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**Issue  
46**

# Insight

A Continuing Education Publication for the  
Physician Office Laboratory

**2006-B**

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**Provider Performed  
Microscopy**

**Basics of Quality  
Assessment — Part II**

**Megaloblastic Anemias**

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### 2006-B CME Answers

1.	A	13.	B	25.	B
2.	D	14.	A	26.	D
3.	B	15.	B	27.	C
4.	A	16.	D	28.	B
5.	D	17.	B	29.	A
6.	A	18.	A	30.	A
7.	D	19.	D	31.	D
8.	A	20.	A	32.	C
9.	D	21.	C	33.	A
10.	A	22.	A	34.	D
11.	C	23.	D	35.	B
12.	A	24.	D		

## CME Learning Objectives

Following completion of the self-instructional material, the participant will be able to:

1. Identify the appropriate use and significance of provider performed microscopic exams and apply Quality Assurance principles to each phase of PPM testing.
2. Explain the fundamentals of a quality system essential (QSE), describe at least two quality system indicators and how they might be utilized, and outline the phases of QMS implementation.
3. Discuss the causes, clinical presentation, diagnostic tests, and treatment of megaloblastic anemia.

To earn the CME, answer the questions included with this issue of the *Insight*, using the form included, or submit the test online at [www.aafp.org/pt](http://www.aafp.org/pt) –  click on Continuing Medical Education

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### P.A.C.E.<sup>®</sup> Due Dates and Course Codes

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Event 2006-A .....	February 28, 2007 .....	254-001-06
Event 2006-B .....	May 31, 2007 .....	254-002-06

## Looking into the ‘Scope: Provider Performed Microscopy

By Mina Hawkins, MBA, MT(ASCP)  
COLA Accreditation Manager

Provider-Performed Microscopy (PPM), as a CLIA laboratory category, is moderately complex testing that is performed by a clinical practitioner during or immediately subsequent to the examination of a patient. Training and experience varies widely on these procedures, but they can be mastered by the application of standardized laboratory practices. These practices need to cover the pre-analytical, analytical, and post-analytical phases of the testing process.

The keys to good microscopy testing are to recognize the critical components in the proper use of an adequate microscope, to increase the reliability of the results through correct specimen collection and handling, and to understand what can and can not be reliably determined through the performance of these microscopic tests.

The importance of microscopy testing is evident in its immediate impact on patient care decisions. It is low tech but extremely important in guiding follow up testing and reducing defensive testing. What other clinical scenario can reduce healthcare costs more than a rapid diagnosis?

Laboratories with waived and PPM certificates, the largest category of licensed laboratory practitioners, are undergoing increased regulatory scrutiny, even though they are generally exempt from inspection. Of course, these tests may also be performed by technical staff that has the qualifications for testing in a moderate complexity laboratory. But it is the less regulated setting that may allow less time and attention to good laboratory practice. A survey by CMS of waived and PPM laboratories identified problems with microscope and centrifuge maintenance. The questions to answer are “Are the results reliable?” and “How do you know?” The interventions proposed by CMS

included a focus on education, helping providers to better understand how to perform the tests properly, development of self-assessment tools, and guidance for practitioners to the same information available to the rest of the lab community.

The last note to bring forward on the regulatory side is that this category of testing was driven by the lability (rapid deterioration) of the specimens. It was recognized that delay in performing the test would compromise the accuracy of the results and that control materials were not available to monitor the entire testing process. The best and only control is a well educated and trained practitioner. It is not the same category as waived testing where the premise was that the untrained user gets the same result as a trained user.

The PPM procedures and the most likely area of medicine where they will be utilized are found in Figure 1.

Figure 1

	Primary Care	OB/GYN	Surgical Specialties	Dermatology
Urine Sediment	X	X	X	
Direct Wet Mount	X	X		X
KOH Prep	X			X
Pinworm Exam	X			
Fern Test		X		
Post-coital Test		X		
Semen Analysis			X	
Nasal Granulocytes	X			
Fecal Leukocytes	X			

The three keys to quality PPM testing simply stated are:

- **A Good Specimen** – handled properly
- **A Good Microscope** – operated and maintained properly
- **A Good Practitioner** – trained and assessed properly

The utilization of these keys will reduce variation in the results produced. Let’s look at each area in the path of workflow to see how these keys fit into the processes that must be followed. The steps in laboratory workflow are pre-analytical processes, concerning the critical



aspects of specimen collection; analytic processes, completing the right steps at the right time; and post-analytic processes, comparing the actual results with the expected results.

In the pre-analytical phase, the provider must first make an ordering decision. What are the alternative tests that could be used? In the area of PPM, the ordering provider should clearly understand what can and can not be determined by these tests.

- **Urine Sediment Examinations** may identify the cause of symptomatic presentation or abnormal dipstick results
- **Direct Wet Mounts** may detect the presence of bacterial, fungal, or parasitic organisms
- **KOH Preps** may detect yeast and fungal elements
- **Pinworm Examinations** may detect parasitic infestation
- **Fern Tests** may indicate rupture of the amniotic sac
- **Post-coital Tests of Cervical Mucus** may identify a contributing cause of infertility
- **Qualitative Semen Analysis** may identify presence or absence of sperm
- **Nasal Smears** may indicate the cause of respiratory symptoms
- **Fecal Leukocyte Examinations** may indicate bacterial diarrhea

The additional considerations in the pre-analytical phase are patient preparation, specimen adequacy, specimen labeling, specimen containers, specimen handling, interfering substances, and the biohazards of body fluids.

In the analytic phase, the accuracy of PPM procedures cannot be confirmed with external quality controls, nor are there any internal equipment controls which will alert you if a step has not been performed in the right order. One must follow good laboratory practices which include checking for contamination of solutions, especially saline and KOH, following a written procedure, there are no manufacturers' instructions to follow, assuring specimen identification, and documenting results. A

number of references are available from which step by step procedures can be obtained.<sup>1,2</sup> Take the time to check that the specimen was labeled with proper patient identification. If a number of staff are sharing a microscope in a busy office, carrying an unlabeled specimen in your hand directly to the lab area for testing is "risky business" and a CLIA regulatory deficiency. Critical points in the PPM analytic phase of each of the tests are as follows:

- **Urine Sediment** – Mixing, re-suspension of sediment
- **Direct Wet Mounts** – Delay, saline contamination
- **KOH Preps** – Digestion of cellular elements, reagent contamination, lubricant
- **Pinworm Examinations** – Tape type, insufficient sampling
- **Fern Tests** – Sensitivity, interfering substances, heat
- **Post-coital Tests of Cervical Mucus** – Delay, collection timing in patient's midcycle ovulatory phase
- **Qualitative Semen Analysis** – Timing, contamination of containers or supplies
- **Nasal Smears** – Over-decolorizing, thick smears, artifacts
- **Fecal Leukocyte Examinations** – Delay, debris, contamination, specificity

While there are few quality control practices that can be applied to PPM procedures, consider having another practitioner look through the 'scope and confirm your results. You can document these observations as a quality control measure. Even better is a split sample process which begins with the original specimen (if there is sufficient quantity) and duplicates all the steps in the procedure. A comparison of split sample results is an appropriate quality control process as well as a competency assessment tool.

The single piece of equipment that is the obvious basis of these procedures is the microscope. The instructions for the proper focusing technique to achieve Köhler illumination should be mastered as a competency by all practitioners. This practice will provide the optimum



conditions to focus the image and adjust the microscope for bright, even light and good contrast.<sup>2</sup> Good maintenance of the microscope is an equally important practice. Frequency of the necessary care and cleaning is dependent on the number of providers and procedures performed on the microscope. Keeping the microscope free of dust and covered when not in use will go a long way in maintaining your 'scope in good condition for a long and useful life. Use only lens tissue and lens cleaner and clean the external optical surfaces only.

The last phase is the post-analytical phase. The focus at this stage should be on a consideration of the clinical relevance of the results and their correlation to symptoms. The risks are failure to document the findings, lack of communication to the appropriate provider, and drawing incorrect conclusions from the observations. There is an opportunity to apply quality assurance practices to the technical considerations of the post-analytic phase. An appropriate monitor could be checking results on a laboratory log with results on the patient's chart. It is important to realize the opportunity to learn from errors that may be uncovered by QA or QC activities and utilize training, self assessment tools, or technical resources as corrective actions. There is a higher risk of failing to maintain competency when a procedure is performed infrequently.

The procedures which are included in the Provider Performed Microscopy category have an immediate impact on patient care by providing a rapid diagnosis or ruling out a diagnosis. As a CLIA category, procedures requiring more complicated processing are not included. That requirement eliminates microscopic procedures such as white cell differentials and gram stains, which mandate a moderate complexity license. In many clinical situations the appropriate microscopic procedure can reduce the need for more extensive testing, but like any laboratory test, it must be performed accurately to provide good patient care.

#### Sources:

1. *The Physician Office Laboratory Microscopy Atlas*, Second Edition, AAFP, 2005.
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## Building a Quality System

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As indicated in Part I of this series, a "quality system" is defined as "all of the laboratory's policies, processes, procedures, and resources needed to achieve quality testing"<sup>1</sup> as specimens move along the path of workflow in a clinical laboratory. The phases of the testing process include pre-analytic, analytic, post-analytic, and general laboratory systems<sup>1,2</sup>. This article will discuss the specifics of developing quality system management (QSM) policies and procedures that comply with CLSI-recommended guidelines.<sup>3</sup>

Quality system essentials (QSE's) have been described as the foundation that support the flow of a specimen through the clinical laboratory<sup>4</sup>. In addition to policies and procedures that address each of the QSE's, a quality system will define thresholds for each QSE as well as describe processes which determine and monitor compliance with the thresholds. Periodic review of those thresholds should then be conducted. Quality system essentials not meeting threshold should then be assessed more closely and an appropriate corrective action implemented. At least one monitor per QSE should be included in the quality system. However, multiple monitors may also be used. Although it may be tempting to monitor "everything", this approach can become overwhelming. More is not always better. Complete assessment of a few, well-selected monitors is more effective than incomplete assessment of multiple monitors.

Organization is the first, and one of the most important quality system essentials. Active, visible involvement of all levels of management, especially executive management is critical for successful implementation and continued operation of an effective quality system. Those organizations most successful at effective quality systems management create and maintain a quality culture that is demonstrated by all employees. Incorporation of quality system essentials and related activi-

ties into routine business functions setting as well as monitoring standards for quality outcomes by senior management reinforces a quality systems-driven operation. Management and organizational involvement should be documented by active participation and appropriate signatures on key documents.

Personnel is the second QSE. The quality system management policies and procedures should include processes for the creation, periodic review, and storage of position-specific qualifications and descriptions. Processes for new employee orientation, training, competency assessment, and performance appraisal should be included. Suggested monitors include the percentage of staff with appropri-

Figure 1

Quality System Essential	Monitor
<b>Organization</b>	Documented participation in quality activities
<b>Personnel</b>	% of staff with appropriate licensure and/or certification % of staff with complete training and competency assessment documentation
<b>Equipment</b>	Instrument downtime (minutes) Number & frequency of service calls
<b>Purchasing &amp; Inventory</b>	Shipping costs as a percentage of total supply costs Supply costs as a percentage of revenue Shipping and/or supply order errors by vendor Repeat run rates
<b>Process Control</b>	Map (flowchart) of complicated laboratory processes Procedure manual review Quality control review
<b>Documents &amp; Records</b>	Record or document retrieval success rate
<b>Information Management</b>	Collection and reporting of HIPAA violations Reporting errors LIS downtime
<b>Occurrence Management</b>	<b>Pre-analytic:</b> data entry errors, ordering errors, specimen collection and transport, patient or specimen identification <b>Analytic:</b> testing errors, instrument or test system failures, QC errors <b>Post analytic:</b> reporting errors, transcription or instrument interface, charting errors, billing issues
<b>Assessments: Internal &amp; External</b>	<b>Internal:</b> TAT, QC failures, complaints productivity, profitability <b>External:</b> Proficiency testing results and review, inspection outcomes
<b>Process Improvement</b>	Root cause analysis of identified issues Document corrective action plans
<b>Service &amp; Satisfaction</b>	<b>Internal:</b> performance appraisal, employee satisfaction <b>External:</b> Customer satisfaction (patient/physician/clinic)
<b>Facilities &amp; Safety</b>	OSHA compliance Routine maintenance & housekeeping



ate licensure and/or certification and the percentage of staff with appropriate training and competency assessment documentation.

Equipment and equipment maintenance comprise the next QSE. An effective quality system consists of policies and procedures that address equipment selection and acquisition as well as daily operation and on-going preventative maintenance. Processes which address installation, calibration, method comparisons, troubleshooting, service requests, and daily operation should be incorporated. Quality indicators could include: periodic maintenance and record keeping, cleanliness, regular function checks, instrument downtime (minutes), number and frequency of service calls.

The purchasing and inventory QSE may be documented by including in the quality policy criteria that must be met by vendors as well as by defining processes for managing inventory. The latter may be comprised of ordering procedures, establishing and monitoring par levels, and setting shipping criteria (standard vs. overnight). Suggested monitors consist of calculating shipping costs as a percentage of total supply costs, supply costs as a percentage of total revenue, shipping and/or supply order errors by vendor, and repeat run rates as a way to assess reagents and test systems. Regular test cost analyses could also be included.

Process control is a quality system essential that comprises written procedures which communicate quality requirements and expectations. The goal is to ensure consistent performance throughout all phases of the testing process.<sup>5</sup> The most complicated processes should be mapped out prior to writing the procedures and policies. The generally accepted method for doing this is by flowcharting. Examples of mapped processes include the path of specimen collection to reporting, transport of specimens to the laboratory, and billing procedures. The mapping process is often helpful in the resolution of repeated specimen integrity issues, problems with delayed transport, poor collection rates, and the like. Another key component of this QSE is regular review and revision of the laboratory's procedure manuals by the staff as well as the laboratory director. Quality control record

review and corrective actions are included in this section. Suggested indicators involve: percentage of procedures with annual review, QC records and review, and documentation of mapping (flowcharts) used to resolve repeated process issues in the laboratory.

Both documents (written policies, blank forms) and records (completed worksheets, reports, instrument print outs) should be managed and archived. An effective document control system will include mechanisms to manage the creation and implementation of new procedures and documents, modifications to existing documents, defining and restricting access to original documents and records, and retrieval and retention. Billing records should be included in this QSE. Random attempts at record or document retrieval could be documented as a part of the quality monitoring process.

The purpose of the information management QSE is to monitor and control the flow of information through the clinical laboratory. This process starts at the requisition, comprises accessioning into the laboratory, the collection of data during the testing process, reporting, transmission of the information (verbal, written report, electronic transmission), and billing. This QSE also includes the management and protection of patient and employee private information as covered by HIPAA. All laboratories should have a HIPAA-compliant privacy policy in place. Collection and reporting of HIPAA violations, reporting errors, and documentation of LIS downtime are suggested monitors.

The objective of occurrence management is to capture and analyze information concerning systematic problems in the laboratory.<sup>5</sup> This QSE is closely related to the laboratory's risk management program. Occurrences are defined and then plotted and counted as they occur along the path of workflow. A tally sheet readily available in the laboratory is a good system for smaller volume physician office laboratories. Pre-analytic occurrences that could be monitored: data entry errors, ordering errors, specimen collection and transport problems, patient and/or specimen identification problems. Analytic issues could include: testing errors, instrument or test system



failures, quality control errors. Suggested post-analytic occurrences: reporting errors, including transcription or instrument interface problems, delivery or charting errors, and billing difficulties. Another constituent of this QSE is the laboratory's incident management policy. This policy is required to address any incident or occurrence that could have a significant negative impact on patient care, patient safety, or laboratory personnel safety.

Assessments, both internal and external are a key component of a quality system and they comprise the next QSE. The determination of key indicators can be used to effectively assess a laboratory's performance. Examples of internal assessments include: turn-around-time (TAT) – or the percentage of reported tests that meet published times, QC failures, and complaints – patient, physician, nursing staff, billing staff, laboratory personnel. All should be reported as the number and type per reporting period. Other suggestions include productivity (\$\$ labor/test, by test; labor \$\$ as a percentage of total revenue, #tests/FTE, \$\$ revenue/FTE) and profitability. The latter may be calculated for the laboratory as a whole, by department, or by individual test. External assessments could include proficiency testing results and follow-up as well as inspection outcomes.

Effective management of quality systems requires not only the identification of problematic issues, but the resolution of those issues as well. Process improvement, the development and initiation of corrective actions to address issues identified as a result of monitoring activities is the next QSE.<sup>5</sup> This element is comprised of problem identification, prioritization of the problems, and then selection of the most critical issues to be solved.<sup>5</sup> The most effective process improvement activities include the analysis of the current processes (see the process control QSE) and data collection. A thorough root cause analysis which is documented and validated with data should be incorporated. Once the root cause has been identified, a corrective action plan with a defined resolution agreed upon by all affected parties should be implemented. It is critical in this stage to assign responsibility and accountability for each stage of the corrective

action plan. Continued monitoring post-implementation will ensure resolution. Inadequate resolutions should be modified as necessary.

Service and satisfaction are key pieces of any quality system. Both internal and external components should be evaluated. Internal determinations could include employee satisfaction surveys and information collected from employee comment boxes, exit interviews, and recording comments made during performance appraisals. External satisfaction monitors could include patient satisfaction with regards to phlebotomy and billing services. Physician and/or other provider satisfaction can be used to provide feedback about problems in the laboratory. Data collected during these processes can be used to effect change in key areas of the laboratory.

Facilities and safety make up the final QSE. These indicators are covered in the majority of OSHA and state safety regulations. Indicators are established and mandated for the laboratory. Also included are routine building maintenance and housekeeping contracts.

Once the laboratory's QSE's have been defined, the implementation of the quality system may begin. Incorporated into the initial phases of this stage are the following:<sup>5</sup>

- Establishment of management commitment
- Identification of the laboratory's path of workflow
- Development of quality manual
- Development of document and records system
- Analysis and validation of processes
- Development of standard operating procedures

Management commitment is best communicated by visible and active participation of all levels of the laboratory's staff and the utilization of a steering committee that includes representation of all stages in the path of workflow. The quality manual should be written to provide guidance regarding policies and



processes of the quality system, including a written policy for each QSE.

The remaining phases of implementation include:<sup>5</sup>

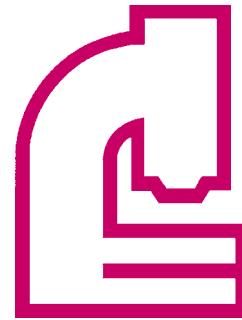
- Equipment management plan
- Training and competency assessment programs
- Purchasing and inventory program
- Occurrence management program
- Internal and external quality indicators and audit schedule
- Process improvement program
- Service and satisfaction program

Once implemented, the quality system will allow the laboratory to manage each aspect of the testing process as the sample flows through the laboratory. The important first step is to establish the quality indicators, set expected thresholds, and begin quality monitoring. Corrective actions should be implemented as acceptable thresholds are exceeded. Regular review of monitors, thresholds, and corrective actions by all levels of laboratory personnel will ensure that the quality system is dynamic and effective. If thresholds are continually met, then the monitors or the expected thresholds should be changed. It is important for the laboratory to start somewhere and then begin ratcheting down (or up) their individual quality monitor limits.

This systems approach to quality not only helps ensure accurate, timely clinical laboratory information, but if used appropriately can help the laboratory director and manager operate the laboratory in both a productive and profitable manner. This type of data-driven approach to laboratory management supports both quality testing and patient care. Quality expectations supported by quality indicators can be used to positively affect change in the clinical laboratory which ultimately will promote and sustain quality-driven healthcare.

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## Megaloblastic Anemia

By Michelle Parker, MT (ASCP)

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When a patient presents with generalized symptoms of anemia such as weakness, fatigue, and/or shortness of breath, one must consider all of the causes of anemia, not only iron deficiency. A complete blood count (CBC) including RBC indices, platelet count, differential, reticulocyte count, and microscopic examination of the peripheral blood smear should be ordered to give preliminary clues.

### ■ Case History

A 50 year old, alcoholic male presented with a sore throat, hoarseness, shortness of breath, weakness and fatigue. Laboratory results from his initial visit are shown in Table 1.

■ Pathogenesis of Megaloblastic Anemia

Impaired DNA synthesis is the basis of megaloblastic anemia; however it is important to note that all rapidly dividing cells are affected, not just hematopoietic cells. Thymidine nucleotides used for the synthesis of DNA are not produced in patients with megaloblastic anemia due to the lack of either vitamin B<sub>12</sub> or folic acid. When these essential elements are missing, DNA replication is defective and cell division is therefore impaired.

Inadequate intake is one cause for both vitamin B<sub>12</sub> and folate deficiencies. The only source of both of these vitamins is through diet. Alcoholics, elderly, and the homeless populations are at higher probability for being nutritionally deficient in these essential vitamins. Strict vegetarians (vegans) who do not eat milk products or eggs are at risk for vitamin B<sub>12</sub> deficiencies. Folate rich foods include green, leafy vegetables, oranges, dried beans, and meat. Folic acid is heat labile so it is important not to overcook these foods. Increased need during pregnancy can also cause vitamin B<sub>12</sub> and folate deficiencies.

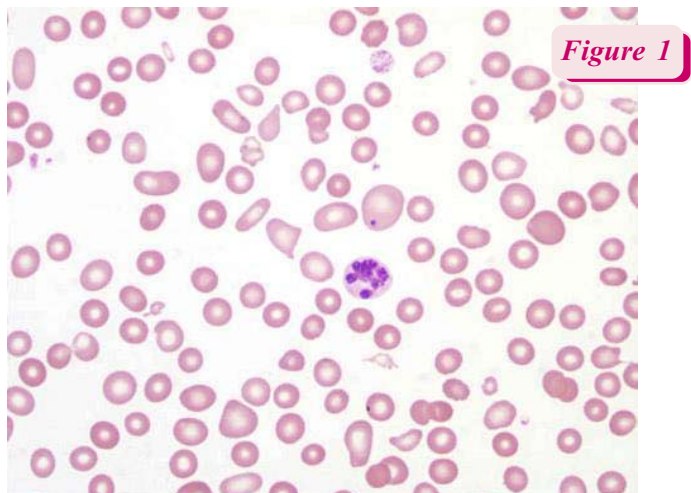


Figure 1

The peripheral blood smear noted moderate anisopoikilocytosis, occasional macrocytes, tear drops, and rare ovalocytes. Hypersegmented neutrophils were noted and platelets were decreased with giant forms seen. (Fig. 1)

The patient was admitted for hospitalization.

■ Diagnosis: Megaloblastic Anemia

The major hallmark of megaloblastic anemia is macrocytic red blood cells with an MCV of 100-150 fL. Other clues that can be seen from the peripheral blood smear are oval macrocytes, hyper-segmented neutrophils (5 neutrophils with 5 or more lobes or one with 6 lobes), nucleated red blood cells, and Howell-Jolly bodies. Patients with megaloblastic anemia also usually have decreased hemoglobin and hematocrit, leukopenia, thrombocytopenia, and an increased RDW. Due to the increase in cell death in the bone marrow and resultant increased catabolism of hemoglobin, there will also likely be an increase in total and indirect bilirubin as well as an increase in lactate dehydrogenase.

Table 1

Laboratory Test	Patient Result	Reference Range
Hemoglobin	4.4 g/dL ↓	14 - 18 g/dL
Hematocrit	13% ↓	40 -54%
RBC	2.31 x 10 <sup>12</sup> /L ↓	4.60 - 6.00 x 10 <sup>12</sup> /L
MCV	125 fL ↑	80 - 90 fL
MCHC	33.8 g/dL (N)	32 - 36 g/dL
RDW	19.3% ↑	11.5 - 14.5%
WBC	6.90 x 10 <sup>9</sup> /L (N)	4.5 - 11.5 x 10 <sup>9</sup> /L
Platelet Count	92.0 x 10 <sup>9</sup> /L ↓	150 - 450 x 10 <sup>9</sup> /L
Reticulocyte Count	0.3 ↓	0.5 - 1.5
Bilirubin (Total)	9.1 mg/dL ↑	0.3 - 1.2 mg/dL
Lactate Dehydrogenase	491 U/L ↑	100 - 190 U/L
Serum Folate	0.4 ng/mL ↓	2 - 10 ng/mL
Serum Vitamin B <sub>12</sub>	181 pg/mL ↓	200-850 pg/mL

Vitamin B<sub>12</sub> deficiency can also be caused from impaired absorption, usually due to the lack of intrinsic factor. Intrinsic factor is a glycoprotein that is produced by the gastric parietal cells and binds to vitamin B<sub>12</sub>. Vitamin B<sub>12</sub> is only



absorbed by the ileal mucosal cells when it is bound to intrinsic factor. The loss of functional intrinsic factor is known as pernicious anemia.

Impaired absorption of folate can be caused by sprue. Sprue is typically seen in the tropics and is caused by the overgrowth of enteric pathogens. Folate deficiency can also be caused by some drugs, such as antiepileptic drugs, or in patients who are on renal dialysis.

### ■ Clinical Presentation

Patients with vitamin B<sub>12</sub> deficiency will often present with mild to severe neurologic symptoms caused by the demyelination of the spinal cord and peripheral nerves. Impaired gait, numbness and tingling of fingers and toes, and memory loss are examples of the neurologic symptoms associated with a deficiency in vitamin B<sub>12</sub>. The delay in cell division affects the epithelium of the tongue (glossitis) and gastrointestinal tract (gastritis, nausea, constipation) as well.

Hyperhomocysteinemia, which leads to vascular occlusions and thrombosis, is strongly associated with folate deficiency. Neuropsychiatric complications due to folate deficiency are usually limited to mild changes in personality and irritability.

### ■ Other Studies

A bone marrow biopsy can be performed as a confirmatory test for megaloblastic anemia. The cells in the bone marrow will be unusually large and display nuclear-cytoplasmic asynchrony, that is the cytoplasm will mature normally, but the nucleus (with impaired DNA synthesis) will lag behind. Due to the invasiveness of a bone marrow examination, other tests are usually preferred.

For many years, the Schilling test was used to evaluate the ability of a patient's intestinal tract to absorb vitamin B<sub>12</sub>. In the first part of the Schilling test, a standardized, radio-labeled dose of vitamin B<sub>12</sub> is administered orally. A few hours later a flushing dose of unlabeled vitamin B<sub>12</sub> is given intramuscularly in order to bind all available storage sites. If intrinsic factor is present and normal absorption occurs, 7-

10% of the labeled vitamin B<sub>12</sub> will be excreted in the patient's urine over 24 hours. If there is malabsorption of vitamin B<sub>12</sub>, a decreased amount of the labeled dose will be excreted.

If malabsorption occurs, the patient should be given intrinsic factor and a second Schilling test should be performed. If the second test is corrected, the patient has pernicious anemia. If the test is not corrected when the patient is given intrinsic factor, other causes of malabsorption must be considered.

It is important to note that the Schilling test is dependent upon complete urine collection and normal renal function. The Schilling test should also be the last diagnostic test done because the flushing dose of vitamin B<sub>12</sub> will start to correct the blood picture.

Recently the Schilling test has been largely replaced by assays that detect antibodies to parietal cells. The antibodies that block intrinsic factor are detected using enzyme-linked immunosorbent assays (ELISAs). Serum from the patient is incubated with cells from the stomach of a mouse that contain parietal cells. If the antibody to parietal cells is present, a reaction will occur between the mouse cells and the serum. Ninety percent of patients with pernicious anemia will test positive for antibodies to parietal cells. Less than 2% of the general population has antibodies to parietal cells, however as age increases, so does this percentage. Up to 16% of patients over the age of 60 will test positive for antibodies to parietal cells.

### ■ Treatment

Once the correct vitamin deficiency has been determined, treatment can be administered. If the patient is lacking functional intrinsic factor, vitamin B<sub>12</sub> is administered intramuscularly. 1000mcg of cobalamin is given daily for two weeks then weekly until the patient's hematocrit returns to normal. After this point, the patient will need cobalamin shots monthly for life. Folate is administered orally and dosage varies between 1-5 mg. Typically the reticulocyte count will increase in about one week and hemoglobin will rise in three weeks.



## ■ Patient Resolution

The patient was released from the hospital after being given seven daily shots of 1000 mcg vitamin B<sub>12</sub>. The patient then returned twice weekly for two weeks to receive supplemental shots of vitamin B<sub>12</sub> followed by once a week shots for four weeks. The patient was also taking a folate supplement orally every day. The patient was also encouraged to stop drinking. The hematological picture for this patient drastically improved with these treatments.

Sources:

1. Best M. *Megaloblastic Anemias*. In Pittiglio DH, ed: Clinical Hematology and Fundamentals of Hemostasis, 2<sup>nd</sup> ed. Philadelphia: F A Davis, 1987: 58-72.
2. Doig K. *Anemias Caused by Defects of DNA Metabolism*. In Rodak BF, ed: Hematology Clinical Principles and Applications, 2<sup>nd</sup> ed. Philadelphia: W B Saunders, 2002: 227-239.
3. <http://www.nlm.nih.gov/medlineplus/ency/article/003351.htm>
4. <http://www.emedicine.com/med/topic1799.htm>
5. <http://www.emedicine.com/med/topic1420.htm>

## 📌 2006-B CME Questions . . . . .

The material necessary to review to answer the following questions may be found in this issue of the *P.O.L. Insight* and the *AAFP-PT Handbook* or on the AAFP-PT website (<http://www.aafp.org/pt> and click on Continuing Medical Education). The Test Sheet may be found on page 16 of the *P.O.L. Insight*. The Accreditation information may be found on the inside cover of this issue.

1. True or False: Provider performed microscopy can reduce healthcare costs by aiding in rapid diagnosis.
  - A. True
  - B. False
2. Provider performed microscopy procedures are commonly found in \_\_\_\_\_ practices.
  - A. Primary Care
  - B. OB/Gyn
  - C. Dermatology
  - D. All of the above
3. True or False: Delay in testing does not affect the results of PPM testing.
  - A. True
  - B. False
4. True or False: The best control for PPM testing is a well-education and trained practitioner.
  - A. True
  - B. False
5. Which of the following are keys to quality PPM testing:
  - A. A good specimen
  - B. A good microscope
  - C. A good practitioner
  - D. All of the above
6. True or False: Direct Wet Mounts may detect the presence of bacteria, fungi, or parasites.
  - A. True
  - B. False
7. True or False: Good laboratory practice in PPM testing include:
  - A. Checking reagents for contamination
  - B. Following written procedures
  - C. Assuring specimen identification
  - D. All of the above
8. True or False: A properly decolorized specimen is a critical element in examining nasal smears.
  - A. True
  - B. False



9. A quality check for PPM testing is:
  - A. Confirmation by another practitioner
  - B. Built-in controls
  - C. Split sample testing
  - D. A & C only
10. True or False: Bright, even light and good contrast provide optimal conditions for microscopic exams.
  - A. True
  - B. False
11. Which of the following should be used to clean microscope lenses?
  - A. Soapy water and a soft cloth
  - B. Cotton ball and alcohol
  - C. Lens cleaning solution and lens tissue
  - D. Autoclave
12. True or False: One or more monitors should be established for each Quality System Essential (QSE).
  - A. True
  - B. False
13. True or False: Using a lot of monitors is always more effective than just selecting a few.
  - A. True
  - B. False
14. True or False: The establishment of a "culture of quality" among all employees begins at the management level.
  - A. True
  - B. False
15. True or False: Competency assessment documentation is not an appropriate personnel monitor.
  - A. True
  - B. False
16. An effective quality system for equipment includes policies and procedures dealing with:
  - A. Equipment selection and acquisition
  - B. Daily operation
  - C. Preventive maintenance
  - D. All the above
17. A suggested quality indicator for equipment might be:
  - A. Sensitivity
  - B. Amount of downtime
  - C. Specificity
  - D. Cost of reagents
18. True or False: The goal of process control is to ensure consistent performance throughout all phases of the testing process.
  - A. True
  - B. False
19. The purpose of the information management QSE is to monitor and control the flow of information through the laboratory. This process includes:
  - A. Specimen requisition and accessioning
  - B. Data collection and reporting
  - C. Protection of HIPPA-regulated information
  - D. All of the above
20. True or False: Flowcharting is the generally accepted method for mapping out complicated processes.
  - A. True
  - B. False
21. Reporting errors, billing discrepancies, and incident reports are all components of:
  - A. Process Control
  - B. Information Management
  - C. Occurrence Management
  - D. None of the above
22. True or False: Process Improvement is the development and initiation of corrective actions to address issues identifies by monitoring activities.
  - A. True
  - B. False



23. The Service and Satisfaction QSE monitors the satisfaction level of:
- A. Lab employees
  - B. Patients
  - C. Physicians
  - D. All of the above
24. Implementation steps for QSE's include:
- A. Test selection
  - B. Development of a Quality Manual
  - C. Development of a documents and records system
  - D. "B" & "C"
25. The Quality System will remain dynamic and effective if:
- A. Monitors never change
  - B. Monitors undergo regular review and revision as indicated
  - C. Monitors identify problems, no further action is required
  - D. All of the above
26. Initial laboratory work up for suspected anemia should include:
- A. Complete CBC
  - B. Differential
  - C. Microscopic exam of peripheral blood smear
  - D. All of the above
27. Classic megaloblastic anemia specimens have macrocytic RBC with MCV values of:
- A. <50 fL
  - B. 80-90 fL
  - C. 100-150 fL
  - D. >200 fL
28. True or False: Hypersegmented neutrophils, nucleated RBCs and Howell-Jolly bodies are rarely associated with megaloblastic anemia.
- A. True
  - B. False
29. True or False: Patients with megaloblastic anemia frequently have elevated serum bilirubin and lactate dehydrogenase.
- A. True
  - B. False
30. True or False: Vitamin B<sub>12</sub> and folate are required for proper DNA replication and cell division.
- A. True
  - B. False
31. Vitamin B<sub>12</sub> and folate deficiencies are frequently noted in which population?
- A. Elderly
  - B. Alcoholics
  - C. Strict vegetarians
  - D. All of the above
32. \_\_\_\_\_ is a source of dietary folate.
- A. Tomatoes
  - B. Chocolate
  - C. Green, leafy vegetables
  - D. All of the above
33. True or False: Intrinsic factor is a glycoprotein that is produced by the gastric parietal cells and binds Vitamin B<sub>12</sub>.
- A. True
  - B. False
34. The Schilling test:
- A. Evaluates the ability of the patient's intestinal tract of absorb Vitamin B<sub>12</sub>
  - B. Is dependent upon complete urine collection and normal renal function
  - C. Has largely been replaced by new assays for anti-parietal cells antibodies.
  - D. All of the above
35. True or False: There is no effective treatment for megaloblastic anemia.
- A. True
  - B. False



# AAFP-PT CME Test Answer Sheet

**ALL INFORMATION MUST BE COMPLETED TO OBTAIN CREDIT**

**2006-B** (submit by May 31, 2007 to obtain credit)

**Fill in the circles for the correct answers:**

**Please print:**

**Individual AAFP #:** \_\_\_\_\_

*(All participants in the AAFP-PT are now assigned a 7-digit AAFP number; AAFP-member physicians should use their AAFP-ID number; non-member physicians and laboratory personnel are assigned an ID number the first time CME is submitted)*

**Lab AAFP #:** \_\_\_\_\_

*(All labs enrolled in AAFP-PT are assigned a 7-digit AAFP number. The Lab ID number may be found on the Order Confirmation and on evaluations.)*

\_\_\_\_\_  
Name (Last) (First) (Initial)

\_\_\_\_\_  
Street

\_\_\_\_\_  
City / State/ Zip Code

\_\_\_\_\_  
Fax Number

\_\_\_\_\_  
Email Address

Address, Fax, or Email change       Name change

**Select one if you are a physician:**

- FP                                       IM  
 PED                                       OB/GYN  
 Other

**Select one if you are laboratory personnel:**

- MT                       MLT                       Nurse Practitioner  
 RN                       LPN                       Physician Assistant  
 Med. Assist.                       Laboratory Manager  
 Laboratory Consultant    Other

**Evaluation:** please fill in bubble between 1 & 5 – 1 denotes poor, 5 denotes excellent:

1. To what extent were the objectives achieved?  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
2. To what extent did the AAFP-PT education program *content* relate to the program's objectives?  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
3. Rate your overall degree of satisfaction with this education program.  
*poor*      ①      ②      ③      ④      ⑤      *excellent*
4. In what general area of laboratory practice would you like to receive educational materials? (please mark all that apply).
  - CLIA and/or regulatory. requirements
  - Good laboratory practices
  - Test Procedures
  - Technical Subjects
  - Business/Financial Aspects
  - Other, please specify \_\_\_\_\_

	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>
1.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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