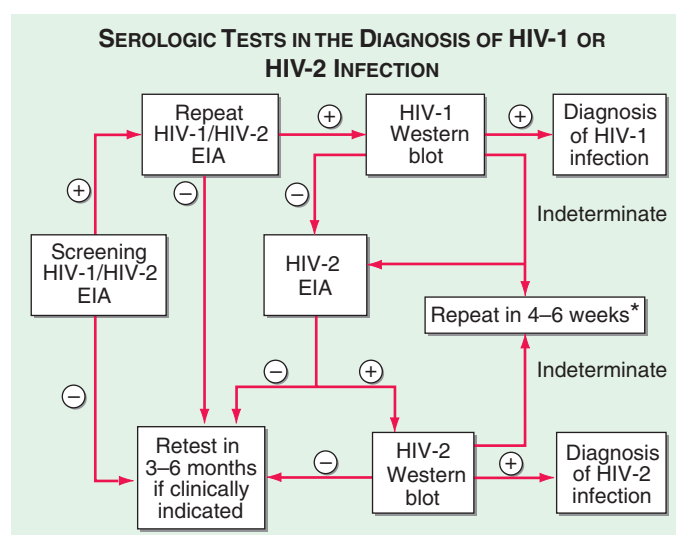


**FIGURE 226-29** Western blot assay for detection of antibodies to HIV. **A.** Schematic representation of how a Western blot is performed. **B.** Examples of patterns of Western blot reactivity. In each instance the Western blot strip contains antigens to HIV-1. The serum from the patient immunized to the HIV-1 envelope gp160 contains only antibodies to the HIV-1 envelope proteins. The serum from the patient with HIV-2 infection cross-reacts with both *reverse transcriptase* and *gag* gene products of HIV-1.

infection. If the Western blot is negative, the EIA can be assumed to have been a false positive for HIV-1 and the diagnosis of HIV-1 infection is ruled out. It would also be prudent at this point to perform specific serologic testing for HIV-2 following the same type of algorithm. If the Western blot for HIV-1 is indeterminate, it should be repeated in 4–6 weeks; in addition, one may proceed to a p24 antigen capture assay, HIV-1 RNA assay, or HIV-1 DNA PCR and specific serologic testing for HIV-2. If the p24 and HIV RNA assays are negative and

there is no progression in the Western blot, a diagnosis of HIV-1 is ruled out. If either the p24 or HIV-1 RNA assay is positive and/or the HIV-1 Western blot shows progression, a tentative diagnosis of HIV-1 infection can be made and later confirmed with a follow-up Western blot demonstrating a positive pattern. In addition to these standard laboratory-based assays for detecting antibodies to HIV, an series of point-of-care tests can provide results in 1–60 min. Among the most popular of these is the OraQuick Rapid HIV-1 antibody test that can be run on blood, plasma, or saliva. The sensitivity and specificity of this test is ~99% when run on whole blood. Specificity remains the same but sensitivity drops to 98% when the test is run on saliva. While negative results from this test are adequate to rule out a diagnosis of HIV infection, a positive finding should be considered preliminary and confirmed with standard serologic testing, as described above. Two rapid test kits are licensed for home use. They are the OraQuick In-Home HIV test and the Home Access HIV-1 test system.

A variety of laboratory tests are available for the direct detection of HIV or its components (Table 226-8). These tests may be of considerable help in making a diagnosis of HIV infection when the Western blot results are indeterminate. In addition, the tests detecting levels of HIV RNA can be used to determine prognosis and to assess the response to antiretroviral therapies. The simplest of the direct detection tests is the *p24 antigen capture assay*. This is an EIA-type assay in which the solid phase consists of antibodies to the p24 antigen of HIV. It detects the viral protein p24 in the blood of HIV-infected individuals where it exists either as free antigen or complexed to anti-p24 antibodies. Overall, ~30% of individuals with untreated HIV infection have detectable levels of free p24 antigen. This increases to ~50% when samples are treated with a weak acid to dissociate antigen-antibody complexes. Throughout the course of HIV infection, an equilibrium exists between p24 antigen and anti-p24 antibodies. During the first few weeks of infection, before an immune response develops, there is a brisk rise in p24 antigen levels (Fig. 226-27). After the development of anti-p24 antibodies, these levels decline. Late in the course of infection, when circulating levels of virus are high, p24 antigen levels



**FIGURE 226-30** Algorithm for the use of serologic tests in the diagnosis of HIV-1 or HIV-2 infection. \*Stable indeterminate Western blot 4–6 weeks later makes HIV infection unlikely. However, it should be repeated twice at 3-month intervals to rule out HIV infection. Alternatively, one may test for HIV-1 p24 antigen or HIV RNA. EIA, enzyme immunoassay.