

IgG Result:

Relative Sensitivity: 100% (95% CI*: 86.0%-100%)

Relative Specificity: 98.0% (95% CI*: 89.4%-99.9%)

Accuracy: 98.6% (95% CI*: 92.3%-99.96%)

*Confidence Interval

IgM Result:

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

*Confidence Interval



Number: 146198600

Effective Date: 2020-02-18

FDA and EUA Registration:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=653267&lpd=QKO>

To get to the Product Classification and Submission type (EUA), please click on the Product Code (QKO) hyperlink.