It is our belief that a negative group A streptococcal antigen detection test from throat swabs obtained from symptomatic patients should be confirmed by culture. This opinion is based on two facts: 1) the quality of results from these tests depend on obtaining proper and adequate throat swab specimens; and 2) a falsely negative test interpretation may result when specimens are obtained at the onset of the disease due to low antigen concentration below the test limits of detection.

The FDA's position is concordant with the standard of practice. It is the recommendation of the American Academy of Pediatrics and the American Heart Association that when a patient suspected of having group A streptococcal pharyngitis has a negative rapid streptococcal test, a culture should be obtained to ensure that the patient does not have group A streptococcal infection.

In our review of a labeling revision, we failed to notice that a statement regarding the need to confirm negative test results with culture, which was present in the cleared labeling, was missing from the labeling of the Strep A OIA test. The FDA is currently working with the device manufacturer to reinstate this missing limitation of the test and make the Strep A OIA test labeling consistent with the current standard of practice and the labeling of other group A streptococcal direct antigen tests.

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REFERENCES

ERRATA

In the September 1995 supplement to Pediatrics, titled Report of the Nationwide Multicenter Acellular Pertussis Trial, the article “Comparison of 13 Acellular Pertussis Vaccines: Overview and Serologic Response” (1995;96;548–557) contains errors. In Table 1 on page 549, the number in line 6 (SKB-2 vaccine), column 9 (Diphtheria Toxoid) should be 17, not 25, as printed. Similarly, in column 1 on page 550, line 22 should read “. . . .17 Lf of diphtheria toxoid,” not “. . . .25 Lf of diphtheria toxoid,” as printed.

Please note the following errors in the 1994 Red Book.

Page 32: In the third column of Table 1.6 (under “For Reporting”), the interval for reporting anaphylaxis should be changed to “7d.”

Page 144: Under the heading “Treatment,” line 11 should read: “sulfamethoxazole 50 mg/kg/d, maximum 2.4 g/d . . . .”

Page 298: Under the heading “Diagnostic Tests,” line 4 should read: “medium, are not commercially available, and growth . . . .”

Page 495: In Table 3.50, the maximum dosage for ofloxacin should read: “800 mg.”
Comparison of 13 Acellular Pertussis Vaccines: Overview and Serologic Response
Kathryn M. Edwards, Bruce D. Meade, Michael D. Decker, George F. Reed, Margaret B. Rennels, Mark C. Steinhoff, Edwin L. Anderson, Janet A. Englund, Michael E. Pichichero, Maria A. Deloria and Adamadia Deforest

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