Rapid diagnostic tests are immuno-chromatographic, instrument-free assays developed to detect malaria antigen quickly

Rapid diagnostic tests are self-contained assays that use mono- or polyclonal antibodies to detect malaria antigens in blood by a colour change on a nitrocellulose strip. In nonendemic settings, these tests provide prompt laboratory diagnosis of malaria when expertise in microscopy is lacking. The results, whether positive or negative, must be confirmed by microscopy at a local reference centre. Polymerase chain reaction (PCR) may be used to confirm the presence of infection or identify the species when the microscopy results are equivocal, and it is available at some reference centres across Canada (Appendix 1, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.131794/-/DC1).

False-positive results of rapid diagnostic tests are rare but occur more commonly in nonendemic settings. Cross-reactivity has been documented in patients with circulating autoantibodies such as antinuclear antibody and rheumatoid factor and in those with infections such as dengue fever, hepatitis C, leishmaniasis, African trypanosomiasis, Chagas disease, schistosomiasis, tuberculosis and toxoplasmosis.

Rapid diagnostic tests are designed to detect Plasmodium falciparum

Rapid diagnostic tests are most useful for the prompt detection of malaria caused by P. falciparum, a species most likely to cause complications and death. Several rapid diagnostic tests are licensed in Canada and have different performance characteristics. Most have high sensitivity (≥99%) compared with PCR for P. falciparum when parasitemia levels are high (≥0.02% or ≥1000 parasites/µL). Their sensitivity is lower (≤75%) when parasitemia levels are 0.002% or less (≤100 parasites/µL). Interpreting a negative result in children under age five and pregnant women requires caution, because they are more likely to have low levels of parasitemia and are at greatest risk for severe disease.

False-positive reactions can occur

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References


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