Certainty of the evidence

Moderate

Diagnostic accuracy (sensitivity and specificity)
The test is considered to be very accurate, with a pooled sensitivity of 94.9% (95% CI 89.4, 97.6) and a pooled specificity of 96.2% (95% CI 93.5, 97.8). See Table “Summary sensitivity and sensitivity of the qualitative tests by threshold” under Evidence profiles/Research evidence.

As the summary estimates for sensitivity and specificity are clearly above the values stated in the target product profile (TPP) *[247]*, and as the lower boundaries of the confidence intervals are close to this limit for the sensitivity or above this limit for the specificity, the accuracy is considered to be very high.

Furthermore, given the low prevalence of individuals with G6PD activity below 30%, the absolute numbers of false negative test results will always be low to very low (<1% of all negatives).

Explanation
A sensitivity of 94.9% means that of all patients who are G6PD deficient (i.e. who have a G6PD activity of less than 30% of normal activity based on spectrophotometry), 94.9% will have a qualitative point-of-care test result indicating G6PD deficiency. The remaining 5.1% of the G6PD deficient patients will have a test result indicating that they are not deficient (false negative test result).

A specificity of 96.2% means that of all patients who have a G6PD activity above 30% (based on spectrophotometry), 96.2% will have a qualitative point-of-care test result indicating that they are NOT G6PD deficient. This does include patients with intermediate G6PD activity of whom the test indicates that they are not deficient. On the contrary, 3.8% of the patients with a normal or intermediate G6PD activity will have a test result indicating that they are deficient (false positive test result).

If a test with these characteristics would be applied to a group of 10,000 patients in which the 5% of patients are G6PD deficient (<30% of normal activity), then this would result in a total of 836 positive test results and thus 836 patients for whom a weekly regimen of primaquine during 8 weeks would be suggested, while 361 of them actually have a normal or intermediate G6PD activity (and 475 will indeed be G6PD deficient). This would also result then in 9164 negative test results and thus 9164 patients who will receive daily doses of 0.5 mg/kg/day primaquine for 14 days or 0.5 mg/kg/day primaquine for 7 days, while 25 of them would actually be G6PD deficient (and 9139 will not be deficient but some of them, especially females, may have intermediate activity).

Guidance
The practical guidance on the use of qualitative near-patient tests for G6PD deficiency should include all aspects of safe implementation of a new diagnostic test e.g. implementation plan, clear national guidelines, quality assurance and prequalification of tests, training of users, quality assurance of testing, and selection of the type of health services where these tests should be deployed. In addition the guidance should also include specific information on the anti-relapse primaquine treatment regimens linked with a negative (normal) test result, i.e. 0.5 mg/kg/day primaquine for 14 days or 0.5 mg/kg/day primaquine for 7 days, and with positive (deficient) test results, i.e. 0.75 mg/kg weekly doses of primaquine for 8 weeks.

Like for the introduction of any new diagnostic tests, this should be implemented with a sound quality assurance to address the specific requirements for the newly introduced diagnostics, reaching all levels of the health care system where these will be co-deployed with the anti-relapse *P. vivax* treatment.

Conclusion
We are moderately confident in the estimates of sensitivity and specificity; the true sensitivity and specificity are likely to be close to the estimates of the sensitivity and specificity mentioned here, but there is a possibility that it is substantially different. This is because: i) some of the studies on which the summary estimates were based, had a high risk of bias; and ii) the prevalence of G6PD deficiency was different in some study sites or some studies only included one gender (indirectness). See Table “Certainty of the evidence table for near-patients qualitative G6PD tests” under Evidence profiles/ Research evidence.