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DIAGNOSIS OF HIV INFECTION INFORMATION SHEET

INTRODUCTION

HIV is a notifiable disease with responsibility for reporting to Health departments resting with the testing laboratories. As such, there are standardised definitions, terminology and diagnostic algorithms relating to HIV diagnosis.

DIAGNOSIS

A reactive antibody screening test result by ELISA does not mean that an individual has HIV infection. Because positive screening antibody tests may not represent true biological positives, the terms reactive and non-reactive are used rather than positive or negative.

Diagnosis of HIV infection requires repeated reactivity on two or more HIV antibody tests, both performed in duplicate, as well as a positive antibody status on a supplemental test, typically a Western blot, in which 4 or more reactive bands are detected. False-positive ELISA reactivity will generally have negative or atypical Western blot results (an exception is in infants born to HIV-infected mothers; the infants will have positive serology for 6 months or more reflecting passive transfer of maternal IgG). These false-positive results will initially be reported as indeterminate pending repeat testing.

A non-reactive antibody screening test result means that HIV-1-specific antibodies cannot be detected in the serum. In most subjects, HIV infection is excluded. Possible causes of a false negative ELISA reactivity include:

Primary/acute HIV infection: antibodies are not usually detectable for 2 to 4 weeks after infection. Primary HIV infection is diagnosed by recognition of an acute viral illness (present in 70%), together with detection of HIV-1 p24 antigen (can generally be detected 10 to 14 days after infection). The screening test for HIV-1 now also screens for HIV-1 p24, so this combined antigen-antibody test is much less likely to miss a patient with acute HIV infection than in years past. The majority of patients will exhibit antibody reactivity on ELISA and an incomplete western blot (0 to 3 bands);

Very advanced HIV infection: when antibody production is substantially impaired (although with assay improvement this is very rare); and

A very unusual strain of HIV-1, usually acquired from a source patient infected outside of Australia.

Molecular testing for HIV proviral DNA can also be used as a supplemental test for HIV diagnosis and is recommended if there is any uncertainty regarding the HIV status after routine screening, if acute HIV infection is suspected or if testing newborn infants of HIV

infected mothers who will carry maternal antibodies. The HIV-1 RNA tests can yield false positive result in healthy adults rarely and is not recommended (nor licensed) for HIV diagnosis.

INDICATIONS

There are numerous clinical settings in which HIV antibody testing should be considered. These include patients at high risk of HIV-infection by virtue of sexual behaviour or other exposures, subjects with symptoms suggesting acute HIV-infection, and subjects with unexplained diseases that might be HIV-related such as thrombocytopenia, dementia, unexplained weight loss, shingles or opportunistic infections.

FURTHER TESTS

Testing for HIV that yields indeterminate results should be followed by repeat tests. In general, a biological false positive result will be unchanged or non-reactive 2 to 4 weeks after the initial serum was collected. For a biological false positive result in a patient with suspected acute HIV infection another sample should be submitted as soon as possible for repeat serology, along with an EDTA blood sample for HIV proviral DNA.

Patients with a new diagnosis of HIV infection should have a:

- CD4+ lymphocyte count (T-cell subsets)
- HIV viral load (HIV RNA)
- HIV resistance genotype (to determine the sensitivity of the acquired HIV to antiretroviral drugs) and
- Serology for commonly associated co-infections such as viral hepatitis and sexually transmitted infections.