

Comment: A number of commenters requested that additional tests be added to PPM. Microscopic tests that were suggested include synovial fluid analysis, qualitative and quantitative semen analysis, nasal smears or sputum for eosinophils or basophils, wet mount examination of prostatic fluid or secretions, stools for leukocytes, scabies examinations, Gram stain, Tzanck preparations, white blood cell counts and leukocyte differentials, microscopic examinations of hair morphology, dark-field examinations and molluscum smears. A number of non-microscopic procedures were also requested, including microbiology cultures, serum glucose and BUN levels, qualitative drug screens, a variety of serologic tests, and miscellaneous tests performed using hand-held or elementary instrumentation.

Other organizations and professionals were opposed to adding tests or criteria to PPM. Two organizations suggested explicit language to limit procedures included in PPM to specific microscopic examinations and exclude any testing that involves automated instrumentation or biochemical reactions.

Response: Tests in PPM are limited to specific microscopic examinations that are moderately complex procedures and meet the criteria for PPM. Most of the tests named by commenters for addition to PPM do not meet these established criteria. However, nasal smear examinations for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility) do meet the criteria for inclusion in PPM. They are all moderate complexity microscopic examinations that are performed during the course of a patient examination. They are performed on labile specimens, require very limited specimen processing and handling, and controls are not available to monitor the entire testing process. Fecal leukocyte examinations and qualitative semen analyses are actually forms of wet mount examinations. The CLIAC recommended that these three examinations be included in PPM, and HHS agrees with CLIAC that these procedures meet the PPM criteria. The other examination that the CLIAC recommended be added to PPM, the wet mount examination of expressed prostatic secretions, is now included in PPM because it meets the clarified definition of wet mounts in § 493.19(c)(1). Tests that the CLIAC reviewed, and recommended not be included in PPM, are the Gram stain, quantitative semen analysis, histoderatology slides, white blood

cell (WBC) differential, and polarization of synovial fluid for crystals. These examinations do not meet the criteria for inclusion in the PPM subcategory. The quantitative semen analysis, histoderatology slides, and polarization of synovial fluid for crystals are all high complexity procedures. Although some Gram stains and WBC differentials are categorized as moderate complexity, these examinations do not meet the additional criteria required for inclusion in PPM. They are not performed on labile specimens, and quality control materials are readily available for Gram stains and WBC differentials. Both of these examinations are performed on specimen preparations that must be stained in order to differentiate and identify cellular elements. These staining procedures require multiple, critical steps. Therefore, HHS concurs with the CLIAC recommendations that these tests not be included in the PPM subcategory, and has not added these tests to the list of PPM examinations.

Comment: Several organizations requested that tests relevant to specific medical specialties, including pediatrics, internal medicine, family practice, rheumatology, and infectious disease, be added to PPM for physicians with appropriate training.

Response: The CLIAC considered a proposal by HHS to expand PPM to include additional medical specialty-specific microscopic examinations when performed by physicians with specialty training. The CLIAC recommended that PPM not be expanded to include medical specialty-specific procedures, due to the difficulty in establishing a mechanism to assure adequate training and competency in performing each of these specialized procedures. HHS agrees with this recommendation and we have not added medical specialty-specific procedures to PPM; however, physicians may continue to perform these procedures in accordance with the applicable requirements for the level of complexity in which the test is categorized.

Comment: One organization stated that, in order to contain costs, physicians should be able to perform essential laboratory tests in their offices without restrictions and recommended that a free-standing physician category be established with the range of tests performed in each laboratory based on the physician's specialty, training and experience. The organization indicated that there should be no specific test list; any testing other than cytopathology would be included in this category. Testing could be performed by the

physician, or by other personnel under the direction and control of the physician. Quality control and proficiency testing would be required, and laboratories would be subject to on-site inspections if it was suspected that they were not in compliance with the regulations.

Response: The CLIA regulations were developed in an effort to ensure the quality of laboratory services in every testing situation and assure that accurate and reliable testing is available to all patients. To do this, minimum requirements were established for laboratory testing that, in accordance with the law, depend on the complexity of the procedures being performed and are independent of the testing location. As test procedures become more complex, more stringent testing requirements are imposed. PPM contains a unique group of microscopic procedures that are routinely performed in the course of a patient examination. They are tests for which it is difficult to enforce regulatory requirements because biological controls that monitor the entire testing process are not readily available and because the inspection process would interfere with a patient examination. The PPM subcategory was established to exempt physicians (and, as discussed below, mid-level practitioners and dentists are now included) from the requirement for routine inspections if the PPM procedures are the only tests, in addition to waived tests, that they perform. Physicians, mid-level practitioners, and dentists are not prohibited from performing other laboratory procedures in their offices or clinics. However, for procedures that can be regulated through an inspection process, routine inspections are required, since this is one mechanism to assure that the quality of testing is maintained.

Changes to the Regulations

In this regulation, we have moved the PPM subcategory, formerly located at § 493.16, to a new § 493.19.

In the list of PPM procedures now located at § 493.19(c), we are changing the description of wet mounts at § 493.19 (c)(1) to clarify the types of examinations that are included in this procedure. Also, to the list of PPM procedures, we are adding three tests: nasal smears for granulocytes, fecal leukocyte examinations, and qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).