialysis.

Monitoring of free phenytoin should generally be reserved for patients in whom:

1. there is inadequate seizure or arrhythmia control to presumed therapeutic doses
2. there are symptoms or signs of toxicity
3. dosage or brand has been changed
4. drug interaction is suspected
5. hepatic or renal function has changed
6. monitoring is required during and for two to four weeks after pregnancy.

Otherwise, routine testing is not medically necessary more than every six months.

Lab Focus

February 2003– *periodic insert to* 'Scope *from Fairview Clinical Laboratories*

Highlights of the Bethesda 2001 System for Pap Test Terminology

The implementation of a new computer system on Dec. 3, 2002, allowed us to convert to the Bethesda 2001 System, the most current Pap test diagnostic terminology. This terminology was adopted by an NCI-sponsored consensus meeting held in May 2001 in Bethesda and was followed in Sept. 2001 by the elaboration of specific treatment guidelines by the American Society for Colposcopy and Cervical Pathology (ASCCP). The full text of the Bethesda 2001 system (bethesda2001.cancer.gov) was published in JAMA and is available online at http://jama.ama-assn.org/issues/v287n16/fpdf/jst10014.pdf and http://jama.ama-assn.org/issues/ v287n16/fpdf/jst10013.pdf as are the ASCCP patient management guidelines. Significant changes brought about by Bethesda 2001 are highlighted below.

Pap Test Terminology for Specimen Adequacy:

Bethesda 2001	Previous	Changes
Satisfactory for evaluation. (Factors that may limit evaluation such as absence of endocervical or transformation zone component and potential obscuring factors will be listed below this comment)	Satisfactory for evaluation.	• "Satisfactory for evaluation" and "Satisfactory for evaluation, but limited by" have been merged into the "Satisfactory for evaluation" category. The quality indicators are now listed under the satisfactory statement. These indicators include presence or absence of endocervical cells, poor fixation or preservation, obscuring blood or inflammation. • Bethesda 2001 has also de-emphasized the importance of endocervical cells for specimen adequacy.
	Satisfactory for evaluation. but limited by:_____	
Unsatisfactory for evaluation, specimen rejected (broken slide, no patient identifiers)	Unsatisfactory for evaluation	The "Unsatisfactory for evaluation" category was broken down to those that are considered unsatisfactory even before they are accessioned and those that were determined to be unsatisfactory only after processing and screening had been performed.
Unsatisfactory for evaluation, specimen processed and evaluated, but unsatisfactory for evaluation of epithelial cell abnormality because of …(Insufficient squamous cells present, completely obscuring blood or inflammation, poor preservation)		

Pap Test Terminology for Cytologic Interpretation:

Bethesda 2001	Previous	Changes
Negative for Intraepithelial Lesion or Malignancy (Descriptors for benign cellular changes are listed under a heading of "Other non-neoplastic findings" used for inflammatory and reactive changes, and "Organisms" used to list infectious agents such as Trichomonas, Candida, and Herpes simplex changes.)	Within Normal Limits	One of the biggest changes in Bethesda 2001 is the grouping of "Within normal limits" and "Benign cellular changes" into one category "*Negative for Intraepithelial Lesion or Malignancy*". Ninety percent of pap tests will fall into this category.
	Benign Cellular Changes	

Pap Test Terminology for Cytologic Interpretation continued:

Bethesda 2001	Previous	Changes
Epithelial cell abnormality: Squamous cell	Epithelial cell abnormality: Squamous cell	

• Atypical squamous cells-of undetermined significance (ASC-US) ("favor reactive" and "favor dysplasia" are not recommended for use)
• Atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion
	• Atypical squamous cells of undetermined significance (ASCUS)
	  • favor reactive
	  • favor dysplasia
		1. It is recommended that tests previously diagnosed as ASCUS-favor reactive to be judiciously reclassified as "Negative for Intraepithelial Lesion or Malignancy"
		2. The remaining cases are placed into two categories:
		  • "Atypical Squamous cells - of undetermined significance" (ASC-US) to include changes *not thought to be reactive*, that are suggestive of a squamous intraepithelial lesion, but lack the criteria to diagnose "Low grade squamous intraepithelial lesion." The vast majority of cases previously diagnosed as ASCUS will fall into this category that should make up 90 to 95 percent of "Atypical Squamous Cells" diagnoses.
		  • The second category, "Atypical squamous cells - cannot exclude a high-grade squamous intraepithelial lesion" (ASC-H) includes cytologic changes that are suggestive of a high-grade squamous intraepithelial lesion, but lack criteria for definitive interpretation.

• Low-grade squamous intraepithelial lesion (LSIL) encompassing: HPV/ mild dysplasia/ CIN 1 (specific descriptors are discouraged)	• Low grade squamous intraepithelial lesion (with specific descriptor)	The categories of low grade and high grade squamous intraepithelial lesion are modified to be inclusive of the specific lesions they describe, but are not broken down into specific diagnosis of mild dysplasia, HPV, moderate dysplasia, severe dysplasia or CIS. See reasoning/ recommendations at: www.bethesda2001.cancer.gov. Click on "post workshop recommendations" and download the recommendations or call the Cytology Laboratory at 612-273-5920.
• High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, carcinoma In Situ/ CIN2 and CIN 3 (specific descriptors are discouraged) • High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, carcinoma In Situ/ CIN2 and CIN 3 • with features suspicious for invasion. (specific descriptors are discouraged)	• High grade squamous intraepithelial lesion (with specific descriptor)	
• Squamous cell carcinoma	• Squamous cell carcinoma	
Other: Negative for Intraepithelial Lesion or Malignancy, See Interpretation/Result	Epithelial cell abnormality: Glandular cell	Bethesda 2001 changes the way we view endometrial cells in patients over 40 years. A new diagnostic category, "Other: see interpretation/ result" was created. We modified that statement to read "Other, negative for intraepithelial lesion or malignancy, see interpretation/result." This category will be used when the specimen is otherwise normal.
• Endometrial cells present • Endometrial cells after age 40, particularly out of phase or after menopause, may be associated with benign endometrium, hormonal alterations, and less commonly, endometrial abnormalities	• Endometrial cells, cytologically benign, in a postmenopausal woman	A secondary result is added to note: • "Endometrial cells present." An educational statement recommended by Bethesda 2001 is also added in this situation. • "Endometrial cells after age 40, particularly out of phase or after menopause, may be associated with benign endometrium, hormonal alterations, and less commonly, endometrial abnormalities." (This wording would also be used as a secondary diagnosis with primary interpretations that indicate epithelial cell abnormalities.)
Epithelial cell abnormality: Glandular cell		

• Atypical-endocervical cells
• Atypical- endometrial cells
• Atypical-glandular cells (NOS)
  • favor neoplastic (may be used when convinced of serious lesion)
• Endocervical adenocarcinoma in situ
	• Atypical glandular cells of undetermined significance
	  • endocervical, favor reactive
	  • endocervical, favor neoplastic or adenocarcinoma in situ
	• Atypical glandular cells of undetermined significance
	  • favor endometrial adenocarcinoma
		In the former AGUS category, now called "Atypical glandular cells" to prevent potential confusion with ASC-US, the category is expanded to allow more descriptive diagnoses and to specify (if possible) if the cells are of endocervical or of endometrial origin.
		
		Adenocarcinoma in situ (AIS) has been recognized as a separate category

• Adenocarcinoma-endocervical • Adenocarcinoma-endometrial • Adenocarcinoma-extrauterine • Adenocarcinoma-NOS	Adenocarcinoma • Endocervical • Endometrial • Extrauterine	Adenocarcinoma in situ (AIS) has been recognized as a separate category.

Limitations: The Pap test is a screening test designed to detect squamous cell carcinoma of the cervix and its precursors. While the Pap test was designed for squamous lesions of the cervix, it may also detect glandular lesions of the cervix. It is, however, inaccurate for the detection of endometrial lesions and should not be used as a primary screening tool to evaluate women with suspected endometrial abnormalities. As a screening test, it has about 5 to 10 percent false-negative results. This rate appears to be reduced, but not eliminated, by liquid based ("thin-layer") Pap tests. Therefore, remind your patient to consult you immediately if she experiences any suspicious signs or symptoms, regardless of her Pap test result.

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